



GOOD SCIENCE  
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**European Society  
for Medical  
Oncology  
(ESMO)**

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## **European Society for Medical Oncology**

The European Society for Medical Oncology (ESMO) is the leading professional organization for medical oncology. With more than 25,000 members representing oncology professionals from over 150 countries worldwide, ESMO was founded in 1975.

### **Annals of Oncology**

Founded in 1990, ESMO's flagship scientific journal, Annals of Oncology, publishes articles addressing medical oncology, surgery, radiotherapy, pediatric oncology, basic research and the comprehensive management of patients with malignant diseases. Annals of Oncology is the official journal of ESMO and from 2008 of the Japanese Society for Medical Oncology (JSMO)

### **ESMO Clinical Practice Guidelines**

The ESMO Clinical Practice Guidelines (CPG) are intended to provide oncology professionals with a set of recommendations for the best standards of cancer care, based on the findings of evidence-based medicine. Each Clinical Practice Guideline includes information on the incidence of the malignancy, diagnostic criteria, staging of disease and risk assessment, treatment plans and follow-up designed to help oncologists deliver an appropriate quality of care to their patients.

### **ESMO Conferences**

The annual ESMO Congress, held every year is attended by 25,000 participants. The congress presents the latest scientific developments in basic, translational and clinical cancer research and contextualizes new findings for practical implementation in every day patient care.

### **Additional Continuing Medical Educational Resources**

ESMO publishes handbooks, scientific meeting reports, and medical oncology training guidelines. The Society provides fellowships for research training for young oncologists, an Exam in Medical Oncology and an accreditation program for institutes providing patients with integrated supportive and palliative care. Through an online professional networking platform ESMO members collaborate, interact and share knowledge on topics of research and clinical practice.

## **European Society for Medical Oncology Magnitude of Clinical Benefit Scale (ESMO-MCBS)**

In 2015, ESMO published the first version of its Magnitude of Clinical Benefit Scale to grade the magnitude of clinical benefit of cancer therapies incorporating efficacy, long-term survival and side-effects of any anticancer agent into a single score. ESMO-MCBS was updated with the publication of the version 1.1 in 2017. Forms are available from the official website of ESMO.

### **Provide your patients with the best care options.**

Keep up to date with all the latest news about ESMO guidelines: find out about new and updated Clinical Practice Guidelines, consensus conference-derived recommendations and e-Updates (including diagnostic and treatment algorithms and ESMO-MCBS grading), along with new and updated Guidelines Slide Sets and updates to the pocket guidelines and the mobile App - providing quick-reference material with key information.

### **Meeting Resources**

Resources such as abstracts, presentations and webcasts from meetings can be accessed by ESMO members and conference delegates throughout all the year.

### **ESMO Courses**

The courses include state of the art lectures, workshops and interactive discussion seminars.

### **ESMO Oncology Journals**

A globally visible platform to publish scientific studies and a source of educational updates.

### **Publications**

A range of publications that can be browsed online by all ESMO members and downloaded for offline use.

# **SARS-COV-2 and CANCER**



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## Adaptive immunity to SARS-CoV-2 infection and vaccination in cancer patients: The CAPTURE study

### Background:

Patients with cancer are at increased risk of severe outcomes from COVID-19. Understanding the impact of SARS-CoV-2 infection and vaccination induced-immunity is an area of unmet need.

### Methods:

CAPTURE (NCT03226886) is a prospective longitudinal cohort study of COVID-19 vaccine or SARS-CoV-2 infection-induced immunity. SARS-CoV-2 infections were confirmed by RT-PCR and ELISA. Neutralizing antibody titers (NAbT) against wildtype (WT) SARS-CoV-2 and variants of concern (VOC; Alpha, Beta, Delta) and SARSCoV-2 specific T-cells (SsT-cells) were quantified.

### Results:

118 patients (89% solid malignancy, [SM]) were SARS-CoV-2-positive (median follow-up: 154 days). 85% patients were symptomatic; 2 died of COVID-19. 82% had S1-reactive antibodies, of whom 89% had neutralizing antibodies (NABs); NAbT were lower against all VOCs. While S1-reactive antibody levels declined over time, NAbT remained stable up to 329 days. Most patients had detectable SsT-cells (76% CD4+, 52% CD8+). Hematological malignancy (HM) patients had impaired immune responses that were disease and treatment-specific (anti-CD20), but with evidence suggestive of compensation from T-cells. 585 patients were evaluated following 2 doses of BNT162b2 or AZD1222 vaccines, administered 12 weeks apart. Seroconversion rates after 2 doses were 85% and 54% in patients with SM and HM, respectively. A lower proportion of patients had detectable NABs against SARS-CoV-2 VOC (Alpha 62%, Beta 54%, Delta 49%) vs WT (84%), with corresponding significantly lower NAbT. Patients with HM were more likely to have an undetectable NAb and had lower NAbT vs solid malignancies to both WT and VOCs. Seroconversion showed poor concordance with NAbTs against VOCs. Prior SARS-CoV-2 infection boosted NAbT including against VOCs. Anti-CD20 treatment was associated with severely diminished NAbTs. Vaccine-induced T-cell responses were detected in 80% of patients, with no differences between vaccines or cancer types.

### Conclusions:

Patients with HM had blunted humoral responses to infection and vaccination, particularly against VOCs, but preserved cellular responses might contribute to protection. Our results lend support to prioritization of all cancer patients for further booster vaccination.

### Clinical trial identification:

NCT03226886.

## COVID-19 vaccine in participants (ptcpts) with cancer: Subgroup analysis of efficacy/safety from a global phase III randomized trial of the BNT162b2 (tozinameran) mRNA vaccine

### Background:

Patients with cancer are at higher risk of developing COVID-19 disease, adverse outcomes, and increased mortality. Phase III COVID-19 vaccine trials have demonstrated safety/efficacy against COVID-19 and prevented hospitalizations and deaths; however, most excluded ptcpts with cancer. We present phase 3 tozinameran mRNA COVID-19 vaccine trial results from ptcpts with a cancer history at baseline, either ongoing or not, per the Charlson Comorbidity Index and up to 6 months of follow-up.

### Methods:

Between Jul 2020-Jan 2021, 46429 ptcpts  $\geq 12$  y at 152 sites in 6 countries were randomized in a placebo-controlled, observer-blinded trial of 2-dose tozinameran, showing 95% protection against COVID-19 and favorable safety (Polack et al NEJM, Dec 2020). After emergency use authorization, ptcpts were allowed to unblind and placebo recipients received vaccine. Data prior to unblinding for crossover up to 13 Mar 2021 are presented for ptcpts  $\geq 16$  y for safety and  $\geq 12$  y for efficacy. Adverse event (AE) data are controlled for follow-up time before unblinding and reported as incidence rate (IR) per 100-person-y of follow-up.

### Results:

Of ptcpts  $\geq 16$  y, 1647 had a prior diagnosis of cancer and were not on active immunosuppressive treatment (755 M; 892 F; median age 66 y [range 22-91]). Most common solid cancers included breast (n=458), prostate (n=360), and melanoma (n=210). AEs were reported at IRs of 94.0 (vaccine) and 49.3 (placebo) per 100person-y; most common AEs were reactogenicity events (injection-site pain [IR: 40.2 vaccine; 4.2 placebo]; fatigue [IR: 21.4 vaccine; 7.6 placebo]; pyrexia [IR: 19.8 vaccine; 0.7 placebo]). 1 vaccine ptcpt withdrew due to a vaccine-related AE. No vaccinerelated deaths were reported. Among ptcpts  $\geq 12$  y with cancer, 3 vaccine and 27 placebo recipients developed COVID-19 from 7 days post-Dose 2; vaccine efficacy (VE) was 89.7% (95% CI 66.5-98.0%). This compares favorably with overall VE of 91.1%. Updated results will be presented.

### Conclusions:

Tozinameran has similar efficacy/safety in ptcpts with cancer as in the overall population. These results inform tozinameran use in COVID-19 and in future trials in patients with cancer.

### Clinical trial identification:

NCT04368728.



## Efficacy and toxicity of BNT162b2 vaccine in cancer patients

### Background:

Efficacy and safety profile of COVID-19 vaccines had been acquired from phase III studies. Nevertheless, cancer patients were not represented in these trials. In 1/2021 mass vaccination of high-risk population, including cancer patients, was initiated in Israel. We aimed to prospectively evaluate efficacy, immunogenicity and safety of BNT162b2 vaccine in cancer patients.

### Methods:

Cancer patients on active treatment were prospectively enrolled following first dose of BNT162b2 or after a second dose. Serum was collected after each dose and additionally in case of seronegative. An age-matched cohort of healthcare workers served as controls. Questionnaires regarding sociodemographic and adverse reactions were employed at serum collection. FDA-approved assay was used to assess IgG at all time-points. Patients' electronic medical records were reviewed for documentation of COVID-19 infection, blood counts, liver enzymes and imaging studies.

### Results:

The study included 232 cancer patients and 261 controls. Following first dose 29% of patients were seropositive compared with 84% of controls ( $p < 0.001$ ). Following second dose seropositive rate reached 86%. Rate per 1000-person days after first dose were 12.5 for patients and 48.5 for controls. Chemotherapy reduced immunogenicity (OR 0.41 (95%CI 0.17-0.98)). In seronegative patients, rate of documented leukopenia reached 39%. No COVID19 cases were documented throughout the study period except two cases following the first dose. Reported adverse events resembled former published studies.

### Conclusions:

Our results indicate the BNT162b2 appear to be safe and effective in cancer patients. There is a pronounced lag in antibody production compared with non-cancer controls, however seroconversion occurred in most patients after the second dose. Future real-world data is warranted to determine the long-term efficacy of the vaccine with regard to type of anti-cancer treatment.

## Prevalence and impact of COVID-19 sequelae on treatment pathways and survival of cancer patients who recovered from SARS-CoV-2 infection

### Background:

The long-term impact of COVID-19 in cancer patients (pts) is undefined.

### Methods:

Among 2795 consecutive pts with COVID-19 and cancer registered to OnCovid between 01/2020 and 02/2021, we examined clinical outcomes of pts reassessed post COVID-19 recovery.

### Results:

Among 1557 COVID-19 survivors, 234 (15%) reported sequelae including respiratory symptoms (49.6%), fatigue (41%) and cognitive/psychological dysfunction (4.3%). Persisting COVID-19 sequelae were more likely found in males ( $p=0.0407$ ) aged  $\geq 65$  years ( $p=0.0489$ ) with  $\geq 2$  comorbidities ( $p=0.0006$ ) and positive smoking history ( $p=0.0004$ ). Sequelae were associated with history of prior hospitalization ( $p<0.0001$ ), complicated disease ( $p<0.0001$ ) and COVID-19 therapy ( $p=0.0002$ ). With a median post-COVID-19 follow up of 128 days (95%CI 113-148), multivariable analysis of survival revealed COVID-19 sequelae to be associated with an increased risk of death (HR 1.76, 95%CI 1.16-2.66) after adjusting for sex, age, comorbidities, tumor characteristics, anticancer therapy and COVID-19 severity. Out of 473 patients who were on systemic anticancer therapy (SACT) at COVID-19 diagnosis; 62 (13.1%) permanently discontinued therapy and 75 (15.8%) received SACT adjustments, respectively. Discontinuations were due to worsening performance status (45.1%), disease progression (16.1%) and residual organ dysfunction (6.3%). SACT adjustments were pursued to avoid hospital attendance (40%), prevent immunosuppression (57.3%) or adverse events (20.3%). Multivariable analyses showed permanent discontinuation to be associated with an increased risk of death (HR 4.2, 95%CI: 1.62-10.7), whereas SACT adjustments did not adversely affect survival.

### Conclusions:

Sequelae post-COVID-19 affect up to 15% of patients with cancer and adversely influence survival and oncological outcomes after recovery. SACT adjustments can be safely pursued to preserve oncological outcomes in patients who remain eligible to treatment.

### Clinical trial identification:

NCT04393974.

## The future of the oncology workforce since COVID-19: Results of the ESMO Resilience Task Force survey series

### Background:

The ESMO Resilience Task Force has investigated wellbeing since COVID19 in relation to work, lifestyle and support factors in oncology professionals globally. We reported on the significant impact of the initial surge of the pandemic on wellbeing and job performance (Banerjee et al. 2021). As the pandemic continues, it is imperative to understand experiences and concerns to better inform support measures for the oncology workforce.

### Methods:

Three anonymous online surveys were conducted during the COVID-19 pandemic (S1, Apr/May 2020; S2, Jul/Aug 2020; S3, Feb/Mar 2021). Longitudinal analysis of responses at these timepoints were conducted. Here, we present responses to questions on job demands and resources, and perceived job performance since COVID-19 (JP-CV).

### Results:

We analyzed 3894 individual responses (S1, n=1520; S2, n=942; S3, n=1432): 53% (n=1961/3731) female, 45% (n=1679/3731) =<40 years, 31% (n=1132/3692) non-white ethnicity, >100 countries. There have been significant increases from S1 to S3 (p<0.001) in feeling overwhelmed with workload (29% vs 45%); COVID-19-related clinical (14% vs 58%) and research (16% vs 64%) work; out-of-hours work (16% vs 41%), shift work (12% vs 26%) and overall working hours (17% vs 47%); and inadequate time for personal/family life (35% vs 45%). 59% (n=1156/1946) were unable to take allocated annual leave. While JP-CV has improved (34% vs 49%, p<0.001), there remained concerns about the negative impact of the pandemic on career development/training (43%), job security (37%) and international fellowship opportunities (76%). Overall, less than half had felt supported by their work management, professional societies or government, and/or had access to wellbeing support services. 25% (n=266/1086) were considering changing their future career with 38% (n=100/266) contemplating leaving the profession.

### Conclusions:

Since COVID-19, oncology professionals have reported increased job demands, concerns over career development/training and job security, and inadequate time for personal life. There is a real threat of potential attrition in the current workforce. National and international stakeholders must act together to ensure robust recovery plans as we emerge from the COVID-19 crisis.

## Effectiveness of COVID-19 vaccination in cancer patients: A nationwide Veterans Affairs study

### Background:

Data is lacking about SARS-CoV-2 vaccination effectiveness in patients with cancer, particularly those on systemic therapy. This retrospective cohort study in the US national Veterans Affairs (VA) healthcare system reports the effectiveness of SARS-CoV-2 vaccination in cancer patients on and off active therapy during the first 140 days following administration.

### Methods:

This is a multicenter study of SARS-CoV-2 infection among vaccinated and unvaccinated Veterans vaccinated during the period from 12/15/2020 to 5/4/2021. Veterans with solid or hematologic malignancy who received systemic cancer-directed therapy at the VA at least one time between 8/15/2010 to 5/4/2021 were included. Vaccinated patients were exactly matched 1:1 to an unvaccinated control on race, VA facility, rurality of home address, cancer type, and treatment timing and modality with minimum distance matching on age. The primary exposure was receipt of a SARS-CoV-2 vaccine. The primary outcome was laboratory-confirmed SARS-CoV-2 infection. Vaccination effectiveness was defined as 1 minus the risk ratio of SARS-CoV2 infection for vaccinated individuals compared to unvaccinated controls.

### Results:

184,485 patients met eligibility criteria and 113,796 were vaccinated during the study period. Of these, 29,152 vaccinated patients were matched 1:1 to 29,152 unvaccinated or not yet vaccinated controls. As of a median 47 days of follow-up, overall vaccine effectiveness in the matched cohort was 58% (95% CI, 39 to 72%) starting 14 days after the second dose. Patients on chemotherapy within three months prior to first vaccination dose exhibited a 14-day post-second dose effectiveness of 57% (95% CI -23 to 90%), versus 76% (95% CI 50 to 91%) for those on endocrine therapy and 85% (95% CI 29 to 100%) for those off systemic therapy for at least six months prior.

### Conclusions:

Vaccination is an effective strategy for preventing COVID-19 in cancer patients. However, effectiveness may be reduced in patients actively receiving immunosuppressive systemic therapy. Future study is needed to determine if these patients would benefit from post-vaccination serologies and/or a booster vaccination following completion of therapy.

## CoVigi phase IV multicentric trial evaluating COVID-19 vaccination adverse events and immune response dynamics in cancer patients: First results on antibody and cellular immunity

### Background:

SARS-CoV-2 infection may be a threat for those undergoing active anticancer therapy. We aim to study adverse events, efficacy, and immune response in Covid-19 vaccinated patients focusing on possibly interfering therapy.

### Methods:

CoVigi is a prospective open-label multicentric phase 4 clinical study (EudraCT 2021-000566-14) enrolling patients on anti-cancer treatment. Vaccines from Pfizer-BioNTech, AstraZeneca, Johnson & Johnson, or Moderna are considered. Data on vaccination side effects, the onset and course of Covid-19, and quantitative analysis of anti-S and anti-N SARS-CoV-2 antibodies (Roche) and SARS-CoV-2 specific cellular response evaluated by IFN-gamma-release assay (Qiagen) and CD69 expression are recorded as follows: at the baseline (prior to the vaccination), prior to the 2nd dose, 4e8 weeks, 3, 6 and 12 months after the first dose.

### Results:

The trial was initiated on March 22th. As of May 4th, 152 solid cancer and 103 hematooncology patients were enrolled. From preliminary baseline data, 22% of solid cancer and 29% of hematooncology patients had detectable levels of anti-S antibodies with a median of 106 U/ml (range 1.4-3666) and 84 U/ml (range 0.75-2528), respectively ( $p = 0.888$ ). Surprisingly, only 44% solid cancer and 53% of hematooncology patients with detectable antibodies prior to the vaccination referred on covid-19 in medical history. In the Ab-positive cohort, the IFN-gamma level upon both CD4 and CD8 stimulation was 0.04 pg/ml (IQR 0.02e0.13), the CD69 expression on NKT-like cells increased to 10.9% (IQR 6.6e17.3), whereas in the Ab-negative cohort was 0.00 pg/ml (IQR 0.00e0.01 and to 7.5% (IQR 4.0e10.1), respectively ( $p < 0.001$  and  $p = 0.079$ ).

### Conclusions:

Substantial number of cancer patients experienced SARS-CoV-2 infection during active anti-cancer treatment prior to vaccination, often with asymptomatic course. In SARS-CoV-2-immunized patients, we observed SARS-CoV-2 positive cellular response. The preliminary results with dynamics of immune response with 3-month follow-up will be presented at the conference. Acknowledgment: CZECRIN LM2018128, Roche Diagnostics, MMCI00209805, MHCZ/DRO (FNBr, 65269705).

### Clinical trial identification:

EudraCT 2021-000566-14.



## Characterization of COVID-19 vaccination response by antibody (Ab) titer and T-cell receptor (TCR) sequencing in patients (pts) with advanced genitourinary (GU) cancers

### Background:

Preliminary studies have characterized potential adverse effects associated with COVID-19 vaccination in pts with cancer. However, biological characterization of vaccine response has yet to be performed.

### Methods:

Eligible pts with advanced GU cancers (metastatic/unresectable prostate, bladder and renal cell carcinoma [RCC]) and had not yet received COVID-19 vaccination. Pts were consented to receive sequential blood draws prior to vaccination and at landmarks of 2, 6, and 12 mos following vaccination. Pts on systemic treatment had additional blood draws coinciding with their first 3 cycles of therapy following vaccination. Ab titers to SARS-CoV-2 were quantified via ELISA and reported as an immune status ratio (ISR). RNA was extracted from PBMC aliquots, converted into cDNA and TCR  $\alpha/\beta$  sequences were selectively amplified. TCR abundance and homology clustering was performed using custom scripts.

### Results:

As of May 14, 2021, 130 pts had consented to the study of whom 126 pts submitted baseline (BL) specimens. The current analysis focuses on 56 pts who submitted cycle 1 (C1) specimens. Among these, 29, 26, and 1 pts had RCC, prostate and bladder cancer, respectively; 19 were on checkpoint inhibitor (CPI)-based regimens while 37 were on non-CPI regimens. BNT162b2 (Pfizer) was the most commonly administered vaccine in the cohort (n<sup>1</sup>/429), followed by mRNA-1273 (Moderna; n<sup>1</sup>/426). COVID-19 Ab titers increased significantly from BL to C1 across the cohort from 0.19 (interquartile range [IQR] 0.12-0.18) to 4.37 (IQR 0.2-6.60; P<0.0001). However, 8/56 pts (14.3%) receiving CPI-based regimens and 8/56 pts (14.3%) receiving non-CPI-based regimens were noted to have negative Ab titers after a median of 18 and 35 days following initial vaccination, respectively. No significant difference was observed in the increase from BL to C1 in pts receiving CPI vs non-CPI based regimens. Specimen collection is ongoing; updated Ab titer data and TCR sequencing data will be presented.

### Conclusions:

Our data prompt concern for delayed or insufficient COVID-19 Ab response in a subset of pts with advanced GU cancers.

## Time-dependent improvement in the clinical outcomes from COVID-19 in cancer patients: An updated analysis of the OnCovid registry

### Background:

Early reports from registry studies demonstrated high vulnerability of cancer patients from COVID-19, with case-fatality rates (CFR) >30% at the onset of the pandemic. With advances in disease management and increased testing capacity, the lethality of COVID-19 in cancer patients may have improved over time.

### Methods:

The OnCovid registry lists European cancer patients consecutively diagnosed with COVID-19 in 35 centers from Jan 2020 to Feb 2021. We analyzed clinical characteristics and outcomes stratified in 5 trimesters (Jan-Mar, Apr-Jun, Jul-Sep, Oct-Dec 2020 and Jan-Feb 2021) and studied predictors of mortality across 2 semesters (Jan-Jun 2020 and Jul 2020-Feb 2021).

### Results:

At data cut-off, the 2634 eligible patients demonstrated significant time-dependent improvement in 14-days CFR with trimestral estimates of 29.8%, 20.3%, 12.5%, 17.2% and 14.5% ( $p < 0.0001$ ). Compared to the 2nd semester, patients diagnosed in the Jan-Jun 2020 time period were  $\geq 65$  (60.3% vs 56.1%,  $p = 0.031$ ) had  $\geq 2$  comorbidities (48.8% vs 42.4%,  $p = 0.001$ ) and non-advanced tumors (46.4% vs 56.1%,  $p < 0.001$ ). COVID-19 was more likely to be complicated in Jan-Jun 2020 (45.4% vs 33.9%,  $p < 0.001$ ), requiring hospitalization (59.8% vs 42.1%,  $p < 0.001$ ) and anti-COVID-19 therapy (61.7% vs 49.7%,  $p < 0.001$ ). The 14-days CFR for the 1st and 2nd semester was 25.6% vs 16.2% ( $p < 0.0001$ ), respectively. After adjusting for gender, age, comorbidities, tumor features, COVID-19 and anti-cancer therapy and COVID-19 complications, patients diagnosed in the 1st semester had an increased risk of death at 14 days (HR 1.68 [95%CI: 1.35-2.09]), but not at 3 months (HR 1.10 [95%CI: 0.941.29]) compared to those from the 2nd semester.

### Conclusions:

We report a time-dependent improvement in the mortality from COVID-19 in European cancer patients. This may be explained by expanding testing capacity, improved healthcare resources and dynamic changes in community transmission over time. These findings are informative for clinical practice and policy making in the context of an unresolved pandemic.

### Clinical trial identification:

NCT04393974.

## Resilience of elective cancer surgery systems during COVID-19 lockdowns: International, prospective cohort study of planned surgery for 15 tumor types in 61 countries

### Background:

Surgery is the main modality of cure for solid cancers and was prioritized to continue even during SARS-CoV-2 outbreaks. This study aimed to identify immediate areas for system strengthening by comparing the delivery of elective cancer surgery during COVID-19 in periods of lockdown versus light restriction.

### Methods:

This international, prospective cohort study enrolled patients with 15 cancer types who had a decision for surgery during the COVID-19 pandemic up to 31st August 2020. Average national Oxford COVID-19 Stringency Index scores were calculated for each patient during the period they were awaiting surgery, classified into light restrictions (index <20), moderate lockdowns (20-60), and full lockdowns (>60). The primary outcome was the non-operation rate (proportion of patients who did not undergo planned surgery). Cox proportional-hazards regression models were used to explore the associations between lockdowns and non-operation.

### Results:

From 20,006 patients (466 hospitals, 61 countries), 9.1% did not receive surgery after a minimum of 3-months' follow up (median:23 weeks, IQR:16 to 30 weeks). Light restrictions were associated with a 0.6% non-operation rate, moderate lockdowns 5.5% (adjusted hazard ratio:0.81, 95% confidence interval 0.77-0.84,  $p<0.001$ ), and full lockdowns with a 15.0% rate (HR:0.51, 0.50-0.53). In sensitivity analyses, this effect was independent of local SARS-CoV-2 rates. Each additional week in lockdown led to a 9% reduction in the likelihood in a patient undergoing their cancer operation. Frail patients, those with advanced cancer, and those in lower-income settings were particularly vulnerable to lockdown effects. Surgery beyond 12weeks from diagnosis increased during lockdowns (9.1% in light restrictions, 10.4% moderate lockdowns, 23.8% full lockdowns).

### Conclusions:

Cancer surgery systems worldwide were fragile to lockdowns, with one in seven patients not undergoing planned surgery and more preoperative delays. During current and future periods of societal restriction, the resilience of elective surgery systems requires strengthening, which may include ring-fenced surgical units and critical care capacity.

### Clinical trial identification:

NCT04384926.



## COVID-19 and cancer: First report of the ESMO international, registry-based, cohort study (ESMO CoCARE)

### Background:

At the height of the first wave of the SARS-COV-2 pandemic, ESMO mobilized to accelerate research for the understanding of COVID-19 in cancer patients (pts). ESMO CoCARE is an international collaborative registry-based, cohort study, gathering real-world data and information from healthcare professionals about the natural history, treatment and outcomes of COVID-19 in cancer pts.

### Methods:

ESMO CoCARE captures information on pts with any solid or hematologic malignancy (including cancer survivors free of disease for 5 years) presenting with a COVID-19 diagnosis in any of the participating centers. Data collected since 06/2020 include demographics, cancer characteristics and status, co-morbidities, COVID-19 clinical features, course, management and outcome. Factors influencing COVID-19 severity (hospitalization +/- ICU support needed) and recovery are investigated using multivariable logistic regression with backward elimination method. The study is ongoing.

### Results:

The current analysis includes 1551 registered pts (19 countries; 87% pts from 23 European centers, 7% and 6% pts from 5 Northern African and 7 Asian centers), with COVID-19 diagnosis as of 11/03/2021. Median age was 64 years, with the majority female (52%), cancer stage III/IV (58%), and on active cancer treatment (60%). 65% had severe COVID-19 requiring hospitalization, with 11% receiving intensive care. In multivariable analysis, in addition to demographics (male gender, older age, other ethnicity than Caucasian, lower BMI), co-morbidities and symptomatic COVID-19, severe disease was associated to higher ECOG PS (Odds Ratio (OR)<sub>2 vs 0</sub>=5.9, OR<sub>1 vs 0</sub>=2.1), hematological malignancies (OR<sub>hemvs solid</sub>=2.0), and active/progressive cancer status (OR<sub>progressives no evidence of disease</sub>=1.6). 98% of pts with mild disease recovered, as opposed to only 70% of those with severe disease. Cancer stage was an additional prognostic factor for recovery (OR<sub>I/II vs IV</sub>=3.4).

### Conclusions:

Demographic characteristics, type and status of cancer, and symptomatology of COVID-19 increase the probability of severe disease, while advanced cancer stage is also associated with the risk of death.

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### Conclusions:

Demographic characteristics, type and status of cancer, and symptomatology of COVID-19 increase the probability of severe disease, while advanced cancer stage is also associated with the risk of death.

## Clinical and laboratory outcomes of solid cancer patients reinfected with SARS-CoV-2

### Background:

COVID-19 reinfection has been increasingly reported. Immunocompromised patients may be more susceptible to COVID-19 reinfection due to impaired immune responses to the virus. The current study aimed to evaluate the clinical and laboratory outcomes of solid cancer patients who were reinfected with COVID-19.

### Methods:

Patients with a diagnosis of solid cancer and COVID-19 PCR positive were screened. The patients enrolled whether patient has at least one negative COVID-19 PCR test and clinical improvement. In addition to that at least 28 days after the previous positive COVID-19 PCR result, the patient must have a confirmed COVID-19 PCR positive result again.

### Results:

Total 1024 patients with COVID-19 PCR positive solid malignancy were screened. Thirty-two patients were included in the study. The median time between the first COVID-19 infection and reinfection was 46 (30-194) days. The reinfection rate was 3.1%. The most common cancer subtype was lung cancer. Mortality rate of reinfection was 34.3% (n=11). Ferritin and creatinine values of serum parameters in reinfection were found to be significantly higher compared to the first infection, respectively (p:0.015, p:0.014). Nine patients with only 1 comorbidity had higher mortality (p=0.052). During reinfection period rate of patients hospitalized in intensive care unit was significantly higher compared with rate of patients during first COV\_ID-19 infection (p:0.002). The mortality rate in 8 patients using antiaggregant or anticoagulant for a long time was not statistically different from the group who did not use it (p:0.681).

### Conclusions:

Solid cancer patients have a higher mortality rate in COVID-19 reinfection. The reinfection rate was 3.1%. This study demonstrated one of the first preliminary clinical results of COVID-19 reinfection in solid cancer patients.

## A multicenter analysis of the outcome of cancer patients with neutropenia and COVID-19 infection optionally treated with granulocyte colony-stimulating factor (G-CSF): A comparative analysis

### Background:

SARS-CoV-2 infection can induce a host hyperinflammatory response induced by a cytokine storm, that is the main cause of mortality. Myelosuppression is associated with higher risk of infections and mortality. Few reports have addressed about the management of patients with neutropenia and COVID-19. Herein, we present a retrospective study during COVID-19 outbreak in neutropenic cancer patients with COVID-19 comparing the outcome and survival between G-CSF treated vs G-CSF non-treated group.

### Methods:

Retrospective data were collected from clinical reports. Inclusion criteria were cancer with neutropenia ( $<1500$  cells/mm<sup>3</sup>) and concomitant COVID-19 infection. Comorbidities, tumor, stage, treatment, neutropenia severity, G-CSF, COVID-19 parameters and mortality were analyzed. Exploratory analysis of both cohorts (G-CSF treated and G-CSF non treated) and a multivariable logistic regression was done to predict respiratory failure and death.

### Results:

Among 943 patients with cancer and COVID-19 from 14 hospitals in Spain, 8% had neutropenia. Two cohorts according to G-CSF treatment were identified: 40 patients received G-CSF vs 43 G-CSF non-treated. Lung (26%) was the main location and most had advanced disease (67%). No differences according to baseline characteristics were found, except for the cancer treatment and the centers protocols for neutropenia management ( $p=0,001$ ). 63% of patients died because respiratory failure. Pneumonia was presented in 76% of patients. Patients treated with G-CSF had a higher rate of respiratory failure vs non-treated ( $p=0.001$ ) and required oxygen support ( $p=0.002$ ). In G-CSF treated cohort, we found that the days with G-CSF showed a significant trend toward worse outcome and higher mortality. A logistic regression model was developed to predict respiratory failure as a function of the days of G-CSF treatment. After adjusting several relevant covariates, a significant effect was obtained for the days of G-CSF treatment (OR = 1.4, 95% CI [1.03, 1.92],  $p$ -value = 0.01).

### Conclusions:

Our findings suggest that G-CSF treatment could be disadvantageous in cancer patients with COVID-19, with a probable worse outcome.

## Outcome and prognostic factors of COVID-19 infection in cancer patients: Final results of SAKK 80/20

### Background:

These are the final results of a national registry on COVID-19 in Switzerland.

### Methods:

We collected data on 501 symptomatic COVID-19 infected cancer patients from 23 Swiss sites, starting March 1, 2020. Testing recommendations were set by the Federal Office of Public Health. The main objective of the study was to assess the outcome (i.e., mortality, rate of hospitalization, ICU admission) of COVID-19 infection in cancer patients, the main secondary objective was to define prognostic factors.

### Results:

With a cutoff date of March 15, 2021 and exclusion of 46 patients who refused consent, 455 patients were included into the final analysis. Most frequent malignancies were breast in 63 cases (14%), lung in 47 (10%), prostate cancer in 25 (6%), myeloma in 19 (4%); 205 patients (45%) had non-curative disease. Systemic treatment within 3 months prior to COVID-19 diagnosis included chemotherapy in 101 cases (23%), targeted therapy in 94 (21%), steroids in 78 (17%) and checkpoint inhibitors in 34 (8%). 285 patients (63%) were hospitalized for COVID-19, 213 (47%) required oxygen, 43 (9%) invasive ventilation, 62 (14%) were admitted to the ICU. Death from COVID-19 infection occurred in 98 patients, resulting in a mortality rate of 21.5%. Age  $\geq 65$  versus  $< 65$  (OR 3.35,  $p=0.001$ ), non-curative versus curative disease (OR 2.21,  $p=0.021$ ), ICU admission (OR 4.53,  $p < 0.001$ ) and oxygen requirement (OR 23.25,  $p < 0.001$ ) were independently associated with increased mortality. Neither male versus female gender (OR 1.20,  $p=0.56$ ), hematological versus solid malignancy (OR 1.01,  $p=0.97$ ), pulmonary comorbidity (OR 0.96,  $p=0.93$ ), cardiovascular comorbidity (OR 1.11,  $p=0.75$ ), chemotherapy as defined above (OR 1.43,  $p=0.31$ ) or checkpoint inhibitors (OR=2.81,  $p=0.082$ ) were significant risk factors for death.

### Conclusions:

We found a high COVID-19 mortality rate of 21.5% in real-world cancer patients for the first wave of the pandemic in a country with a decentralized, high quality health care system with universal access (COVID-19 mortality of 1.7% in the general population during the same time interval). The rate of hospitalization and ICU admission for COVID-19 in cancer patients is substantial.



## COVID-19 positivity rates in patients with an active cancer diagnosis in the University of California Cancer Consortium

### Background:

The impact of active cancer on susceptibility to coronavirus disease 2019 (COVID-19) remains controversial. This study leverages the infrastructure across the University of California (UC) Cancer Consortium, pooling electronic health record (EHR) data to assess the relationship between active cancer diagnoses (n=151,392) and COVID-19 positivity.

### Methods:

In this cohort study, patients with COVID-19 test results and active cancer diagnoses were identified from the UC Health System COVID Research Data Set (CORDS). This data set collects COVID-19 test results from the 5 academic medical centers in the UC Health System and their NCI-designated Comprehensive Cancer Centers. COVID-19 test results were identified by Logical Observation Identifiers Names and Codes (LOINC). Active cancer was defined as an EHR-based malignant diagnosis within 9 months of testing, irrespective of active therapy. Total daily positivity rates were aggregated, and overall rates were compared across patients with and without active cancer using the Pearson’s Chi-squared test.

### Results:

We identified 1,032,588 COVID-19 tests from March 3, 2020 to April 15, 2021, with 151,392 tests (14.7%) associated with an active cancer diagnosis. Monthly trends in positivity rates throughout the pandemic were similar between patients with and without cancer (Table). Overall positivity was lower in patients with active cancer (2.0% versus 4.4%;  $p < 0.001$ ). This was consistent across individual UC sites.

### Conclusions:

COVID-19 positivity rates were not increased for individuals with active cancer diagnoses in the UC Cancer Consortium. A lower positivity rate amongst cancer patients may be due to demographic, behavioral, occupational or environmental factors, as well as greater asymptomatic testing of cancer patients at some UC sites. Interactions with local prevalence and patient and cancer characteristics will be presented.

Table: 1571P

	Mar 2020	Apr 2020	May 2020	Jun 2020	Jul 2020	Aug 2020	Sep 2020	Oct 2020	Nov 2020	Dec 2020	Jan 2021	Feb 2021	Mar 2021	Apr 2021	Total
Cancer	4.1%	1.9%	0.8%	1.0%	2.0%	1.3%	0.9%	0.7%	1.8%	5.2%	5.2%	2.2%	0.6%	0.8%	2.1%
Non-cancer	8.3%	4.7%	2.1%	3.3%	5.3%	3.3%	2.0%	1.6%	4.3%	9.7%	8.8%	3.0%	1.3%	1.0%	4.7%

## The impact of COVID-19 pandemic on Spanish genitourinary (GU) cancer patients: SOGUG-COVID-19 study

### Background:

The COVID-19 pandemic is a huge health problem in all countries. To know how COVID-19 infection affected GU cancer patients in Spain, an ambispective clinical registry was elaborated to get clinical information about cancer, its treatment, and the evolution of COVID-19 infection.

### Methods:

From November 2020 to April 2021, 369 patients (pts) with PCR, antigen or antibody documented SARS-CoV2 infection who were diagnosed or/and treated for a GU tumor, were evaluated in 32 Spanish hospitals. Data were collected in a unitary database with information about cancer diagnosis, treatment, COVID-19 symptoms and outcome.

### Results:

Median age was 68.4 y (range 17-100), 322 pts (87.3%) were male. Tumor origin was kidney in 82 pts (22.7%), urothelial in 110 (29.8%), prostate 198 (40.7%), testis in 17 (4.6%) and other in 5 (1.4%). 216 (58.5%) pts were receiving active treatment at the moment of the infection: 20 neo/adjuvant treatment and 196 metastatic/palliative treatment. 81 pts (22%) were receiving immuno-oncology (IO), 69 (18.7%) chemotherapy (CT), 36 (9.8%) tyrosine kinase inhibitors (TKI), 67 (18.2%) new anti-androgen therapy, and 101 (27.4%) were on steroids. Most frequent symptoms of COVID-19 were: cough in 138 pts (37.4%), with a median duration of 6.6 days; fever 176 (47.7%), median duration 5.76 days; dyspnea 119 (32.2%), asthenia 82 (22.2%), diarrhea 44 (11.9%) and myalgia 36 (9.8%). Laboratory abnormalities were common, 166 pts (45%) had lymphopenia and 137 (37.1%) D-dimer elevation. 153 (41.5%) presented pneumonia and 119 (32.3%) had patchy pulmonary infiltrates. 132 patients had to be hospitalized (35.8%) and 55 (14.9%) died. The presence of radiological findings, hospitalization and mortality were not related to sex or treatment with IO, CT, TKI or corticosteroids. Median age of pts with radiological pneumonia (72 vs 65.8;  $p<0.0001$ ), patchy infiltrates (71.4 vs 76;  $p=0.002$ ), admitted to the ICU (75 vs. 67;  $p<0,0001$ ) and died (76.1 vs 67.77;  $p<0,0001$ ) was higher.

### Conclusions:

Mortality secondary to COVID-19 was higher in GU cancer patients than that described in the general population. As described in other settings, age was the most important risk factor for COVID-19 severe outcomes regardless of tumor type or treatment.

### Clinical trial identification:

NCT04578132.

## First wave mortality data versus full pandemic period from the COVID-CANCER HUIL study

### Background:

Cancer patients are one of the most affected by the current pandemic caused by SARS-CoV-2. Social inequalities influence the incidence rate of this disease, as we have seen in the high incidence in our center. In our study, we asked whether the last covid-19 treatment advances, the capacity for restructuring the health centers and their non-saturation, influences the cancer patient's outcomes.

### Methods:

Retrospective review of 189 cancer patients diagnosed in our center with COVID-19 from March 5, 2020 to February 28, 2021. Study data was collected and managed using REDCap. We compared COVID-19 diagnoses in first-wave cancer patients versus the full pandemic period until data cut-off, as well as patient characteristics and mortality rates.

### Results:

Mortality rate: 55/189 patients during the entire pandemic period vs 40/85 patients in the first wave ( $p = 0.03$ ). Median age: 72 years (34-95) vs 76 (34-94), 125/ 189 men in all the period vs 50/85 ( $p = 0.2$ ). Most frequent histologies: lung cancer (72/189 vs 22/85,  $p = 0.07$ ), colorectal (31/189 vs 19/85,  $p=0.23$ ), breast (24/189 vs 10/85,  $p=0.82$ ). Staging: 113/189 metastatic disease at diagnosis of infection vs 32/ 85 in first wave ( $p<0.001$ ). During the 2 subsequent waves in our center, where 104 more patients have been detected, mortality has dropped significantly: from the initial 47% to 14.4% in the rest of the period (40/85 vs 15/104,  $p <0.001$ ), despite having more metastatic involvement in infected patients.

### Conclusions:

In our center, one of the worst hit by the coronavirus crisis in Spain, with a supersaturation of almost 250% in the middle of the first wave, we have verified how the knowledge of the behavior of this disease, improvements in its treatment and a multidisciplinary management in Oncology ward have led to a significant decrease in mortality, going from almost 50% in the first wave to less than 15%, despite having suffered the disease during the two subsequent waves a greater number of patients with metastatic disease.



## Mortality of 1,636 COVID-19 cancer patients (pts) and associated prognostic factors

### Background:

We assessed mortality risk by COVID-19 (C19) infection among treated cancer patients (pts) and the impact of anti-cancer treatment (tx) on mortality.

### Methods:

Optum de-identified Electronic Health Record dataset (2021-01-07 release) were used to find cancer pts with a C19 positive (ICD-9/10-CM codes U071/U072 or positive test result) or negative (negative test and no positive test at any time after the first negative result) status on the first test/diagnosis date (i.e. the “index date”). Pts with <1 year database history, with no tx 0-90 days before index, <18 years old, with implausible death dates, and with index dates outside of 02/2020 - 11/2020 were excluded. C19 positive and negative pts were exact-matched on cancer type, then 1:1 nearest-neighbor matched on propensity scores (variables in table). Missing values were imputed (n= 5), and outcomes were evaluated by multivariable logistic regression, including interaction terms between tx and C19 positivity.

### Results:

We identified 21,060 pts, of whom 1,636 (7.8%) were positive for C19 and 19,424 (92.2%) negative. Among 1,636 matched pairs of positive/negative C19 pts, the odds ratio (OR) of 30-day mortality comparing C19 positive vs negative patients was 2.14 (95% CI: 0.71- 6.52). Among the strongest predictors of 30-day mortality were age 75+ (OR=5.42, 95% CI: 2.21-13.28), inpatient C19 testing/diagnosis (OR= 4.78, 95% CI: 3.04,7.53), CCI of 3+ (OR= 2.24, 95% CI: 1.30-3.89), and metastatic disease (OR=1.80, 95% CI 1.21- 2.68). Anti-cancer therapies do not appear to modulate risk of death due to C19. Beyond 30-day mortality, matched mortality rate ratios (MRRs) suggested increased risk for C19 positive patients (MRR= 1.85, 95% CI: 1.26- 2.44).

**Table: 1574P Select` OR and 95% CIs for 30-day mortality**

	OR	95% CI, lower	95% CI, upper	p
Anti-cancer tx				
Chemotherapy	2.10	0.98	4.52	0.06
Hormone	0.75	0.27	2.09	0.57
Immunotherapy	1.56	0.56	4.39	0.39
Targeted biologic	1.58	0.49	5.07	0.41
Targeted small molecule	2.00	0.74	5.44	0.16
C19 positive	2.14	0.71	6.52	0.18
Interactions with C19				
Chemotherapy	0.81	0.31	2.15	0.67
Immunotherapy	0.45	0.14	1.52	0.20
Hormone therapy	1.58	0.46	5.36	0.46
Targeted biologic	0.49	0.13	1.77	0.26
Targeted nonbiologic	1.42	0.46	4.39	0.54

- Not shown (statistical significance\*): (intercept)\*, age\*, CCI\*, index month\*, insurance, metastasis\*, obesity, region, setting\*, sex, smoking status, years since first cancer diagnosis

### Conclusions:

C19 showed a trend towards increased 30-day mortality risk (not statistically significant), and increased overall mortality risk. Specific tx did not appear to modulate 30-day mortality due to C19.

## Systemic anti-cancer therapy and metastatic cancer are independent mortality risk factors during two UK waves of the COVID-19 pandemic at University College London Hospital

### Background:

Data from the first wave of COVID-19 infection demonstrated that a history of cancer and SACT was associated with poorer outcomes. Our study compares outcomes for cancer patients matched to non-cancer patients between the two waves in order to explore further how cancer and its treatment may impact COVID-19 mortality.

### Methods:

Data was collected for patients with positive PCR and history of cancer between 1 Mar to 20 May 2020 and 1 Dec to 8 Feb 2021 for wave 1 and 2, respectively. A contemporaneous cohort of patients without cancer were age- and sex-matched for comparison.

### Results:

The total number of patients presenting with COVID-19 was higher in wave two (1135 vs 626). 207 of these patients had cancer, and were matched to 452 patients without cancer from both waves. There was a significantly improved chance of mortality in wave 2 (HR 0.41,  $p < 0.0001$ ). When adjusting for age, sex and comorbidities, cancer was an independent risk factor for mortality amongst patients hospitalized with COVID-19 in wave 1 (HR 1.62,  $p=0.02$ ), but not in wave 2. There was a trend towards improved survival for hospitalized patients in wave 2 receiving COVID-19 specific treatment including dexamethasone, remdesivir, tocilizumab (HR 0.75,  $p= 0.086$ ). For the combined cancer cohort, SACT was an independent predictor of mortality, as was metastatic disease.

	HR (95% CI)	P-value
Malignancy status		
Metastatic	2.1 (1.02 - 4.34)	0.04
Active cancer	0.55 (0.28 - 1.08)	0.08
Active anti-cancer treatment	1.75 (0.97 - 3.18)	0.06
SACT	2.01 (1.10 - 3.66)	0.02
Cytotoxic chemotherapy	1.93 (0.93 - 4.00)	0.08
Endocrine therapy	1.66 (0.69 - 3.96)	0.25
Targeted therapy	0.84 (0.11 - 6.28)	0.86
Immunotherapy	1.73 (0.4 - 7.41)	0.46
Radiotherapy	2.04 (0.62 - 6.74)	0.24
Surgery	0.67 (0.09 - 4.98)	0.69

### Conclusions:

The mortality for both cancer and non-cancer patients improved between waves of the pandemic. Advances in detection, prevention and treatment may account for this. Cancer was no longer a risk factor for mortality in the second wave, however SACT and metastatic cancer remained risk factors for mortality within the cancer cohort. This emphasizes the need for ongoing protection of patients with advanced cancer and those on SACT, including through their prioritization for COVID19 vaccination globally.

## COVID-CANCER HUIL - Registry of oncological patients with diagnosis of COVID-19 at Hospital Universitario Infanta Leonor in Madrid (Spain): One year of pandemic

### Background:

During the first year of the SARS-CoV-2 pandemic the management and treatment of COVID-19 have been improved. However, cancer patients continue to be one of the most affected. We evaluate the mortality rate due to COVID-19 and associated risk factors in the cancer population diagnosed in our center during the first year of pandemic.

### Methods:

We retrospectively reviewed the medical records of 189 cancer patients who were diagnosed with COVID-19 between March 5, 2020 and February 28, 2021. Mortality rate and associated risk factors were studied.

### Results:

Mortality rate: 55/189 patients. Mean age: 72 years (34-95), 125/189 male patients. Predominant histologies: lung cancer (72/189), colorectal (31/189), breast (24/189). Predominant staging: metastatic disease (113/189). Predominant cancer treatment: chemotherapy (63/189); 118/189 patients were receiving any type of oncological treatment with palliative intention. Mortality was associated with male gender (45/55 vs 10/55,  $p=0.004$ ), presence of comorbidities (48/55 vs 7/55,  $p=0.01$ ), lung cancer (28/72 deaths with this tumor vs 27/117 with the rest,  $p=0.02$ ), palliative intention cancer treatment (41/55 vs 12/55,  $p=0.02$ ), older median age (76 vs 71,  $p=0.02$ ), higher median CRP ( $p=115.6$  mg/dl vs 46 mg/dl), lower median lymphocytes ( $600/\text{mm}^3$  vs  $1000/\text{mm}^3$   $p<0.001$ ). No specific treatment against COVID-19 significantly decreased mortality. Neither IL-6 nor ferritin were prognostic biomarkers. In multivariate analysis, male gender (OR 2.58, 95% CI 1.1-5.9,  $p=0.02$ ), lung cancer (OR 2.0, CI 1.0-3.8,  $p=0.03$ ), cancer treatment with palliative intention (OR 2.4, CI 1.07-5.3,  $p=0.03$ ), higher median CRP (OR 1.0, CI 1.00-1.01,  $p<0.001$ ), as well as low lymphocyte median (OR 0.5, CI 0.25-1.0,  $p=0.56$ ), continued to be evidenced as risk factors, regardless of comorbidities, staging, sex, and palliative intention cancer-specific treatment, among other variables.

### Conclusions:

Men with lung cancer under cancer-specific treatment with palliative intention who present, at the diagnosis of SARS-CoV-2 infection with elevated CRP above 115 mg/dl and a decrease in lymphocytes below  $600/\text{mm}^3$  have a higher risk of presenting fatal complications.

## Early mortality linked to COVID-19 in cancer patients as compared to historical control in pre-pandemic times

### Background:

The COVID-19 pandemic remains a public health emergency of global concern, with higher mortality rates in cancer patients as compared to the general population. However, early mortality of COVID-19 in cancer patients has not been compared to historical real-world data from oncology population in pre-pandemic times.

### Methods:

Longitudinal multicenter cohort study of patients with cancer and confirmed COVID-19 from Oncoclínicas Group in Brazil from March to December 2020. The primary endpoint was 30-day mortality after isolation of the SARS-CoV-2 by RT-PCR. As historical control, we selected patients from Oncoclínicas Data Lake treated before December 2019 and propensity score-matched to COVID-19 cases (3:1) based on the following clinical characteristics: age, gender, tumor type, disease setting (curative or palliative), time from diagnosis of cancer (or metastatic disease) to COVID-19 infection.

### Results:

In total, 533 cancer patients with COVID-19 were prospectively registered in the database, with median age 60 years, 67% females, most frequent tumor types breast (34%), hematological (16%), gastrointestinal (15%), genitourinary (12%) and respiratory tract malignancies (10%). Most patients were on active systemic therapy or radiotherapy (84%), largely for advanced or metastatic disease (55%). In the overall population, early death rate was 15%, which was numerically higher than the Brazilian general population with COVID-19 diagnosis in 2020 (2.5%). We were able to match 442 cancer patients with COVID-19 to 1,187 controls with cancer from pre-pandemic times. The 30-day mortality rate was 12.4% in COVID-19 cases as compared to 5.4% in pre-pandemic controls with cancer (Odds Ratio 2.49, 95% CI 1.67 - 3.70; P value < 0.01, Power 97.5%). COVID-19 cancer patients had significantly higher death events than historical controls (Hazard Ratio 2.18, 95% CI 1.52 - 3.12; P value < 0.01, Power 99.7%), particularly from 20 to 30 days after diagnosis of the infection.

### Conclusions:

Cancer patients with COVID-19 have an excess mortality 30 days after the infection when compared to matched cancer population from pre-pandemic times and the general population with COVID-19, reinforcing the need for priority vaccination in public health strategies.

## Clinical outcomes of patients with cancer who tested positive for COVID-19 hospitalized in a UK district general hospital

### Background:

Individuals diagnosed with cancer have been particularly affected by the COVID-19 pandemic. Most of the relevant information so far has come from tertiary cancer centers and less is known of the outcomes of patients in District General Hospitals (DGH). In this audit, we aimed to investigate the clinical outcomes of patients with cancer who tested positive for COVID-19 and were admitted in a DGH.

### Methods:

Electronic records of patients admitted at Tameside General Hospital (TGH) (>500 beds) between March 2020eMarch 2021 were reviewed retrospectively. Clinical outcomes of those who tested positive for COVID-19 and factors relating to death were analyzed. Cox regression and Kaplan-Meier survival analyses were performed (SPSS v26.0).

### Results:

Within the 12-month study period, there were 2417 inpatients who tested positive for COVID-19 at TGH. Of 235 individual patients with cancer admitted during this period, 14% (n=33) tested positive. Median age was 75 (68;81) years; majority female (67%). The most prevalent primary site of cancer were lung (21%) and breast (12%). Most were ECOG PS 1 (39%) or PS 2 (36%), and had high Charlson Comorbidity Index (median 5 (3;6), range 0-10). 24% of patients were on curative treatment, 39% palliative treatment, 18% best supportive care and 18% not on treatment. Types of treatment included chemotherapy (37%), hormonal treatment (26%), radiotherapy (21%) and immunotherapy (5%). On average, patients were admitted at least once (range 0-4) prior to positive test for COVID-19. At last follow-up, there were n=664/ 2417 (27%) and n=22/33 (67%) deaths in the non-cancer and cancer patient subgroups, respectively. The median time from diagnosis of COVID-19 to death/censor date was 44 (4;85) days. In univariate Cox regression analysis, only ECOG PS was significantly correlated with death, HR 1.523 (95% CI 1.064-2.181, p=0.022).

### Conclusions:

The outcomes of our cohort of patients with cancer who tested positive for COVID-19 and hospitalized were poor. The high comorbidity burden and poor ECOG PS could potentially account for this rather than the recent oncological treatment. Acute oncology input to general medical teams treating cancer patients with COVID-19 is pivotal for best possible outcomes for patients.



## The risk of severe/critical COVID-19 infection in patients diagnosed with solid malignancies: Two center experience from Armenia

### Background:

Nowadays, the data on Coronavirus Disease 2019 (COVID-19) among cancer patients is controversial. It is debatable whether cancer patients are at a significantly higher risk of severe COVID-19. The current study aims to assess the risk of severe and critical COVID-19 cases among patients receiving systemic anticancer treatment (SACT).

### Methods:

This was a retrospective cohort study utilizing census sampling. The data was obtained through medical records. Inclusion criteria: COVID-19 diagnosis through RT-PCR/chest CT among those who received SACT in the Chemotherapy Departments of Hematology Center after prof. Yeolyan and Institute of Surgery after Mikaelyan Yerevan, Armenia between March 1, 2020, and February 1, 2021. Descriptive analysis was done to characterize the cohort. We run logistic regression to evaluate the risk of COVID-19 severity (mild, severe/critical) among those receiving SACT (high, intermediate, and low-risk protocols of febrile neutropenia (FN), age, gender, smoking status, comorbidities).

### Results:

In total 75 cancer patients were diagnosed with COVID-19 in both centers. Data of only 72 patients were analyzed, as the outcome variable of the excluded patients was unknown. The male-to-female ratio was 1:1.5, age range was 31-80 years (median age: 61). The patients received SACT with high (13.9 %), intermediate (63.9 %), and low (8.3 %) risk for FN. The others did not receive SACT at the moment of COVID-19 diagnosis. Infection-associated pneumonia was developed in 63% of cases. Mild COVID-19 was diagnosed in 76.4% and severe/critical in 23.6% of cases. Infected patients' hospitalization rate was 28%. The case fatality rate was 8%. Only patients who underwent SACT at the time of COVID-19 infection were included in logistic regression analysis (n=62). Significant association between COVID-19 severity and the risk of SACT-induced FN, gender, smoking status, comorbidities was not found. Contrary, COVID-19 severity was significantly associated with age when adjusted to other predictors ( $p=0.017$ , 95% CI= 1.021-1.230).

### Conclusions:

Thus, we demonstrate the lack of rationale to reschedule SACT during the pandemic as it does not affect the COVID-19 severity and may bring unnecessary treatment delays.

## Impact of COVID-19 infection on breast cancer patients: Experience in Latin-American country ACHOCC-19B study

### Background:

There are not specific information about outcomes of COVID-19 infection in patients with breast cancer. We aimed to describe the outcomes in this population in our national cohort of patients with cancer and infection for COVID-19.

### Methods:

ACHOCC-19B registry is a multicenter observational study composed of a cross-sectional and a prospective cohort component. Eligibility criteria were the diagnosis of breast cancer and COVID-19 infection confirmed with RT-PCR. Follow-up of 30 days was completed. Clinical data were extracted of the multicentric register of cancer and covid-19 in Colombia (ACHOCC-19), collected from Apr 1 until Oct 31, 2020. The primary outcome was 30-day mortality from all causes and secondary outcome was asymptomatic disease. Associations between demographic or clinical characteristics and outcomes were measured with odds ratios (ORs) with 95% CIs using multivariable logistic regression.

### Results:

132 patients were included (18,5% of global ACHOCC-19 cohort). 18,2% died and 25,8% was asymptomatic. In relation to the patients who died vs did not died, 68 vs 66% were > 50 years, 20 vs 10,2% with obesity, 32 vs 51,4% without comorbidities: 24 vs 12% with Diabetes, 56 vs 29% arterial Hypertension, 17,75 vs 3.88% ECOG >2, 50 vs 12,5% progressive cancer, 20 vs 5,6% bacterial coinfection, 65 vs 25,2% received antibiotic and 68 vs 19% steroids for Covid-19 infection. 11.3% had severe infection and received ventilatory support and 66% died. About the asymptomatic patients 74% were > 50 years, 2,9% had obesity, 56% without comorbidities, 56% with ECOG 0 and 17,6% had metastatic disease. In the logistic regression analysis, age > 50 years (OR 2,7 95% 0,54-13,81), >2 comorbidities (OR 3,48 95% 0,26-45,71), progressive disease (OR 3,52 95% 0,47-26,57), steroids (OR 6,62 95% 1,5-26,6) and antibiotic treatment for Covid19 (OR 6,88 95% 1,60-29,76) behaved as a risk factor for mortality, but only steroids and antibiotic was statistically significant.

### Conclusions:

In our study, breast cancer patients have high mortality by Covid-19 infection. Age, comorbidities, ECOG >2, progressive disease, and use of antibiotic and steroids are factors for worse prognosis.

## Impact of the COVID-19 pandemic on patients with head and neck cancer assisted in a public cancer center in Brazil

### Background:

Since the beginning of the COVID-19 pandemic, over 400,000 Brazilians have died and its impact on other diseases is yet to be revealed. Due to contingency strategies, there was a significant reduction in screening programs and this will probably affect cancer treatment outcomes. There is no updated national data regarding the real impact on delaying diagnosis and cancer treatment in Brazil. Objective: To analyze whether the COVID-19 pandemic impacted delaying cancer treatment, yielding more advanced cases as analyzing patients' clinical features before oncological treatment.

### Methods:

This is a retrospective cross-sectional study with patients assisted in a public cancer center in southeastern Brazil between 2019 and 2020 with a comparison of patients' clinical features in both years. We analyzed all 207 patients with head and neck treated in 2019 and 2020 (85 and 122 patients, respectively) and stratified them by clinical stage (CS), tumor size, lymph node status (LNS), the occurrence of metastatic disease (MD), body mass index (BMI), need of enteral nutrition, age, performance status (PS) and the indication of exclusive palliative care. We performed comparisons between these groups using Student t-test and chi-square test with a significance level of 5%.

### Results:

Our results reported a statistically significant difference on tumor size ( $p 0,024$ ); in 2019 50,6% of the tumors were classified as T4 in comparison with 66,4% in 2020. Data showed no statistically significant difference among groups regarding age (median of 56y in 2019 and 58,5y in 2020;  $p 0,056$ ), BMI (47% had a BMI below 20 on each group,  $p 0,595$ ), need of enteral nutritional (54,1% in 2019 and 59,8% in 2020,  $p 0,254$ ), CS (75,3% had stage IV disease in 2019 and 81,1% in 2020 e  $p 0,486$ ), LNS (42% were N2 in 2019 and 38,5% in 2020,  $p 0,243$ ), MD (9,4% in 2019 and 13,9% in 2020,  $p 0,326$ ), PS (59% had PS 1 in 2019 and 45% in 2020,  $p 0,061$ ) and indication of exclusive palliative care (4,7% in 2019 and 10,7% in 2020,  $p 0,125$ ).

### Conclusions:

The real impact of the COVID-19 pandemic in cancer treatment is yet to be discovered but so far, our results from 2020 patients indicated a tendency of advanced primary tumor size at the time of cancer diagnosis.



## Thromboembolic disease in COVID-19 cancer patients: Impact on overall survival and prognostic factors

### Background:

An increased risk of thromboembolic events (TE) is associated with COVID-19 infection. However, information available about thrombosis risk in COVID19 cancer patients (Ca-P) is still scarce.

### Methods:

We retrospectively evaluated 219 Ca-P who were diagnosed of COVID-19 infection in our institution during the first pandemic wave. The study population was monitored for 12 months, and TE were recorded. A descriptive analysis of baseline and follow-up clinical characteristics was performed. Potential prognostic factors for developing TE and overall survival (OS) were analyzed using logistic and cox proportional regression models.

### Results:

Overall TE rate was 13%. TE was reported during COVID-19 hospitalization (52%) and during follow-up (48%), the median time from COVID-19 diagnosis to TE was 12 weeks (w). Reported TE included pulmonary embolism (68%), deep vein thrombosis (16%), and other arterial thrombosis (16%). Pooled mortality rate among patients with TE was 52%, and 41% among patients without TE. Univariate analysis revealed hemoglobin <10g/dL, D-dimer >3000 ng/mL, PCR >5 ng/mL, LDH >190 UI/L and ferritin > 296 ng/mL during follow-up as significant prognostic factors for TE. Only ferritin > 296 ng/mL remained significant after multivariate analysis. Neither being on any specific oncological treatment nor prior anticoagulant therapy influenced TE risk. No differences in OS were found between patients who developed TE and those who did not. Though, diagnosis of TE during COVID-19 hospitalization conferred poorer survival (12 vs 52 w,  $p=0.02$ ). Also, being hospitalized for COVID-19 infection was a prognostic factor for worse survival (27 vs 52 w,  $p=0.03$ ). On multivariate analysis, only acute respiratory distress syndrome, metastatic disease, poor performance status, and history of TE before COVID-19 diagnosis remained significant predictors for poorer survival, and thromboprophylaxis during COVID-19 hospitalization as a predictor for better survival outcomes.

### Conclusions:

TE in COVID-19 Ca-P can lead to fatal outcomes. Thrombotic risk may persist after acute infection; therefore, routine active surveillance should be considered. Larger studies are needed for developing a risk prediction tool for TE in COVID19 Ca-P.

## COVID-19 related risk in patients enrolled in early-phase clinical trials

### Background:

Early phase clinical trials often represent a therapeutical opportunity for cancer patients (pts). However, high logistic commitment is demanded for participation. Here we explore the COVID-19 related risk during the pandemic for pts enrolled in clinical trials compared to pts receiving standard treatments.

### Methods:

We retrospectively assessed the incidence of COVID-19 in pts treated in our Department from March 2020 to April 2021. Pts were divided into two groups; those enrolled in phase I/II clinical trials (A) and those being treated with standard therapies (B). Logistical (telemedicine and drug home-delivery), as well as clinical, characteristics of susceptibility to COVID-19 and number of events (SARS-CoV2 infections) were collected. The number of teleconsultations and COVID-19 events among the two groups were compared through Fisher's exact test.

### Results:

115 pts were evaluated: 36 pts (31%) in A and 79 pts (69%) in B. Pts in A were younger, with a median age of 55 years (range 39-77) compared to 62 years (range 31-83) in B. Performance status (PS, ECOG) was similarly distributed: 0 (A 78%, B 83%), 1-2 (A 22%, B 17%). The median of previous treatment was 1 in A (range 0-9) and 2 (range 0-14) in B. The majority of the pts had at least one comorbidity in both groups (A: 72% and B: 83%). None of the pts had pulmonary comorbidity in A and 6% in B. Obesity was similarly distributed (A 11%, B 14%). The mean of monthly scheduled accesses was 1,5 in both groups. However, teleconsultation and delivery of oral cancer treatments at home were given, at least on one occasion, to only 6% of pts in A compared to 43% in B ( $p < 0.01$ ). A total of 15 COVID-19 cases were observed (13%): 8 (22%) in A and 7 (8%) in B. No statistically significant difference was observed ( $p = 0.068$ ).

### Conclusions:

Pts enrolled in early phase clinical trials had a significantly lower chance to perform teleconsultations compared to pts receiving standard therapy. Even if a trend was observed, they did not have a higher risk of contracting COVID-19. Future pts should then be encouraged to participate, if indicated. Considering the small numbers of pts in our cohorts, the foreseen trend toward a higher infection risk and the subsequent implications should be further explored in larger populations.

## Prevalence and risk factors of COVID-19 in cancer patients: A prospective monocentric study

### Background:

The COVID-19 is a worldwide health threat because of its severity and rapid spread. Cancer patients have been reported to be at an increased risk of COVID19 infection. We aimed to assess the prevalence of COVID-19 in Tunisian cancer patients and to identify its risk factors.

### Methods:

A prospective study was conducted at the department of Medical Oncology in Sfax from November 2020 to February 2021. We analyzed data of 226 patients treated for solid cancer. We used the modified Milano Policlinic ONCOVID Score to quantify the risk of infection in patients with cancer. We defined 3 groups of risk (score<4: low risk, score¼ 4-6: intermediate risk and score>6: high risk).

### Results:

Patients aged under 70 years represented 85%. The sex-ratio was 0.5. The most common primary tumors were breast cancer (37%), colorectal (22%), ovarian (7.5%) and lung cancer (5.5%). Metastatic disease was observed in 58%. 95% had recently received anticancer treatment (chemotherapy n=171), (hormonotherapy /targeted therapy n¼44). Primary lung cancer or pulmonary metastases were founded in 16%. 22% of patients had a history of thoracic radiotherapy. Among 226 cancer patients, 19 patients (8.4%) had COVID19 disease. Fifteen patients (79%) presented with symptoms such as fever, dyspnea, cough, myalgia and ageusia/ anosmia. A severe form of COVID-19 requiring hospitalization was seen in 4 cases (21%). 47 % had an intermediate and high risk of infection. COVID-19 infection was correlated with intermediate or high risk ( $p=0.018$ ,  $\chi^2=18.4$ ,  $ddl=8$ ), age <70 years ( $p=0.035$ ,  $\chi^2=4.437$ ,  $ddl=1$ ) and chemotherapy ( $p=0.032$ ,  $\chi^2=4.613$ ,  $ddl=1$ ). Severe cases were correlated with stage IV ( $p=0.041$ ,  $\chi^2=4.156$ ,  $ddl=1$ ), chemotherapy ( $p=0.004$ ,  $\chi^2=7.367$ ,  $ddl=1$ ) and intermediate or high risk ( $p=0.04$ ,  $\chi^2=3.754$ ,  $ddl=1$ ).

### Conclusions:

The prevalence of COVID-19 infection among cancer patients was higher than that described in the literature (0.79%) but with a lower rate of severe forms. The occurrence of COVID-19 was correlated with intermediate or high risk, age<70 years and treatment with chemotherapy which highlights the importance of risk scores.

## COVID-19 cancer patient's outcomes in an intensive care setting: A case-control study

### Background:

Cancer patients appear to be a vulnerable group in COVID-19 pandemic. We aimed to compare clinical characteristics and outcomes of cancer and non-cancer patients with COVID-19 admitted to an intensive care unit (ICU).

### Methods:

We conducted a retrospective case-control study in patients with laboratory-confirmed COVID-19, with and without cancer, admitted to the ICU of “Centro Hospitalar Universitário do Porto” from 2nd March 2020 to 31st January 2021. Patients were matched according to age, gender and underlying comorbidities. Clinical, laboratory and radiological findings were obtained from medical records. COVID-19 related outcomes of both groups were compared using logistic regression.

### Results:

29 critical COVID-19 cancer patients (cases) and 29 critical COVID-19 noncancer patients (controls) were enrolled. Fever, dyspnea and cough were the most common presenting symptoms in both groups. Lymphopenia and elevated lactate dehydrogenase were the most common laboratory findings in both groups and anemia was observed significantly more often in cancer patients (75.9% vs 44.8%;  $p=0.031$ ). Ground glass opacities were more frequently seen in controls (100% vs 67%;  $p=0.018$ ). Univariate regression revealed that invasive mechanical ventilation (IMV) need on ICU admission was significantly higher among cancer patients [48% vs 7%; odds ratio (OR)= 12.600, 95% confidence interval (CI) 2.517-63.063,  $p=0.002$ ] but there was no significant impact either on global need of IMV during all-length ICU stay (76% vs 55%; OR= 2.554, 95% CI 0.831-7.842,  $p=0.102$ ) or on mortality rates (59% vs 38%; OR= 2.318, 95% CI 0.809-6.644,  $p=0.118$ ). A multivariate model showed an increase in the adjusted risk of IMV need at ICU admission (adjusted OR=14.036, 95% CI 1.337-153.111,  $p=0.028$ ). The length of ICU stay, time to death and rate of complications were not impacted by the presence of cancer.

### Conclusions:

In this study critical cancer patients with COVID-19 had an increased risk for IMV need at ICU admission but not for IMV need during all-length ICU stay or mortality rates. Despite evolving more rapidly to respiratory failure (RF) cancer patients did not have significant increase on mortality, stressing the importance of aggressive treatment in this group of patients.

## Assessment of side effects of radiation therapy in patients with COVID-19 treated for early-stage breast cancer

### Background:

The COVID-19 caused by the SARS-COV-2 coronavirus is at the origin of a global pandemic. We report the early and late toxicity in patients infected with COVID-19 treated at the same time for early-stage breast cancer (BC) toxicity.

### Methods:

This is a monocentric prospective study of patients treated in our hospital between March and June 2020. The monocentric registry was created for all cancer patients who were diagnosed with COVID-19 infection. The inclusion criteria of the patients evaluated were to be irradiated for early-stage breast cancer and to have a positive COVID-19 diagnosis on a PCR test and / or a lung computed tomography (CT) scan and / or suggestive clinical symptoms. All of them needed 6 months follow up clinic after the end of the radiotherapy with clinical examination, as well as CT scan to evaluate the lung status. Radiotherapy (RT) consisted of 50 Gy to the breast or chest wall with or without lymph node irradiation, as well as hypo fractionated schemes adapted to the pandemic situation. The treatment-related toxicity was graded according to the CTCAE.

### Results:

Three hundred fifty patients (pts) have been treated for early-stage BC in our department. Of them, 16 were presented with clinical symptoms of COVID-19 infection and of them 12 had clinical, CT scan and PCR confirmation. This entire cohort of 12 pts with median age of 56 (42-72) underwent their RT. All patients were invited to realize CT scan 6 months after the end of RT and to come in the hospital for clinical and radiological evaluation. During the radiotherapy, 9 pts presented with radio dermatitis, of these 8 (66%) grades 1 and one (8%) grade 2. Two patients treated to the regional lymph nodes presented grade 2 esophagitis. The late toxicity as well as the lung radiological evaluation was realized 6 months after the end of the radiotherapy and there was no RT or COVID lung sequel on the CT scans. There was one patient who presented COVID-related dyspnea, and 2 patients with post-treatment fibrosis.

### Conclusions:

The half-year follow-up of prospective COVID-19+ cohort, treated for early-stage BC demonstrated an acceptable toxicity profile with few low-grade adverse events. It seems that the COVID-19 infection does not appear to increase the side effects of RT. Therefore, the RT should not be delayed.



## SARS-CoV-2 infection risk and COVID-19 prevalence in cancer patients during the first wave of COVID-19 pandemic in a Northern Italy's virus epicenter area

### Background:

Patients (pts) with cancer are purported to be more vulnerable to coronavirus disease 2019 (COVID-19). However, cancer encompasses a spectrum of heterogeneous tumor subtypes. The aim of this study was to investigate severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection risk and COVID-19 prevalence according to tumor subtype in the resident cancer population of the Province of Parma (Emilia Romagna Region, Northern Italy) during the first wave of COVID-19 pandemic in Italy.

### Methods:

We analyzed data from the Parma Province Cancer Registry, COVID-19 hospital medical records, and local surveillance system of all laboratory-confirmed cases tested positive for SARS-CoV-2 from the beginning of the outbreak (February, 20) to July 19, 2020. All the Parma resident cancer population was classified as either "active" or "inactive" according to the evidence of any referral to health services, for any reason, during the observation period. Study analyses were adjusted for patient demographics, tumor subtype and period of cancer diagnosis.

### Results:

40,148 cancer pts (mean age 68; 57.8% females; 45.1% active) were analyzed. The cumulative risk of SARS-CoV-2 infection was 11.2% for cancer pts vs. 7% for non-cancer subjects ( $P < 0.0001$ ). The overall COVID-19 attack rate was 2.2% (95% CI, 2.0-2.4) and 2.6% (95% CI, 2.4-2.9) for inactive and active cancer pts, respectively. The cumulative incidence of COVID-19 was higher in active vs. inactive cancer subjects (HR 1.18,  $P = 0.01$ ). In the active cancer group, the cumulative incidence of COVID-19 was higher in lung cancer pts vs. other tumors (HR 4.3). In the same group, HR for breast cancer pts was 0.86. Interestingly, the subgroup analysis of COVID-19 cumulative incidence showed a significant interaction between active patient status and hematological malignancies.

### Conclusions:

In our study, cancer pts were more susceptible to SARS-CoV-2 infection. The cumulative incidence of COVID-19 was higher in active vs. inactive cancer subjects. However, cancer is a heterogeneous group of diseases and pts with different tumor types had differing susceptibility to COVID-19 phenotypes. COVID-19 fatality rates for subgroups will be reported at the meeting.

## SARS-CoV-2 antibody seroprevalence and safety of vaccines in cancer patients who recovered from COVID-19

### Background:

Little is known about natural anti-SARS-CoV-2 antibody seroprevalence post COVID-19 and safety of vaccines in COVID-19 survivors with cancer.

### Methods:

Among 2795 consecutive patients (pts) with COVID-19 and cancer registered to OnCovid between 01/2020 and 02/2021, we examined natural seroprevalence of anti-SARS-CoV-2 Antibodies (SC2Ab, IgM or IgG) in pts tested post-infection. We analyzed prevalence and safety of SARS-Cov-2 vaccine administration in pts who underwent clinical re-assessment at participating institutions.

### Results:

Out of 350 pts tested for SC2Ab, 318 (90.9%) had a positive SC2Ab titer postconvalescence. Neither baseline features (sex, age, comorbidities, smoking history, tumor stage/status, anticancer-therapy and primary tumor) nor COVID-19-specific features (complications, hospitalization, sequelae) were significantly associated SC2Ab status. Receipt of COVID-19 specific therapy was higher among SC2Ab+ pts (62.6% vs 40.6%,  $p=0.0156$ ). Out of 593 pts with known vaccination status, 178 (30%) had received 1 dose, whilst 38 pts (6.4%) received 2 doses of mRNA based (70.2%) or viral vector vaccine (17.4%). Vaccinated pts was more likely aged  $\geq 65$  years (59% vs 48.3%,  $p=0.0172$ ), with loco-regional tumor stage (56% vs 40.8%,  $p=0.0014$ ), on anti-cancer therapy at COVID-19 (49.1% vs 38.2%,  $p=0.0168$ ) and history of prior hospitalization due to COVID-19 (61.8% vs 48.3%,  $p=0.0029$ ). Vaccine-related adverse events were reported for 18/56 evaluable pts (32.1%) and included injection site reactions (50%), fever (44.4%), arthralgias (33.3%), fatigue (33.3%) and allergy (5.5%). No long-term vaccine-related morbidity was reported.

### Conclusions:

We report high seroprevalence (>90%) of SC2Ab in convalescent cancer pts who survived COVID-19 irrespective of baseline demographics, oncological characteristics and COVID-19 severity. COVID-19 vaccines appear to be safe in cancer pts with history of prior infection.

### Clinical trial identification:

NCT04393974.

## Safety of the BNT162b2 mRNA COVID-19 vaccine in oncologic patients undergoing numerous cancer treatment options

### Background:

The COVID-19 pandemic, caused by the SARS-CoV2 virus, has infected millions worldwide with cancer patients demonstrating a higher prevalence for severe disease and poorer outcomes. Recently, the BNT162b2 mRNA COVID-19 vaccine was released as the primary means to combat COVID-19. The currently reported incidence of local and systemic side effects was 27% in the general public. The safety of the BNT162b2 mRNA COVID-19 vaccine has not been studied in patients with an active cancer diagnosis who are either ongoing or plan to undergo oncologic therapy.

### Methods:

This retrospective single center study reviewed the charts of 210 patients with active cancer diagnoses that received both doses of the BNT162b2 mRNA COVID19 vaccine. The development of side effects from the vaccine, hospitalizations or exacerbations from various oncologic treatment were documented. Type of oncologic treatment (immunotherapy, chemotherapy, hormonal, biologic, radiation or mixed) was documented to identify if side effects were related to treatment type. The time at which the vaccine was administered in relation to treatment onset (on long term therapy, within one month of therapy or prior to therapy) was also documented to identify any relationships.

### Results:

65 (31%) participants experienced side effects from the BNT162b2 mRNA COVID-19 vaccine, however most were mild to moderate. Treatment protocol was not linked to the development of vaccine related side effects ( $p = .202$ ), nor was immunotherapy, specifically, ( $p = .942$ ). The timing of vaccine administered in relation to treatment onset was also not related to vaccine related side effects ( $p = .653$ ). 6 (2.9%) participants were hospitalized and 4 (2%) died.

### Conclusions:

The incidence of side effects in cancer patients is similar to what has been reported for the general public (31% vs 27%). Therefore, we believe that the BNT162b2 mRNA COVID-19 vaccine is safe in oncologic patients undergoing numerous cancer treatments.



## Treatment outcomes and antibody immunity to SARS-CoV-2 in patients with hematological malignancies

### Background:

Since SARS-CoV-2 infection heavily affects vulnerable populations including those with immune suppression, it is of special value to study clinical course, treatment outcomes, and immunity in patients (pts) with hematological (hem) malignancies.

### Methods:

CHRONOS19 is an ongoing observational study in adult pts (18 years) with hem diseases (malignant or non-malignant) and COVID-19 in Russia. This web-based registry collected de-identified data from 15 centers all over the country at 30, 90, and 180 days after lab-confirmed or suspected (based on CT and/or clinical symptoms) COVID-19 diagnosis. The primary endpoint was 30-day all-cause mortality.

### Results:

As of data cut-off on April 14, 2021, 626 pts were enrolled in the study; 562 were eligible for primary endpoint assessment, n (%): M/F 271 (48%) / 291 (52%), median age 56 [18-90] years, malignant disease in 516 (92%) pts, among them induction phase / relapse or refractory / remission / NA in 180 (35%) / 120 (23%) / 187 (36%) / 29 (6%) pts. Thirty-day all-cause mortality in pts with hem malignancies was 19%; 83% of deaths were due to COVID-19 complications. No increase of hem disease relapse rate after COVID-19 was observed at Day 90 or Day 180, although 180-day data was still not mature at the time of analysis. IgG to SARS-CoV-2 was detected in 84% of pts with hem malignancies (167/199). The highest rate of detected antibody immunity was found in pts with chronic myeloproliferative neoplasms (100%; 13/13), HL (100%; 12/12), and multiple myeloma (97%; 34/35), the lowest in pts with CLL (62%; 8/13) and NHL (60%; 6/10 and 56%; 10/18 for low-grade and high-grade lymphoma, respectively). IgG detection rate in CD20+ lymphoma (60%) was significantly lower than in HL or T-cell lymphoma (p=0.004). Pts with ECOG 0-2 throughout the disease had a high rate of antibody immunity (90%; 104/116) vs. those with ECOG 3-4 at the time of COVID-19 diagnosis (77.5%; 31/40) or with worsening of ECOG to 3-4 during the disease (78%; 36/46). Five cases of SARS-CoV-2 re-infection were described.

### Conclusions:

Pts with hem malignancies and COVID-19 have higher mortality than the general population. Low post-disease antibody immunity to SARS-CoV-2 and cases of re-infection may justify vaccination of these pts and warrant further research.

### Clinical trial identification:

NCT04422470.

## Immune response after vaccination against SARS-COV-2 in lung cancer (LC) patients (p). Prospective study in the Medical Oncology Department at the Catalan Institute of Oncology-Badalona, Spain: COVID-lung vaccine

### Background:

With the approval of the vaccines against SARS-CoV-2, oncologic scientific societies have recommended cancer p to be prioritized for vaccination. Since cancer p have not participated in vaccine development studies, these recommendations arise some questions regarding their efficacy, safety and impact on survival. The aim of this prospective study is to evaluate the immune response to the SARSCoV-2 vaccine in LC p. Secondary objectives include vaccine-related adverse events (AE), cancer treatment AE after vaccination, impact of the vaccine on survival, immune response, toxicity and survival outcomes in p>75 y, (re)infection after vaccination, complications and mortality.

### Methods:

LCp who receive the vaccine against SARS-COV-2 are candidates to participate in this study. A pre-vaccination IgG determination will be performed to identify p with previous infection, but asymptomatic course. After vaccination, IgG will be repeated at 3, 6 and 12 months. Information on short and long term vaccine related AEs will be collected, as well as, serological results, tumor and treatment related data, and survival.

### Results:

From March, 31 to April 15, 2021, 106p have participated in the study. 58.5% were male, median age was 66 y (46- 83), 90.6% were Non-Small Cell LC, 83% has stage IV at diagnosis, Systemic therapy included EGFR/ALK/ROS1/RET/MET TKI (22.6%), immunotherapy (IT) (39.6%), chemotherapy (CT) (19.4%) and CTIT (14.1%). 4p were not receiving active therapy. 94.3% received Moderna vaccine on behalf of the Hospital Vaccination Program. AES to 1st dose (1D) included local pain (16%), swelling (0.9%), fever (2.8%) and myalgia (0.9%). 5p had prior known COVID infection. No vaccine-related AE were reported in this group. 6p were admitted after vaccination due to cancer-related symptoms. No deaths were reported. Definitive data on baseline and 3-m serological data, as well as complete 1D and 2D related-AE and potential interactions with cancer therapy will be presented later.

### Conclusions:

1D of SARS-COV-2 vaccine appears to be safe irrespective of systemic therapy in our cohort of LCp.

## Willingness to vaccinate and side effects of COVID-19 vaccination in patients with breast cancer and gynecological malignancies

### Background:

Cancer patients are at increased risk of developing severe COVID-19 disease. Possible side effects of systemic therapy and the lack of clinical data on safety and efficacy of COVID-19 vaccination in cancer patients cause uncertainty regarding the vaccination. Here, we evaluated attitude towards and effects of COVID-19 vaccination in patients with breast or gynecological cancer. The aim was to improve counseling of our patients in clinical routine.

### Methods:

Since March 15th 2021, patients who received one of the approved COVID19 vaccines were routinely interviewed about immediate (0-2 days) and late side effects (within two weeks after vaccination). Clinical parameters such as current therapy, time interval between therapy administration and vaccination, and changes in the therapy schedule due to the vaccination were documented. Furthermore, the willingness of non-vaccinated patients to be vaccinated was assessed. The collected data were anonymously analyzed as a part of routine quality assurance.

### Results:

By May 10th 2021, 111 out of 217 (51.1%) interviewed patients had received at least one shot of COVID-19 vaccine and 21 patients both shots. More than half of the vaccinated patients were >55y (60.2%; mean: 60.7y, range 30-92y); 69% with UICC/FIGO stage III/IV cancer. 74.6% received Comirnaty (BioNTech/ Pfizer), 18.9% Vaxzevria (AstraZeneca) and 6.5% Covid-19 Vaccine Moderna. After the first shot, 33.3% of the patients described no side effects, 49.1% reported a local reaction (swelling or pain), 23.4% flu-like symptoms, 10.8% headache and 3.6% nausea. 11 patients had symptoms that lasted longer than two days. In 11 cases, COVID-19 vaccination had an impact on delivery of the systemic therapy (n=10 postponements of therapy and n=1 dose reduction). 61.3% of the non-vaccinated patients (in total n=118) were already registered to get vaccinated; 32.8% chose to postpone vaccination for personal reasons; 5% refused vaccination.

### Conclusions:

Breast and gynecological cancer patients appear to tolerate COVID-19 vaccination well under systemic therapy and only in few cases the vaccination interfered with the treatment schedule. Updated results will be presented at the ESMO Congress.

## COVID-19 vaccine acceptance among Tunisian cancer patients: A cross-sectional study

### Background:

Since the approval of several Covid-19 vaccines, the vaccination process worldwide was facing several challenges, one of them is vaccine uptake among the population, for instance cancer patients. We aimed to measure the acceptability towards the Covid-19 vaccination in cancer patients and to investigate determinant factors associated with the patient's choice.

### Methods:

Since the approval of several Covid-19 vaccines, the vaccination process worldwide was facing several challenges, one of them is vaccine uptake among the population, for instance cancer patients. We aimed to measure the acceptability towards the Covid-19 vaccination in cancer patients and to investigate determinant factors associated with the patient's choice.

### Results:

Fifty-point four percent (n=166) reported their intent to be vaccinated as soon as the vaccine is available, 28.4% (n=93) reported to definitely refuse the vaccine and 21.2% (n=70) did not make their decision yet. High educational level, history of comorbidities, history of influenza vaccination in the current season and patient's opinion about the severity of Covid-19 did not predict vaccine resistance. However, patients who think that the vaccine may interfere with treatment efficacy (OR=7.28, 95%CI [2.5-12.32]), or may impact cancer outcome (OR=6.14, 95%CI [2.27-16.7]), were significantly more likely to refuse the vaccine. Patients who disagree that the vaccine is a major weapon against the pandemic (OR=6.07, 95%CI [2.34-9.52]) or that it could reduce the virus transmission (OR=7.34, 95%CI [4.22-11.81]) were also significantly more likely to reject the vaccination. Safety concerns were also significant predictive factors (OR=7.9, 95%CI [4.10-11.27]). Confidence level in the authorities played a significant role in patient's acceptance of the vaccine (OR=2.9, 95%CI [1.475-23]), indeed patients who were not registered (OR=5.9, 95%CI [1.58-8.7]) or not informed about the Tunisian national vaccination platform EVAX (OR=5.51, 95%CI [2.1-7.9]) were more likely to be against the vaccine.

### Conclusions:

Cancer patient's education about the impact of the vaccine on their disease and on the Covid-19 is needed. Governments should build strategies to gain more population confidence.

## SARS-CoV-2 vaccines in cancer patients (pts), real-world data (RWD) from 1069 Belong. Life users

### Background:

The COVID-19 pandemic continues to have a serious impact on many people, including cancer pts. The US CDC and oncology groups (ASCO, ESMO, ACS) made recommendations as to what high risk groups should be vaccinated first which includes cancer pts. Users of Belong. Life, a worldwide, free, and voluntary, digital health application for cancer pts, replied to a targeted survey including demographic & clinical questions related to the pts cancers, ongoing therapies and the Covid 19 vaccination characteristics, and interactions.

### Methods:

In this prospective study, 1069 cancer pts, Belong. Life users, voluntarily replied to a survey asking demographic and clinical questions related to their Covid 19 vaccination and cancer status characteristics.

### Results:

Most of the pts were North American based (91 %), with 6.3 % from Europe and 2.6% from the rest of the world. 72% were between 50-69 years of age, and 79.5% were females. Five most common diagnosis were Breast Cancer (35.2%), gynecological (14.4%), gastrointestinal (13.3%), lung cancers (9.7%) and genitourinary (7%). 59% of the pts received chemotherapy, 14.2% immunotherapy and 32.8% had radiotherapy over the past 12 months prior to receive the Covid 19 vaccination, which consisted of mRNA vaccines in 82.2% (Pfizer 46.2%, Moderna 36%). 4.9% of the pts refused vaccination. 82.3% of the pts had none (39.3%) or mild (43%) side-effects (S/E) and only 2.4% reported severe S/E. Most S/E lasted 1-3 days (89.4%) consisting mainly of sore arm (42.5%), headache (23.3%), fatigue (21.1%), and temperature (18.5%). Swollen lymph-nodes and allergic reactions were only reported in 0.7% (each). 49% of the pts were vaccinated while actively engaged on treatment, and in 96% there was no delay, interruption, or stoppage of the anticancer therapy.

### Conclusions:

This is the first large report on Real word data voluntarily obtained from 1069 Belong. Life users undergoing anticancer treatment with 90% of them receiving a Covid 19 vaccination. The large majority of pts had none or mild S/E (82.3%), and those were short lived (1-3 days in 89.4%) while only in 2% it was graded as severe. In 96% of the pts their ongoing anticancer therapy did not necessitate to be delayed, interrupted, or stopped.



## Acceptance of COVID-19 vaccination among cancer patients in an Irish cancer center

### Background:

Hospitalized cancer patients have a three times higher risk of death (14%) from COVID-19 than the general public. Vaccination provides an unprecedented opportunity to decrease morbidity & mortality, however, there is a limited data regarding cancer patients' attitudes towards COVID-19 vaccination.

### Methods:

An anonymized questionnaire was completed by volunteering cancer patients attending the ambulatory care unit of a large tertiary cancer center (Feb to April 2021), prior to vaccination rollout in this cohort. It assessed patients' acceptance of, and attitudes toward, COVID-19 vaccination. Statistical significance was assessed with Chi-square test ( $\chi^2$ ).

### Results:

There was an 80% response rate (143/179). This included 79 females (55%) with a median age range of 51e60 yrs. ( $n=35/24\%$ ). Most (78%) had a good performance status (PS= 0-1) & lung was the most frequent (28%) cancer type. Eight (6%) had previous COVID-19 infection. Among respondents, 128 (90%) intended on getting vaccinated, 12 (8%) were unsure & three (2%) would refuse. Those intent on vaccination were less concerned with side effects, viewed the pandemic as serious & perceived cancer as a cause for more severe infection compared to the rest (Table). All 101 (71%) patients who received the influenza vaccine were intent on COVID vaccination. Almost 20% ( $n=28$ ) reported that they were more likely to receive the flu vaccine due to the pandemic. Twelve (8%) identified attending their GP as a barrier, with 97% ( $n=135$ ) willing to attend hospital for vaccination. While this service is free, 69% ( $n=99$ ) were willing to pay, with nearly 40% ( $n=57$ ) up to V50.

**Table: 1595P Comparison of determinants for COVID-19 vaccination**

Determinants for vaccination	Yes n (%)	No / Unsure n (%)	p-value ( $\chi^2$ )
Concern re side effects	35 (27)	11 (73)	0.02
Pandemic is not serious	17 (5)	8 (53)	<0.01
Cancer results in serious infection	88 (69)	3 (20)	0.04
Vaccine could deteriorate my cancer	9 (7)	3 (20)	0.13
Vaccine ineffective due to cancer	13 (10)	3 (20)	0.32

### Conclusions:

Our study demonstrates a very high acceptance rate of COVID-19 vaccination among Irish cancer patients such that many would be willing to pay & attend hospital to receive it. The barriers to uptake provide an opportunity to improve education. An unexpected consequence, may be a beneficial increased uptake of the influenza vaccine.

## SERONCOVID: Seroconversion in solid-tumor cancer patients (p) after COVID-19 diagnosis

### Background:

Cancer p represent a high-risk population for severe COVID-19. Cancer associated immunosuppression may hinder in the development of anti-SARS-CoV-2 antibodies.

### Methods:

Data regarding baseline characteristics (age, cancer type, cancer activity, cancer treatment), COVID-19 infection and anti-SARS-CoV-2 IgG were collected from p with solid tumors who tested positive for COVID-19 (PCR+) between 10th March and 9th December 2020 at Catalan Institute of Oncology. We prospectively assessed anti-SARS-CoV-2 IgG seroprevalence at different timepoints (<2, 2-6, >6 months [m] since first PCR+) and explored factors associated with long-term IgG positivity.

### Results:

Out of 79 registered p, 19 died without IgG testing (all of them <3 months after a PCR+), and 8 refused to participate, leaving 52 tested for IgG. Tested and not tested p were similar according to baseline characteristics, cancer treatment and COVID-19. At the 1st timepoint, 19/23p were IgG+; at the 2nd, 29/33p were IgG+ and 1 inconclusive; at the 3rd timepoint, 18/22 were IgG+ (median time from PCR + to 3rd timepoint determination was 9.4 m (Interquartile range [IQR]: 8.5-9.7). Importantly, 1 p changed from IgG+ (2<sup>nd</sup> timepoint) to IgG- (3rd timepoint), and 1 inconclusive result (2<sup>nd</sup> timepoint) changed to negative (3<sup>rd</sup> timepoint). Potential factors associated to IgG+ >6m is shown in the table.

### Conclusions:

High seroprevalence of anti-SARS-CoV-2 IgG was observed at several timepoints after COVID-19 diagnosis in solid tumor p. P with IgG+ at >6 m was older, and more likely to have required hospitalization and oxygen during prior COVID-19 in comparison to IgG- p >6m, suggesting that infection severity may promote durable immunity. Frequency of active cancer and active chemotherapy at COVID-19 diagnosis were higher among p with IgG- >6m, suggesting deeper immunosuppression.

## Vaccination against SARS-CoV-2 infection in patients with solid tumors: Experience from Institute for Oncology and Radiology of Serbia (IORS)

### Background:

We evaluated between February and May 2021. 114 patients with solid tumors who were actively been treated at the IORS and have received vaccine against SARS-CoV-2 virus. Demographic data, diagnosis, current therapy and comorbidities were collected from patients' records. Data about vaccination: first and second dose, type of the vaccine and side effects were collected by questionnaire approved by the Ethics Committee.

### Methods:

We evaluated between February and May 2021. 114 patients with solid tumors who were actively been treated at the IORS and have received vaccine against SARS-CoV-2 virus. Demographic data, diagnosis, current therapy and comorbidities were collected from patients' records. Data about vaccination: first and second dose, type of the vaccine and side effects were collected by questionnaire approved by the Ethics Committee.

### Results:

114 patients received the vaccine, 89 (78%) female, 25 (22%) male. Patients' mean age was  $61.3 \pm 13.5$  years, youngest was 37.8, the oldest was 83.9 years old. 105 of them received both doses of the vaccine. 36 pts (31.6%) had one and 30 (26.3%) had 2 or more co-morbidities requiring active therapy. 58 patients (50.9%) had early disease, 56 (49.1%) had metastatic disease. 42 patients (36.8%) were receiving cytotoxic chemotherapy. Out of 114 vaccinated patients, 7 of them (6.1%) had previously COVID-19 infection. One patient had COVID-19 infection 5 days after receiving second dose of vaccine. 81 patients (71.1%) received vaccine made by Sinopharm company, followed by Pfizer-BioNtech vaccine (14 patients, 12.3%), Sputnik V (10 patients, 8.8%) and Oxford/AstraZeneca vaccine (9 patients, 7.9%). 85 of them (74.6%) didn't have any side effects after receiving the vaccine. 13 patients (11.4%) had 2 or more symptoms. The most common side effect was pain at the injection site of the vaccine and it was present in 12 patients (10.5%). 10 patients (8.8%) reported chills and shivering. Fever was present in 9 patients (7.9%). Only two patients had allergic-like reactions that was present with skin rash. None of the patients had severe allergic reactions.

### Conclusions:

In our study 114 patients with solid tumors and active oncology treatment had been vaccinated against SARS-CoV-2 virus without severe side effects. Our study supports current guidelines which promote vaccination in oncology patients as priority.

## Acceptance of SARS-CoV-2 vaccination among patients with cancer undergoing immunosuppressive therapy: Portuguese study

### Background:

Until April 2021, WHO declared more than 140 million cases and 3 million deaths due to COVID-19. To effectively control the pandemic, a significant part of the population has to acquire immunity, which is best achieved through vaccination. None of the clinical trials evaluating the effectiveness and safety of the vaccines included cancer patients. This study aimed to evaluate the acceptance of the COVID19 vaccine by cancer patients undergoing immunosuppressive therapy in a Portuguese cancer center.

### Methods:

Unicentric, cross-sectional survey conducted on cancer patients with a solid malignancy under chemotherapy, targeted agents or immunotherapy, between March and April 2021.

### Results:

We included 169 patients (109 female; 60 male) with a median age of 61 years old (29-82). More than half (n=105; 62.1%) had a lower literacy degree, 97 (57.4%) lived in the countryside. The majority of the patients were receiving palliative treatment (n=148; 51.5%). Most of the patients intended to be vaccinated (n=142, 84.0%), 24 (14.2%) were unsure and 3 (1.8%) did not. All the negative answers were given by patients receiving palliative treatment. Logistic regression analysis revealed that high school qualification (p=0.007), divorced status (p=0.037), rural residence (p=0.047), and believing in the vaccine (p=0.001), had a statistically significant effect on the probability of the patients wanting to be vaccinated. The most frequent reasons for wanting to be vaccinated were the sense of collective responsibility and the fear of having severe disease. The most frequent reasons for not wanting to be vaccinated were the lack of evidence and the wish to wait for the end of treatment. The need for more information on effectiveness and safety were the main reasons for uncertainty related to the vaccine.

### Conclusions:

Despite the lack of information regarding efficacy, duration of immunity and timing of vaccination in cancer patients under immunosuppressive therapy, this study demonstrated that the majority of patients intend to be vaccinated against COVID-19. These results were related to residence type, literacy and belief in the effectiveness of the vaccine. The higher acceptance rate in our study when compared with other studies must be noted.

## Vaccination in the COVID-19 era: Attitudes amongst oncology patients

### Background:

Early data suggested a higher risk of COVID-19 in oncology patients, in particular those with co-morbidities or on systemic anticancer therapy (SACT). Immunization strategies are likely to be critical in risk-reduction patient management. We examined patients' attitudes towards COVID-19 vaccines, studying factors affecting uptake such as demographics, socioeconomics, cancer diagnoses and treatments, and previous influenza vaccination.

### Methods:

An anonymized questionnaire was distributed among oncology patients attending for SACT from November to December 2020. Statistical analyses were performed using SPSS v23 (IBM, Armonk, NY, USA).

### Results:

In total 115 patients completed the survey. Of these, 30 (26%) were aged > 65, 65 (56%) were female and 54 (47%) were treated for metastatic disease. Overall, 68 (59%) were receiving cytotoxic chemotherapy, and 15 (13%) were receiving immunotherapy. The most common cancer was breast (29%), followed by colorectal (18%) and lung (10%). Most patients (72%) had received or were intending to receive the influenza vaccine. Of patients surveyed 19 (17%) had friends or family who had been diagnosed with COVID-19, while only 3 (2.6%) had had COVID-19. The majority (81%) were in favor of receiving a COVID-19 vaccine if it was recommended for them. A small number however (5.2%) were against receiving a vaccine. Similar numbers of patients worried (30%) and did not worry (33%) that a COVID-19 vaccine could be unsafe. Interestingly 42% stated they if a COVID-19 vaccine were to be made available they would prefer to wait rather than to get it immediately. Patients who had received or intended to receive the influenza vaccine were less likely to want to delay receiving a COVID-19 vaccine ( $p=0.018$ ). Age group, education level and palliative treatment was not associated with a significant difference in vaccine acceptance.

### Conclusions:

The majority of patients surveyed were agreeable to COVID-19 vaccination, particularly those with prior influenza vaccination. An interesting finding was that though 42% of patients would prefer not to be first to receive the vaccine the majority welcomed vaccination. This finding, especially within a cohort regarded as being "highly vulnerable" to COVID, may have implications for the vaccine program in the general population.



## Suboptimal response to COVID-19 mRNA vaccines in older patients with cancer

### Background:

SARS-CoV-2 mRNA vaccines were approved to prevent COVID-19 infection, with reported vaccine efficacy of 95%. Older patients with cancer are at risk for lower vaccine immunogenicity and were not included in the registration trials. We assessed vaccine immunogenicity in this special population.

### Methods:

We recruited elderly vaccinated patients from the René Muret hospital between Apr 5, 2021 and May 8, 2021. All were inpatients in a 48-bed geriatric rehabilitation ward, where a cluster of B.1.1.7 (VOC-202012/1) variant COVID-19 cases occurred. We measured SARS-CoV-2 IgG production in all patients. We observed patients who developed symptomatic SARS-CoV-2 infection (confirmed by RT-PCR) despite previous vaccination with mRNA vaccine.

### Results:

Thirty vaccinated patients were enrolled. Mean age was 83 years and 60% were female. The IgG S-protein serology was positive in 16 of 18 (89%) patients without cancer. Immunogenicity among patients with cancer was significantly lower with positive serology in only 7 of 12 (58%,  $p < 0.001$ ). Antibody level was also significantly lower in this group (mean 2946 AU/mL vs. 4447 AU/mL in controls,  $p < 0.001$ ). Severe SARS-CoV-2 infection occurred in 7 patients included 5 with cancer. Predictors for infection among older patients were: negative serology, hematological cancer (CLL or NHL), lung cancer, and treatment with high dose steroids. Covid-19 related deaths occurred in 5 patients included 4 with cancer.

### Conclusions:

Routine measurement of post-vaccine antibodies in older patients with cancer should be considered. Novel strategies are needed to prevent COVID-19 in these individuals.

## SARS-CoV-2 serological response in cancer patients in the Principality of Andorra (COVONCO study)

### Background:

Little is known about the duration of SARS-CoV-2 antibodies and the factors that influence their durability in oncologic patients. This study aims to study serological response over time by means of a follow-up period of 6, 9 and 12 months. This study also compares patient characteristics by duration of antibody seroprevalence ( $\geq 6$  months and  $< 6$  months) according to treatment groups within the oncological population.

### Methods:

Observational, unicentric, prospective cohort study. All adult patients with cancer diagnosis within 5 years (2016-April 2020) who accepted participation were included since May 2020. During subsequent months, a comprehensive follow-up of these patients has been performed. Demographic and clinical data was taken from medical records (HCIS, software SAAS) and inputted into a web form (<https://forms.epidemixs.org/form/study/covoncoand>).

### Results:

182 oncologic patients with complete data who underwent population serological screening in May 2020 were selected. At baseline, 152 (83.51%) patients had solid tumors and 30 (16.48%) presented with metastatic diseases. Breast cancer was the main primary cancer site with 49 (26.92%) patients. 102 (56.04%) patients received active anti-cancer treatment, of which 48 (47.06%) received chemotherapy, 25 (24.51%) hormonal therapy, 64 (62.74%) biologics and 8 (7.84%) radiotherapy. Of these, 14 patients were seropositive (7.69%). At the 6-month analysis, 156 patients underwent a serological test (1 patient died and 25 did not perform the test) and 10 patients (6.41%) were seropositive. Among the 14 seropositive patients at baseline, only 3 (30.0%) remained positive at 6 months.

### Conclusions:

Seroprevalence at baseline and at 6 months was lower than observed in the general population in Andorra. Only 3 (30%) patients remained positive at 6 months. No significant differences were observed between overall seroprevalence and anti-cancer treatments. Drawing definitive conclusions is limited by a small sample size.

## COVID-19 vaccination efficacy in cancer patients: An ongoing prospective trial

### Background:

Cancer patients (pts) have higher risk of severe COVID-19 infection. However, observations are based on non-comparative retrospective studies. Evidence regarding vaccination in cancer pts is limited, but there is enough evidence to support COVID-19 vaccination, even under active treatment. Data on humoral and cellular immune response to antiviral vaccination in cancer pts are scarce. In pts receiving immunosuppressive therapies (IST) like chemotherapy and targeted therapies, seroconversion/protection rates are expected to be lower than general population, but not in pts receiving immune checkpoint inhibitors (ICI). Serum antibodies against an infectious agent may be an immunity indicator.

### Methods:

Prospective observational longitudinal study with the intent of evaluating the humoral response of cancer pts to COVID-19 vaccination. The study includes pts diagnosed in any stage, without or under active treatment, or survivors followed in Hospital Prof. Dr. Fernando Fonseca, in partnership with Instituto Gulbenkian de Ciência. Pts are divided into 4 arms, independently of the vaccine: A-IST; B-ICI; C -Hormone therapy (HT); D-Cancer survivors. Recruitment started in March 2021, expecting at least 50 pts per arm. IgG, IgA and IgM anti-SARS-CoV-2 antibodies ELISA determination in 9 timepoints: before 1<sup>st</sup> dose and at the 3<sup>rd</sup>, 6<sup>th</sup>, 12<sup>th</sup>, 15<sup>th</sup>, 24<sup>th</sup>, 36<sup>th</sup>, 48<sup>th</sup> and 60<sup>th</sup> weeks post 1<sup>st</sup> dose. Side effects' questionnaire will be implemented after 1<sup>st</sup> and 2<sup>nd</sup> doses.

### Results:

Recruitment is ongoing and a total of 202 pts were enrolled, of which 178 pts have 3-weeks post 1<sup>st</sup> dose evaluated: 101 in arm A: 11 in B: 31 in C; and 35 in D. The mean age is 61.6 years, with 53.4% females. Regarding vaccines, 55 pts were submitted to ChAdOx1-S/nCoV-19, 5 to Ad26.COVS.2.S, 89 to BNT162b2 and 12 to mRNA1273 vaccines. At 3 weeks, 33/97 pts (34%) in arm A, 2/11 pts (18%) in B, 14/28 pts (50%) in C and 15/35 pts (43%) in D already generated anti-spike IgG. Most common side effects were local inflammatory reaction (47%), generalized muscle pain (17%), fatigue (11%), and chills (10%).

### Conclusions:

Efficacy and safety profiles of vaccines against COVID-19 infection in cancer pts is still unknown. This study hopes to assess differences in immunization between pts' treatment profiles and duration profiles and safety profiles.

## SARS-CoV-2 seroconversion among oncology healthcare workers in Brazil

### Background:

The study aimed to estimate the incidence of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) seroconversion after baseline screening among oncology healthcare workers (HCW).

### Methods:

This is a prospective longitudinal cohort study of HCW, applied at Centro de Terapia Oncológica (CTO), an Oncology clinic in Petrópolis, Brazil. Baseline screening for SARS-CoV-2 occurred between April 9 -29, 2020 using rapid IgM and IgG serological tests for all HCW. Follow-up serology testing took place once between November 5-December 28, 2020 and included retesting with indirect chemiluminescence immunoassay LIAISON SARS-CoV-2 S1/S2 IgG all HCW for seroconversion incidence. Reverse transcriptase-polymerase chain reaction (RT-PCR) testing was offered at baseline and follow-up for all symptomatic staff. The McNemar test was used to assess the change in positive serology incidence in both tests.

### Results:

The study included 60 HCW, with 40 females (66.7%). Mean age was of 43.4 years old (SD=14.5). At baseline SARS-CoV-2 antibody assessment, 57 (95%) were negative and 3 (5%) positive; 59 (98%) asymptomatic HCW, and 1 symptomatic (1.6%) tested positive in RT-PCR. A total of 11 RT-PCR were performed since baseline until follow-up in symptomatic HCW, with 9 (81.8%) positive results, all of them with seroconversion. 6 (10%) asymptomatic HCW were seropositive at follow-up screening. None of baseline positive-serology asymptomatic HCW sustained their serology. Seroconversion occurred in 15 (25%) HCW - Table. The incidence of positive serologies in follow-up screening was statistically higher than at baseline ( $p=0.008$ ).

Baseline / Follow - up	Negative	Positive	Total	p
Negative	42 (70%)	15 (25%)	57 (95%)	0.008
Positive	3 (5%)	0 (0%)	3 (5%)	
Total	45 (75%)	15 (25%)	60 (100%)	
McNemar Test				

### Conclusions:

Most seroconversions were in symptomatic HCW, although the substantial number of positive serologies in asymptomatic HCW accent the importance and direct impact of regular universal testing. Seropositivity increased five-fold compared to baseline results. This detected increase in infections reflects a national pattern, suggesting community-based and not nosocomial transmission.

## Global survey of 104 cancer patient organizations reveals devastating impact of COVID-19

### Background:

The Global Cancer Coalitions Network (GCCN), established in May 2020, collectively represents over 750 cancer patient organizations representing over 14 million patients around the world. Cancer services have faced challenges as a result of COVID-19, including suspension of screening and diagnostic services; delays in diagnosis leading to higher mortality rates; cancellation/deferral of life-saving treatments; changes in treatment regimens and suspension of vital research. Substantial increases in the number of avoidable cancer deaths are to be expected as a result of diagnostic delays due to the COVID-19 pandemic.

### Methods:

6 global cancer coalitions surveyed their member organizations in December 2020.

### Results:

Among 104 organizations from 46 countries representing advanced breast, bladder, colorectal, lymphoma, ovarian, and pancreatic cancer patient groups: Demand for services has increased. 2/3 organizations experienced a fall in income from December 2020, averaging -48%. Over 1 in 10 organizations have closed temporarily, and some permanently. Only 1 in 10 organizations believe their 2021 income will return to levels seen before the pandemic. Almost half report that their ability to operate is under threat. Half do not have access to any national funding schemes to ensure operation during the pandemic. Staff shrunk -20%; volunteer numbers -70%. <20% organizations report normalized cancer services in December 2020; more respondents report services are “worse than ever”. Patient distress, isolation and financial hardship have increased markedly.

### Conclusions:

For organizations providing support to cancer patients, declining income, the need to reduce staff and move to virtual working practices has added strain while demand for support due to the pandemic has increased. Emergency support, including funding, must be made available to these organizations to ensure that the needs of cancer patients worldwide continue to be met.



## Being a medical oncologist during the COVID-19 pandemic: Perception, expectations and concerns. OATH study

### Background:

In COVID-19 pandemic, medical oncologists worked actively both in their own fields and in COVID-19 health services. In this process, they made efforts not only to disrupt the medical needs of their patients, but also to protect them from COVID19 mortality with actively or telemedicine integrated. This study aims to determine both the perspective of medical oncologists on the pandemic process and their profession, and their burnout during the pandemic process within the scope of implicit questions.

### Methods:

This research was conducted between April and August 2021, when the pandemic caused obscurity and devastating consequences around the world. The study was initiated after the ethics committee and administrative permissions were completed. 760 medical oncologists registered with the Turkish Medical Oncology Association were asked to participate in the survey by reminding them via e-mail or telephone.

### Results:

The number of attendees was 397. The average age was  $47 \pm 11$  years, and the average duration of work in oncology was  $9 \pm 7$  years. Most of the participants were women (59%), with academic titles (61%), married (79%), who had at least 2 oncologists in the institution was 67%, and have a multidisciplinary council were 72%. The average number of patients per day was  $40 \pm 11$ . 85% of the participants had sufficient knowledge about the COVID-19 pandemic. The rate of those who were worried about spreading disease to their patients, colleagues and families during the pandemic process was 85%. Disease anxiety for themselves was 35%. The proportion of those who stated that the pandemic process consumed them was 75%, 67% worried that scientific productivity would decrease, and 76% worried that oncology-related occupational productivity would decrease. The rate of those who had a hobby and had to leave it was 92%. When compared with the pre-pandemic, the rate of those who considered themselves exhausted was 86%.

### Conclusions:

It was determined that in the pandemic, the level of burnout of medical oncologists increased and they were more concerned about their loved ones and their patients. It can be concluded that it would be appropriate to develop methods of coping with burnout in the continuation of the pandemic process or in similar conditions.'

## Impact of COVID-19 (SARS-CoV-2, C19) on medical oncologists (MOs) and cancer care: A Canadian Association of Medical Oncologists (CAMO) survey study

### Background:

The pandemic has presented professional and personal challenges for the MO workforce. CAMO sought to examine the temporal effects of C19 on MOs and care practices across Canada.

### Methods:

Three serial multiple-choice, web-based surveys were conducted in 2020 e from Mar 30<sup>th</sup> to April 4<sup>th</sup> (S1), May 6<sup>th</sup> to May 15<sup>th</sup> (S2) and Dec 10<sup>th</sup> to 18<sup>th</sup> (S3). The surveys were distributed by email to MOs identified through CAMO and the Royal College of Physicians and Surgeons directory (n=618). Participation was voluntary with no compensation. Descriptive analyses with frequency distributions are reported.

### Results:

The timing for S1 and S3 coincided with the 1st and 2nd C19 waves in Canada. Response rates decreased slightly: 26% S1, 25% S2 and 20% S3. Per table, demographics were similar across surveys: majority of respondents were from a comprehensive cancer center and in practice for < 15 years. Concerns regarding PPE access and C19 personal risk decreased over time. A high rate of telemedicine was observed in S1 but this notably decreased by S3, despite the 2nd wave. A similar decreasing trend was observed in the proportion of altered chemotherapy plans due to C19. Similar levels of anxiety, depression, lack of focus and concerns for personal wellness were maintained over time. In S3, respondents noted delayed cancer diagnoses and oncologist burnout as the top 2 post-pandemic challenges, and 87% believed their workload would increase.

**Table: 1606P**

	S1	S2	S3
N	159	157	124
Less than 15 years in practice	59%	54%	61%
Cancer centre (vs community)	87%	86%	81%
Concern re: PPE access	69%	28%	16%
Moderate-extreme concern about getting C19	79%	54%	59%
Anxiety on most-all days	54%	32%	34%
Depressed on most-all days	19%	14%	16%
Lack of focus on most-all days	33%	31%	29%
Concerned for personal wellness	57%	56%	62%
Use telemedicine for > 75% of encounters	45%	50%	13%
Altered chemo plans for > 20% of patients	33%	20%	4%

### Conclusions:

As the pandemic continues, positive trends can be observed in concerns around PPE access and C19 risk. A high level of telemedicine adoption was observed early in the pandemic but is decreasing, and chemotherapy plans remained unchanged for most patients. Concerns regarding personal wellness remained high across all 3 surveys. Proactive strategies to support physician wellness, mitigate burnout and manage MO workload are needed.

## Trends in cancer imaging by indication, care setting, and hospital type during the COVID-19 pandemic and recovery

### Background:

The delivery of cancer care has been greatly affected by the COVID pandemic. We aim to investigate the effect of the pandemic on computed tomography (CT) imaging of cancer.

### Methods:

Cancer-related CT exams were retrospectively analyzed during three periods of 2020: pre-COVID (1/5/20-3/14/20), COVID peak (3/15/20-5/2/20) and post COVID peak (5/3/20-11/14/20). Volumes were assessed by 1) Imaging indication: cancer screening, initial workup, active cancer, surveillance; 2) Care setting: outpatient, inpatient, ED; 3) Hospital type: quaternary academic center (QAC), university affiliated community hospital (UACH), sole community hospitals (SCHs).

### Results:

During the COVID peak, a significant drop in CT volumes was observed (-42.2%,  $p<0.0001$ ), with cancer screening, initial workup, active cancer and cancer surveillance experiencing declines by 81.7%, 54.8%, 30.7% and 44.7% respectively ( $p<0.0001$ ). The emergency department (ED) was the only setting with stable cancer-related CT volumes. In the post-COVID peak period, CT volumes for cancer screening and for initial workup did not recover (-11.7%,  $p=0.037$ ; -20.0%,  $p=0.031$ ), with the outpatient setting particularly affected. CT volumes for active cancer recovered post-peak, but inconsistently across hospital types with the QAC experiencing a 9.4% decline ( $p=0.022$ ) and the UACH a 41.5% increase ( $p<0.001$ ). Outpatient CTs recovered during the post-peak period, but a shift in utilization away from the QAC (-8.7%,  $p=0.020$ ) toward the UACH (+13.3%,  $p=0.013$ ) was observed. Inpatient and ED-based cancer-related CTs increased post-peak (+20.0%,  $p=0.004$  and +33.2%,  $p=0.009$ , respectively).

### Conclusions:

COVID severely impacted cancer imaging care. CTs for cancer screening and initial workup did not recover to pre-COVID levels well into 2020, a finding that suggests higher numbers of patients with advanced cancers may present in the future. A redistribution of imaging utilization away from the QAC and outpatient settings, toward the community hospitals and inpatient setting/ED was observed. The ED has remained a dependable healthcare delivery setting for patients with cancer throughout the pandemic.

## The impact of COVID-19 on the delivery of systemic anti-cancer treatment at Guy's Cancer Centre

### Background:

Early reports in the COVID-19 pandemic suggested higher mortality for cancer patients. The impact of potentially immunosuppressive systemic anti-cancer treatments (SACT) was unknown. This study analyzed the delivery of SACT for patients with solid malignancies during the COVID-19 outbreak in 2020 compared to the same period in 2019 to inform future clinical decision-making.

### Methods:

All patients receiving at least one SACT at Guy's comprehensive Cancer Centre during the COVID-19 outbreak for solid tumors (1st March- 31st May 2020) were compared to the same period in 2019. SARS-CoV2 infection was by positive RTPCR test. Data collected: demographics, tumor type/stage and treatment (chemotherapy, immunotherapy (IO), biological-targeted (BT)).

### Results:

2125 patients received SACT in 2020, compared to 2450 in 2019 (13% decrease). Demographics were comparable with mean age of 62. 56% females in 2020 vs 54% in 2019, 85% vs 83% in the low socio-economic category, 63% vs 73% PS 0-1; 30% vs 29% uro-gynaecological, 27% vs 24% breast and 20% vs 23% GI tumors. In 2020 compared to 2019, there was an increase in metastatic disease (71% vs 62%), decrease in CT (34% vs 42%), increase in IO (10% vs 6%), but similar rates of BT treatments (38% vs 37%). Treatment paradigms were similar in 2020 and 2019: neo/ adjuvant (28% vs 29%), radical (4% vs 5%) and palliative (69% vs 67%). Earlier palliative treatments were prioritized in 2020 with significant increase in treatments in 1st-2nd line (72% vs 67%;  $p=0.02$ ) and reduction in > 3rd line (12% vs 27%;  $p<0.05$ ). 42 of 2125 patients (2%) developed SARS-CoV2 infections; 38% GI, 26% breast with 69% on CT. Of 42 patients with COVID-19, 24 (57%) had severe infections and 6 (14%) resulted in COVID-related death.

### Conclusions:

These data suggest that SACT does not put solid tumor patients at much a higher additional risk from COVID-19. Despite a 13% decline in treatment rates, radical and early palliative treatment were prioritized. There was a low frequency (2%) of SARS-CoV-2 infection; comparable to the 1.4%-point prevalence rate in our cancer population. However, this was during national lockdown with limited COVID-19 testing. The next steps are to evaluate the impact of new variant strains and COVID vaccination program.

## COVID-19 outbreak repercussions on breast cancer diagnoses and access to treatment: Preliminary data from the COVID-DELAY study

### Background:

The coronavirus disease (COVID-19) has profoundly impacted on cancer care since March 2020. With our country in the eye of the pandemic storm, cancer patients (pts) faced an unprecedented challenge in accessing crucial services. Cancer screening programs were postponed to preserve health care system capacity. Breast cancer (BC) mainly benefits from early detection. Our multicenter study aimed to assess impact of COVID-19 outbreak on access to cancer diagnosis and treatment for BC pts compared to pre-pandemic period.

### Methods:

All consecutive medical records of new diagnosed BC pts pertained to 3 Italian Oncology Departments between March and December 2020 were evaluated. Monthly access rate and temporal intervals between date of symptoms onset, radiological, cytohistological diagnosis and treatment start were computed and compared with those of the same period in 2019. Differences between the two years were analyzed using Fisher's exact test or chi-square test for categorical variables and unpaired Student t test, or the Mann-Whitney U test for continuous variables.

### Results:

A significant reduction (27%) in newly diagnosed BC cases was seen when compared with 2019 (430 vs 595). Newly BC pts in 2020 were less likely to be diagnosed with early stage (stage I-II) BC (75% vs 84%,  $p < 0.01$ ), had a worsened ECOG PS (20% had PS  $> 0$  in 2020 vs 15% in 2019) and were more symptomatic at diagnosis (37% vs 17%,  $p < 0.01$ ). Other clinical and tumor characteristics such as histotype and molecular subtype were similar regardless of the year. Looking at pts management, time intervals between symptom onset and radiological diagnosis (median 13 days in 2020 vs 21 days in 2019,  $p=0.04$ ), symptom onset and cytohistological diagnosis (23.5 vs 27.5 days,  $p=0.11$ ), cytohistological diagnosis and treatment start (median 62 vs 76 days,  $p < 0.01$ ) were maintained or even improved. However, less BC were discussed in multidisciplinary meetings during 2020 (66% vs 78%,  $p < 0.01$ ).

### Conclusions:

As COVID-19 continues to rage, our data shed light on the concerning decrease in BC early detection with potential lasting effects on cancer outcomes. Despite the pandemic context, Oncology Departments were able to guarantee the tightness of diagnostic-therapeutic pathways.



## Delivery of ONCOlogic care at HOME: Ready for “ONCOHOME”

### Background:

During COVID pandemic, many cancer patients (pts) refused to come to hospital, suspending therapies, with ominous consequences. Based on positive (+) results of DOMONCOVID, our homecare project for COVID+ cancer pts, we created a new model of assistance, ONCOHOME, delivering cancer care at home to immunocompromised pts. We aim to provide data on feasibility, efficacy and costs of this innovative model.

### Methods:

ONCOHOME is a multicenter project involving 3 Cancer Center (CC) of the North of Italy: National Cancer Institute, San Raffaele in Milan and Cremona CC. We created an organizational homecare model based on a medical and nursing team with a car equipped for home visits and a secretariat managing patient calls, with a dedicated phone number. The team administers cancer care at home and provides pts with the same assistance usually delivered in hospital. Patient-reported outcome (PRO) assessment is performed.

### Results:

From August 3rd 2020 to May 5th 2021, 79 cancer pts were assisted at home by Cremona team, receiving oral (62 pts), subcutaneous (10pts) or intravenous therapy (7 pts). All types of cancer were included. 77% of pts had a metastatic disease, 88% had a PS ECOG 0-1. Median duration of assistance was 126 days [range 2-270 days]. Most of the pts received oral chemotherapy (41pts). TKIs (25 pts), hormonal therapy (12 pts), supportive care with denosumab and zoledronic acid (5 pts) and immunotherapy (1 patient, pt) were successfully administered at home, too. 13 pts required hospitalization due to clinical complications. In this group, only 2 pts were admitted to hospital due to severe toxicity; in particular, 1 pt treated with trifluridin/tipiracil developed febrile neutropenia and 1 pt treated with gefitinib reported Grade 3 diarrhea. Both pts was discharged and continued to be assisted at home.

### Conclusions:

ONCOHOME showed that inpatient or outpatient cancer drug administration could be successfully replaced by home administration, for appropriate therapies and selected pts. This model is feasible at an affordable cost. The project is ongoing, planning to accrue other 100 pts for each center. ONCOHOME will be implemented with electronic devices for PRO evaluation, certified telemedicine service and non-invasive wearable smart tissue monitoring physiological parameters devices.

## Health-related quality of life, vaccine uptake and immune response among cancer patients undergoing treatment during the COVID-19 pandemic

### Background:

Cancer patients are at increased risk of severe COVID-19 illness because of their systemic immunosuppressive state. The potential effects of cancer and/or anticancer treatments on COVID-19 vaccine response, adverse events and progression are unknown. Moreover, the impacts of financial, familial and societal stressors during the pandemic on health-related quality of life are unclear. To address these concerns, we report data from the ongoing U.S. NCI-funded SeroNet COVID-19 Risk Associations and Longitudinal Evaluation Study (CORALE) at a large health care system in Los Angeles.

### Methods:

Cancer patients are invited to complete questionnaires, donate blood specimens and engage in long-term follow-up with repeat questionnaires and biosampling. Patient-reported outcomes are assessed at baseline, post-vaccination, 6, 12 and 24 months. Clinical information on cancer type, stage, treatment, dates, medications and outcomes (adverse events, SARS-CoV-2 infection, COVID-19 vaccination and cancer-related outcomes) are extracted from electronic medical records.

### Results:

From December 2019-May 2020, we enrolled 317 patients with malignancies or hematologic disorders (70.0% response rate). The median age was 63 (interquartile range (IQR)=54-73) years, 47% were women, 30% self-identified as non-White minorities and 18% were unable to work due to health status. 3% were known to be infected with SARS-CoV-2. An overall COVID-19 vaccine acceptance rate of 80% was reported. Among unvaccinated patients, women expressed more hesitancy than men ( $p=0.045$ ). Concerns about adverse events (56%), rushed vaccine development (44%), and insufficient knowledge (44%) were reported. Self-reported symptoms after the first dose included injection site pain (21%) and fatigue (11%). We observed low levels of depression and high emotional support. Enrollment is ongoing.

### Conclusions:

Individuals with cancer are a complex and extremely diverse population with a multitude of considerations for both immediate clinical care and long-term survivorship. Updated results including findings on antibody response to vaccination across cancer types/treatment protocols will be presented.

## The impact of COVID-19 pandemic on distress level in cancer patients, a cross-sectional multicentric study

### Background:

The pandemic of coronavirus disease 2019 (COVID-19) was declared in March 2020. The first wave of the pandemic was marked by strict epidemiological measures: lockdown, social distancing, and self-isolation. Cancer patients receiving systemic oncology treatments were considered a high-risk population regarding COVID-19. These new circumstances posed possible obstacles for the treatment continuation, which in turn potentially led to an increase in distress. This study aimed to examine the impact of COVID-19 outbreak on a distress level among cancer patients.

### Methods:

A total of 728 cancer patients, in 9 oncology centers, were approached to participate in the study. The study questionnaire with disease and sociodemographic characteristics was completed by 422 patients. Patients were stratified by cancer type: breast, gastrointestinal (colon, gastric, pancreatic), and other cancer types (lung, prostate, ovarian); and by disease stage, early or metastatic. All patients had to have an ongoing active oncology treatment which required regular visits to outpatient clinics or inpatient oncology departments. Distress level was measured using the Distress Thermometer with a cut-off value of 4.

### Results:

There were 201 (47%) patients with breast cancer, 130 (32%) patients with gastrointestinal cancer (colon, pancreatic and gastric cancer), and 92 (21%) patients with other types of cancer (lung, prostate, ovarian). A total of 192 (46%) patients had early disease stage while 230 (54%) patients had advanced disease, respectively. A high distress level was reported in 189 (44.8%) of all patients. The breast cancer patients had significantly higher levels of distress when comparing with other types of cancer. There was no significant difference in distress level regarding disease stage.

### Conclusions:

Almost every second cancer patient with ongoing active oncology treatment was highly distressed during the first wave of the COVID-19 pandemic, regardless of the disease stage. Breast cancer patients tend to have higher levels of distress when comparing with other cancer types. When evaluating distress during a pandemic one should take into account the possible impact of various aspects of COVID-19 disease and pandemic on a distress level in cancer patients.

## What are the barriers to routine clinical use of teleconsultation in oncology? A retrospective study on patient's and their physician's satisfaction with 603 video teleconsultations

### Background:

Although video teleconsultations (TCs) have shown benefits for clinical follow up in oncology, its development appears very delayed in routine practice. The COVID pandemic has required French physicians to use them, mostly during the first lockdown period. This study aims to identify barriers to TCs development by assessing patient's and physician's satisfaction regarding this experience.

### Methods:

Patients who took part in at least one TC during the 7 weeks of strict confinement (from March 7 to May 11, 2020) were asked via email to complete a questionnaire of close-ended questions (5 points Likert scale) with the possibility of additional comments. Their answers were anonymized and gathered via Sphinx, a secured statistical analysis software. A second questionnaire was sent to each physician who conducted these TCs. We then aimed to analyze each patient and physician characteristics and comments, according to their degree of overall satisfaction.

### Results:

531 patients and 35 physicians (oncologists, surgeons, anesthetists, radiotherapists) used TCs; 307 patients (57.8%) and 31(88.5%) physicians completed the survey. Patient's average age was 59. 140 (46.7%) of them lived in a rural area and 193 (64.3%) lived more than one hour away from their cancer center; 66.9% of them were overall satisfied. Unsatisfied patients (12.1%) had the same characteristics as the overall population. Apart from the lack of clinical examination, the main complaints of this group of patients were about altered communication with their physician (44.4% vs 22%), troubles with technical set up (38.9% vs 13.5%) leading to 50% of consultations by phone. Average satisfaction rate among physician was 80.7%. They mainly reported altered relationship with their patient, mostly during tough announcements. Preferred indications were surveillance consultation and treatment monitoring.

### Conclusions:

This study shows high rate of overall satisfaction, from both patients and physicians. TCs seem to provide a suitable alternative to standard in-person consultations, therefore improvements are needed to optimize this technique.

## Impact of the COVID-19 pandemic on diagnosing and treatment referrals of lung cancer patients: A single-center experience

### Background:

Due to the global pandemic of COVID-19 in 2020, a substantial drop in the rate of cancer diagnosis, treatment and prognosis is anticipated owing to limited health resources dealing with cancer. Here, we present single-center data of University Clinic Golnik, which addresses more than 40% of all cases of diagnosis and treatment of lung cancer in Slovenia, but was also one of the main COVID-19 treatment centers in the country during the last year.

### Methods:

Data for lung cancer diagnosis and treatment referrals through multidisciplinary tumor board (MDT) were prospectively collected through the clinical hospital registry and analyzed in comparison with the year before. Descriptive statistical analysis was performed.

### Results:

There were 583 patients diagnosed with lung cancer in year 2019 and 614 in 2020. There was no major difference in symptom duration prior to diagnosis: no symptoms in 17% vs 22%, symptoms lasting less than 1 month in 12% vs 5%, 1-3 months in 43% vs 39% and more than 3 months in 25% vs 24% for years 2019 and 2020, respectively. Also, at the time of diagnosis patients did not present in worse ECOG performance status (PS): 90% vs. 89% had PS 0-2 and 10% vs. 8% had PS 3-4 in 2019 and 2020, respectively. Limited stage of disease was diagnosed in 31% and 37% of patients, loco-regionally advanced in 10% and 8% of patients and metastatic disease in 57% and 53% comparing the years 2019 and 2020. Referrals to the first oncological treatment by the MDT in years 2019 and 2020 were as follows: 31% and 37% proceeded to surgery, 9% and 9% to chemo-radiotherapy, 15% and 16% to palliative radiotherapy, 33% and 28% to systemic therapy and 11% and 10% to best supportive care alone. No major differences in any of these parameters was found comparing the two years.

### Conclusions:

In our small single-center experience, there seems to be no decline in newly diagnosed lung cancer cases, neither increase in later-stage diagnosis. Later analysis will show if this might be attributable to increased radiological investigations performed due to respiratory symptoms and fear of COVID-19 and surely due to timely performed diagnostic procedures and excellent organization despite the pandemic.



## Drop in early-stage colorectal cancer diagnoses after COVID-19: Preliminary report from the COVID-DELAY study

### Background:

By the end of 2020, coronavirus disease 2019 (COVID-19) would have indelibly marked the cancer care setting. With Italy at the forefront of pandemic, unprecedented measures were adopted to tackle the quality care issue. As a result of pausing screening programs, diagnostic delays might affect the years to come. Aim of our multicenter Italian study is to evaluate whether the COVID-19 outbreak has impacted on likelihood of receiving timely diagnosis, staging and treatment for colorectal cancer (CRC) patients (pts) after March 2020 compared to pre-pandemic time.

### Methods:

Medical records of all consecutive newly diagnosed CRC pts referred to 4 Italian Oncology Departments between March and December 2020 were examined. Access rate (number of pts/days) and temporal intervals between date of symptoms onset, radiological and cytohistological diagnosis, treatment start and first radiological evaluation were analyzed and compared with the same months of 2019. Differences between the two years were evaluated using Fisher's exact test or chi-square test for categorical variables and unpaired Student t test, or the Mann-Whitney U test for continuous variables.

### Results:

A reduction (20%) in newly diagnosed CRC cases was seen when compared with 2019 (214 vs 268). The decline was greater in the lockdown period compared to the other months (percentage drop 40 % vs 12%). Newly CRC pts in 2020 were less likely to be diagnosed with early stage (stage I-II-III) CRC (67% vs 72%). Other clinical and tumor characteristics were similar regardless of the year. Looking at pts management, no differences emerged in terms of interval between symptom onset and radiological diagnosis (median 19 days in 2020 vs 28 days in 2019,  $p=0.88$ ), symptom onset and cytohistological diagnosis (25 vs 36 days,  $p=0.27$ ), symptom onset and treatment start (median 86 vs 100 days,  $p=0.79$ ). However, less CRC were discussed in multidisciplinary tumor meetings during the 2020 (45% vs 54%,  $p=0.07$ ).

### Conclusions:

While COVID-19 repercussions will be likely felt for decades to come, our data suggest an alarming drop in early-stage CRC diagnoses during the first pandemic year. Conversely, our study draws the attention on the efforts made to ensure diagnostic-therapeutic pathways proper operation.

## Sustained cancer clinical trial activity during the COVID-19 pandemic

### Background:

The COVID-19 pandemic deeply threatens the rigorous conduct of clinical trials, notably by delaying site initiation visits, patient enrolment, treatment administration, trial-associated procedures, and data monitoring. Unlike most other medical specialties, clinical trials are an integral part of patient care in oncology. Limiting access to clinical trials therefore results in a loss of chance for patients.

### Methods:

In this retrospective single-center study, we collected clinical trial-specific items (including patient-related or trial management-related items) during the first pandemic wave (March-June 2020) and lockdown (March 17<sup>th</sup>-May 11<sup>th</sup>) at Gustave Roussy, and compared them to those of the same period in 2019.

### Results:

In March 2020, 84 phase I (P1) and 210 phase II/III (P2/3) trials were open. During the first pandemic wave, 21 (25%) P1 and 20 (9%) P2/3 trials were temporarily halted, following a unilateral sponsor decision in virtually all cases; all but one was industry-sponsored. Despite this, all important metrics of the P1/2 trial activity remained similar to those of 2019, including the number of patients referred for inclusion (599 vs 620), inclusion consultations (215 vs 247), patients starting treatment (130 vs 130), Internal Review Board (IRB) submissions (14 vs 16), and site initiation visits (11 vs 15), all in 2020 vs 2019, respectively. The impact of the first lockdown was more marked on P2/3, with 152 patient inclusions (vs 346 in 2019), 125 randomizations (vs 278), 43 IRB submissions (vs 50) and 34 site initiation visits (vs 40). However, in parallel, 475 patients were included in three “COVID and cancer” trials. Among the 443 P1 and 2851 P2/3 patients, 198 and 628 COVID-19 PCR were performed internally, and five and 15 (2.5%) were positive, respectively. One patient with a community-based COVID-19 died after transfer in intensive care.

### Conclusions:

Cancer clinical trials can, and must be maintained despite challenges brought by COVID-19. Sharing experiences and retrospectively evaluating the impact on patients' safety and cancer-related outcomes will be critical to durably improve the clinical trials conduct and to anticipate at best challenges brought by future similar crises.

## Worsening of breast and cervical cancer stage at diagnosis due to COVID-19 pandemic

### Background:

The COVID-19 pandemic affected health services by overloading hospitals' capacity, impacting cancer screening and treatment. Unfortunately, a late cancer diagnosis has a detrimental effect in prognosis. We aimed to assess the staging of breast cancer (BC) and cervical cancer (CC) patients (pts) during their first consultation, comparing the periods during and prior to the pandemic.

### Methods:

Data were collected from pts who started follow-up and treatment in a cancer center in Brazil from Sep/20-Jan/21 and from Sep/19-Jan/20. These periods were selected considering the beginning and duration of the COVID-19 pandemic in Brazil, which started on Feb/20 and is still ongoing. We considered the period (Sep/20-Jan/21) to be representative of the pandemic impact on cancer diagnosis. The primary endpoint was BC and CC stages at diagnosis. CC staging was defined according to 2018 FIGO staging. Clinical or pathological (for those with upfront surgery) BC stage was defined according to the TNM anatomic stage from AJCC 8th edition. The comparison of cancer stages between the two periods was performed using ChiSquare test.

### Results:

268 BC pts and 44 CC pts had their first consult from Sep/20-Jan/21; 457 and 60, respectively, occurred from Sep/19-Jan/20. Pts who attended their first consult during the pandemic period presented with higher BC ( $P<0.001$ ) and CC ( $P=0.328$ ) stages than those prior to the pandemic, although the difference was not statistically significant for cervical cancer. The proportion of CC pts diagnosed with locally advanced disease (stages III-IVA) was 56.8% ( $N=25$ ) in Sep/20-Jan/21 compared to 43.3% ( $N=26$ ) in Sep/19-Jan/20. Similarly, 37.3% ( $N=100$ ) of BC pts had stage III disease in Sep/20-Jan/21 compared to 23.2% ( $N=106$ ) in Sep/19-Jan/20. Fewer pts were diagnosed with stage I BC during the pandemic (9.3% vs 20.6%). Additionally, fewer BC pts were diagnosed due to screening tests during the pandemic (13.7%;  $N=36$ ) than before it (25.5%;  $N=113$ ) ( $P<0.001$ ).

### Conclusions:

BC and CC pts presented with a higher stage in their first consultation at a cancer center during the period of the COVID-19 pandemic compared to a similar period prior to the pandemic, confirming the long-term negative impact of the pandemic for oncologic pts. Thus, efforts should be made not to compromise essential cancer services.

## Transition to a virtual cancer multidisciplinary team meeting during the COVID-19 pandemic: Experience from a regional Irish Cancer Centre

### Background:

The COVID-19 pandemic has dramatically changed how healthcare services are provided. In order to comply with public health recommendations, the multidisciplinary team (MDT) network of the South East Cancer Centre at University Hospital Waterford made a transition to a virtual meeting format. The center coordinates a network of eight individual cancer MDTs with three satellite hospitals. Following adaptation to virtual format, remote participants now join by videoconference, telephone call, or by phone application.

### Methods:

A 30-part questionnaire was developed in electronic format and distributed to consultants who comprise the senior membership of the cancer MDTs. The objectives were to investigate experience of the virtual meetings post-implementation, and assess preference regarding the future of the meetings.

### Results:

Among 36 respondents, surgeons accounted for 38.9%, medical oncologists (22.2%), pathologists (13.9%), radiologists (11.1%), hematologists (5.6%) and radiation oncology, palliative care and physicians for 2.8% each. The most common means of joining the meeting included videoconference (61.1%), physical attendance at MDT room (19.4%), telephone (11.4%) and by phone application (8.3%). 67% experienced difficulties using the technology including issues connecting (67%) and screen-sharing (50%). 78% reported that the virtual format did not affect their attendance at MDT, with 11% reporting increased attendance. 56% thought the case discussion at the virtual MDT was not as in-depth as the conventional MDTs, but a majority (81%) believe that decisions made are not impacted by the virtual format. 71% believe it has negatively impacted on education. Most respondents (40%) preferred the traditional face-to-face format, with 37% preferring a combination of virtual and face-to-face. The majority of consultants determine that virtual MDTs should continue past social distancing guidelines.

### Conclusions:

The results of this study suggest that virtual MDT meetings can be implemented into routine MDT practice. Although challenges are encountered, transition to a virtual format enables continuation of MDT meetings in uncertain times and may become a lasting legacy of COVID-19.

## COVID-19 vaccines and cancer: Tailored information for Australia's diverse populations

### Background:

As the COVID-19 vaccine rollout commenced in Australia in early 2021, limited evidence was available internationally about the safety and efficacy of the COVID-19 vaccines for people with cancer, particularly because cancer patients were largely excluded from the initial clinical trials. As such, people with cancer had many questions about the COVID-19 vaccines. Australia's Indigenous and culturally and linguistically diverse (CALD) populations experience poorer cancer outcomes and have specific information needs. As the national cancer control agency, Cancer Australia has a leadership role in providing information to support optimal outcomes for people with cancer, including Australia's Indigenous and CALD populations.

### Methods:

To understand and address the information needs about COVID-19 vaccines for people with cancer, Cancer Australia undertook a scoping review of national and international published literature and guidance, and sought input from key cancer control experts and consumers. In collaboration with Indigenous health and multicultural communications experts, Cancer Australia developed tailored information for Indigenous Australians and CALD populations affected by cancer.

### Results:

Cancer Australia developed a range of information resources relating to the COVID-19 vaccines and cancer, including Frequently Asked Questions (FAQs), and multimedia promotional collateral including animation and radio advertisements. The FAQs were adapted to provide culturally appropriate messaging for Indigenous Australians with cancer and translated into the ten most spoken languages in Australia. Multi-channel social media communication promoted uptake of the resources to CALD and Indigenous communities, and between March and May 2021, the social media campaign received over 800,000 impressions and the FAQs approximately 20,000 page views.

### Conclusions:

Throughout the pandemic, Cancer Australia has been responsive to the unique needs of the Australian cancer community. The development and dissemination of tailored information about COVID-19 vaccines for Indigenous and CALD populations is one example of how Cancer Australia aims to improve outcomes for all people with cancer in Australia.



## Emotional distress in cancer patients during the first wave of the COVID-19 pandemic in Madrid

### Background:

The COVID-19 pandemic has emerged as the most important international health problem of the last decades. This study explores the psychopathological implications that Covid-19 has caused on cancer patients during the first wave of the pandemic in Spain.

### Methods:

In this prospective study, we included cancer patients in active treatment from March to June 2020. A 24-question semi-structured questionnaire was designed to measure baseline demographic, clinical and Covid-19 exposure characteristics. Mental health was assessed using the validated Hospital Anxiety and Depression Scale. A descriptive and analytical univariate analysis of the variables studied was performed. Results have been compared with baseline emotional distress rates from historical cohorts in cancer patients.

### Results:

104 cancer patients were included; a 52.8% of emotional distress, 42.3% of anxiety and 58.6% of depression were detected. 51% of patients expressed higher concern about cancer diagnosis vs COVID-19 infection. Tumor type, stage, type of oncologic treatment or rescheduling of cancer therapy were not related with higher levels of psychological symptomatology. Patients with previous consumption of psychotropic drugs and those who adopted additional infection prevention measures because they considered themselves at risk of having a more aggressive COVID-19 disease had higher levels of emotional distress ( $p=0.008$ ;  $p=0.003$ ), anxiety ( $p=0.026$ ;  $p=0.004$ ) and depression ( $p=0.013$ ;  $p=0.008$ ). Emotional distress was higher in patients whose financial status had worsened ( $p=0.002$ ). Anxiety rates were higher among patients who often used relaxing therapies ( $p=0.011$ ) and those who were frequently exposed to media ( $p=0.05$ ). Depression rates were higher among patients with lower educational level ( $p=0.032$ ), in those whose economic situation had worsened ( $p=0.003$ ), and those who relied on Religion or Faith ( $p=0.029$ ).

### Conclusions:

High rates of emotional distress have been detected during the first wave of the Covid-19 pandemic among cancer patients in active treatment, however, not higher than expected in this population. The cancer disease itself continues to be the main factor of concern for cancer patients, above and beyond the distress generated by Covid-19 pandemic.

## The impact of COVID-19 on cancer treatment delivery in Sub-Saharan Africa

### Background:

There is limited data on the impact of COVID-19 on cancer care in sub-Saharan Africa (SSA). Here, approximately 14 months into the pandemic, we report survey results to understand how the delivery of cancer care has changed in SSA.

### Methods:

We created a global consortium of cancer specialist from Africa and North America to collect data related to COVID-19 and cancer care in SSA. This abstract represents the results of a survey to consortium members, and other colleagues, from 8 cancer centers in Ghana, Nigeria, Kenya, Ethiopia, South Africa, Rwanda, and Zimbabwe. The survey was completed in February 2021.

### Results:

All sites report relatively low rates of confirmed SARS-COV-2 infection (range, 0-83 cases) with a wide range in the case fatality rate (0-50%). With a median duration of 2.3 months (IQR .9-4.2 months), all sites report a temporary lock down with no (12.5%), minimal (12.5%), moderate (50%) and severe (25%) impact on patient care. Examples of this impact include intra-city travel restrictions (25%), intercity travel restrictions (62.5%), and excessive patient travel costs (75%). Most sites report changes in radiation therapy (RT) delivery strategies including transition to hypofractionation (50%), selection of single fraction RT for metastasis palliation (62.5%), deferral of RT for low-risk adjuvant situations (37.5%), or no change (25%). Changes in chemotherapy delivery strategies include transition to oral options (37.5%), use of hormone therapy over chemotherapy (37.5%), deferral of palliative chemotherapy (50%), and delivery of RT without concurrent chemotherapy (12.5%), or no change (50%). A total 3 sites (37.5%) reported the existence of breast or cervical cancer screening programs prior to the pandemic. Only one site reported return to pre-pandemic levels of cancer screening. HPV vaccination programs were active at 2 sites prior to the pandemic with only partial recovery at one site.

### Conclusions:

The pandemic has challenged cancer patients despite relatively low rates of reported infection and death. To minimize transmission, oncologist utilize treatment strategies minimizing patient time in hospital. The negative impact on the limited screening and preventative services in SSA is concerning for an impact that may continue for years to come.

## Phase I clinical trials (CT) forge on despite COVID-19

### Background:

Phase I CT are a cornerstone in the treatment of cancer patients. Given the future uncertainties due to COVID19 pandemic, one of the concerns is the potential decrease of new phase I CT entering the clinic in subsequent years. Our aim was to evaluate the impact of COVID19 in the Start-up activities of the phase I Unit at Vall d'Hebron Institute of Oncology (VHIO).

### Methods:

We analyzed the activity of VHIO Clinical Trials Start-Up Unit from 2019 to April 2021. The number of new proposals/studies (NS), pre-selection site visits (PSSV), and site initiation visits (SIV) for phase I CT were analyzed. Specific measures in response to COVID19 pandemic were registered.

### Results:

Regarding NS, a 9.6% decrease was observed in 2020 in comparison to 2019 (132 vs 146 with an average of 11 NS/month vs 12.16 NS/month respectively). This was mainly due to a decrease during the first wave of COVID19 (Mar -May 2020) with 8.33 NS/month vs 12.66 NS/month in 2019. In 2021 (Jan to Apr), NS increased with an average of 17.25 NS/month. Sponsors were 56.4% Pharma vs 43% Biotech during 2020 and 47.05% vs 52.94% in 2021. Despite the decrease of NS in 2020, an increase of remote PSSV was detected (40 in 2019 vs 60 in 2020). During the first wave of COVID19 we performed an average of 5.66 PSSV/month vs 2.33 PSSV/month in 2019. In 2021, PSSV are still increasing with an average of 6.4 PSSV/month. Forty SIV were performed in 2019, 69 in 2020 and 17 from Jan-April 2021 (average 3.3 SIV/Month, 5.75 SIV/month and 4 SIV/month respectively). On the first wave, 4.33 SIV/month were carried out vs 5 SIV/month in 2019. Remote SIV were performed during COVID19, and hybrid (remote/on-site) during 2021. Documents to explain sponsors the measures undertaken for safe trial implementation have been generated (i.e., remote monitoring, shipment of medication, habilitating COVID free monitoring rooms and treatment wards).

### Conclusions:

Despite COVID19 and an initial decrease of new studies during 2020, the number of new proposals for phase I CT is increasing in 2021. This appears to be equal for biotech and big pharma proposals. Remote PSSVs are an efficient alternative to on- site visits. Digitalization and measures taken are effective to maintain the Clinical trial start up activity in VHIO and will probably remain after the pandemic is over.

## Impact of the COVID-19 pandemic in the cancer fast-track programme

### Background:

The COVID-19 pandemic has disrupted many aspects of clinical practice in oncology, particularly in making timely cancer diagnosis. Our public health system has been concerned about potential delays leading to a higher proportion of patients with advanced stages. Our cancer diagnosis fast-track program (CFP) in the ClinicMalvarrosa Health department in Valencia (Spain) is connecting primary care (PC) with different specialists to speed cancer diagnosis and treatment upon well founded suspicion. A 10-year evaluation of our CFP has recently been published. The aim of this analysis was to investigate the impact of the COVID-19 pandemic on the CFP.

### Methods:

We analyzed the programme flow during the state of emergency starting on March 16, 2020 for one year.

### Results:

During that year, 975 suspected cancer cases were submitted to the CFP. The submissions only decreased during the times of highest COVID-19 incidence and stricter lockdown (March, April and October 2020). However, referrals were slightly higher than in the two previous years (average 877). Of those 975 patients, 817 were seen by the corresponding specialist. A cancer diagnosis was confirmed in 197 (24.1%) with 33% urological, 23% breast, 16% gastrointestinal and 9% lung cancer. Median time from referral to the specialist visit was 13 (interquartile range, 8 to 22 days) days and a diagnosis was reached in a median of 18 days (interquartile range, 10 to 30 days). In cancer patients, treatment was started in around 30 days (interquartile range, 13.5 to 51 days) from the time of diagnosis. Sixty-one percent of cancers were found in an early stage, 20% in a locally advanced stage, and 19% in an advanced stage. These intervals and proportions were similar to the previous years.

### Conclusions:

Our programme has proven to be a reliable tool to help PC physicians referring patients with cancer suspicion cancer, maintaining its normal flow and efficacy despite the current pandemic.

## The virtual clinic: An insight into the patient and clinician experience in cancer during COVID-19

### Background:

Technology in healthcare has been evolving with an amplified use over the last year, due to the coronavirus 19 (COVID-19) pandemic. Face-to-face consultations for cancer patients were reduced and virtual clinics (VCs) in the form of telephone or video were offered in replacement. The aim of the study was to assess the experiences of VCs in cancer care amongst patients and healthcare professionals at Barts Health NHS Trust.

### Methods:

Patients were identified from the electronic patient system who had received cancer care at Barts Health NHS Trust from 01/09/20-15/01/21 and attended at least one VC. Clinicians actively working within cancer were invited if they had attended at least one VC. Individual semi-structured telephone interviews were conducted with separate interview guides designed for each participant group. Questions related to the use of VCs in the future, accessing technology, waiting times and communicating issues, wider worries or fears. Participants rated their experiences from 1-5 (1 being low and 5 being high). Interviews were recorded with verbal consent and transcribed verbatim. Data was thematically analyzed using NVivo12.

### Results:

A total of 36 patients and 10 clinicians participated. Themes were acceptance, time, technology, purpose of clinic, communication, equipment, benefits and choice. Participants were accepting of the VC with 80.5% of patients (n=29/36) and 90% of clinicians (n=9/10) supporting future use. Both groups agreed that VCs are not suited to everyone and the use of the VC should be individualized for the patient based on several criteria including patient preference, reason for consultation and patient characteristics. The average satisfaction rating of the VC was higher among patients (4.45/5) than clinicians (3.75/5), with many clinicians suggesting that support setting up video clinics may improve the score.

### Conclusions:

The study showed the promising use of VCs in the future. Recommendations were suggested to optimize the patient and clinician experience. These include implementing a patient triage system to advise which patients should have a virtual consultation, providing enhanced training and equipment to staff and ensuring the chosen method of VC provided is individualized to the patient's needs.



## The perks of SARS-CoV-2 monitoring through serial nasopharyngeal (NP) swabs in an Italian high prevalence area

### Background:

The outbreak of SARS-CoV-2 infection and the associated COVID-19 pneumonia have dramatically disrupted the delivery of cancer care worldwide. Indeed, this crisis has raised the urge of thoughtfully balancing the risk of delaying potentially curative treatments against the harm of developing a life-threatening respiratory infection. In this study, we report the experience of an Italian Reference Cancer Center, where strict triage procedures had to be promptly adopted.

### Methods:

We retrospectively analyzed a consecutive cohort of 787 cancer patients (pts) who accessed the Day Hospital (DH) of the Oncology Department of Udine from April 6th to June 19th 2020. Screening NP swabs and RT-PCR analysis were performed at every access in pts who, after passing the triage, were admitted to receive intravenous therapies. Clinicopathological data were collected from electronic health records and include sex, age, tumor type, disease stage, type of treatment, number of swabs received and RT-PCR results.

### Results:

Overall, 2602 NP swabs were performed in a population of 787 cancer pts receiving intravenous therapies, including 55.7% female and 44.3% male pts, respectively, with 54.9% aged 65. Of note, 28.2% of pts had gastrointestinal tumors, 23% breast cancer, 19.8% lung cancer and 14.2% tumors of the genitourinary tract. Approximately 32% of pts had early-stage disease whereas 68% of them was receiving therapies for advanced disease. Treatments most frequently included chemotherapy (60%), immunotherapy (14.7%) and target therapies (9.8%) whereas 11.1% of swabs were performed in pts entering the premises for supportive therapy. The median number of SARS-CoV-2 tests per patient was 3 and 26% of pts received  $\geq 5$  swabs. In the whole population, only 10 SARS-CoV-2 tests (1.3%) resulted positive and were promptly isolated.

### Conclusions:

In the pandemic context, the adoption and gradual refinement of rigorous procedures aimed at minimizing COVID-19 diffusion among pts and healthcare professionals are mandatory to ensure continuity of care. In our experience systematic triage, sequential screening with NP swabs and the prompt identification of asymptomatic SARS-CoV-2 carriers limited COVID-19 spread among cancer pts accessing the Oncology DH.

## Management of locally advanced rectal cancer during the COVID-19 outbreak: First results of a shift towards short course neoadjuvant radiotherapy

### Background:

Alike other tumor types, it was recommended that the management of locally advanced rectal cancer (LARC) during the COVID outbreak would shift towards hypofractionated RT schemes. Short-course neoadjuvant radiotherapy (SCRT) is comparable to long-course chemoradiation (CRT) in terms of toxicity and survival; nevertheless, CRT is still largely used, especially in advanced tumors. We aim to report the clinical-pathological characteristics and first treatment results of patients treated in a 3-month period during COVID-19 outbreak and to compare them to those treated in the previous year.

### Methods:

We retrospectively reviewed consecutive cases of patients with LARC treated with neoadjuvant RT during Apr-Jun 2020 and Apr-Jun 2019 (control group). Chi square and independent T tests were used for comparison.

### Results:

During Apr-Jun 2020, 35 patients (median age 62 [31-86] years, median Charlson score 4 [2-8]) were treated with neoadjuvant RT. Primary tumor was staged as cT2 (6%), cT3 (57% T3a-b, 17% T3c-d) and cT4 (17% T4a, 3% T4b); 83% were cN+; 11% patients were M1 at diagnosis and had primary CT. All patients were treated with SCRT (25Gy/5Gyfr); 20% patients had perioperative CT and 46% had adjuvant CT. In the control group (n=34), 9 patients had SCRT and 25 had CRT (50.4Gy, 1.8Gyfr, plus capecitabine); 6% had primary CT for M1 disease and 6% had perioperative CT. Both groups (2019 vs 2020) were comparable in terms of clinical-pathological variables (age, comorbidities, TNM stage, mesorectal fascia involvement, R0 margin). Pathological complete response (9% vs 11%, p=0.720), modified Ryan tumor regression score  $\geq 2$  (74% vs 80%, p=0.456) and rate of postoperative complications  $\geq$ III-b (20% vs 9%, p=0.357) also did not differ. Median time from diagnosis to start of RT was 58 $\pm$ 43 days vs 61 $\pm$ 31 days, p=0.448. Median time to delayed surgery was 66 $\pm$ 18 days vs 67 $\pm$ 18 days, p=0.948. The start of RT was postponed in 1 patient due to COVID+.

### Conclusions:

Patient characteristics and time to neoadjuvant RT did not appear to differ during COVID-19 outbreak. A shift towards a safer treatment for LARC during this period did not seem to impact pathological response neither postoperative complication.

## Impact of COVID-19 pandemic on the diagnosis of breast cancer in one region of north of Portugal: One year experience

### Background:

The onset of COVID-19 pandemic forced lockdown and halted breast cancer screening programs. We aimed to investigate the impact of COVID-19 on the new diagnosis and staging of breast cancer.

### Methods:

In this cohort study, we included all patient with new diagnosis of breast cancer who were admitted to our Hospital (Hospital Pedro Hispano, Matosinhos, Portugal), between March 2019 and March 2021. We collected data on baseline clinical conditions such as age, stage at diagnosis and treatment. We created two different groups were created: 1<sup>st</sup> group- before COVID-19 pandemic (March 1, 2019 to March 16, 2020); 2<sup>nd</sup> group - COVID-19 pandemic (March 17, 2020 to March 31, 2021). A comparative assessment between groups was carried out.

### Results:

Were included 483 patients; n<sup>1</sup>/<sub>4</sub>289 in the 1st group and n<sup>1</sup>/<sub>4</sub> 194 in the 2nd group. The median age was 60 years old in the 1st group and 59 years old in the 2nd group. In the 1st group, 13% patients were diagnosis with ductal in situ carcinoma (DCIS), 51% in stage I, 24% in stage II, 9.5% in stage III and 3% in stage IV. In 2nd group, 9% had DCIS, 30% were in stage I, 40% in stage II, 11% in stage III and 10% in stage IV. Stage at diagnosis was significantly higher in the 2nd group ( $p < 0.001$ ) This situation was mainly due to tumor size (T). In the 1st group, most patients ( $n=91$ ; 38%) had tumor size between 10 e 20mm (T1c in TNM classification). One the other hand, 40% ( $n=78$ ) of patients included in the 2<sup>nd</sup> group had tumor size between 20 e 50mm (T2), with significant differences between them ( $p=0.004$ ). No difference was found between groups in nodular involvement ( $p=0.189$ ), with the majority of patients (~50% in both groups) presenting without nodular involvement (N0 in TMN classification). 10% of patients in 2nd group and 3% in 1<sup>st</sup> group had metastatic disease at diagnosis, with differences between them ( $p=0.006$ ). 49% ( $n=119$ ) of patients in 1<sup>st</sup> group and 52% ( $n=100$ ) in the 2nd group were treated with chemotherapy, without differences between those groups.

### Conclusions:

Our results show that during one year after COVID-19 pandemic the incidence of breast cancer decreased, and patients were diagnosis in more advanced stages. This situation could have been related to patient referral to non-COVID-19 Hospitals or correspond to a true sub-diagnosis.

## SARS-Cov-2 and Cancer Trials Ireland: Impact, resolution, legacy

### Background:

The SARS-Cov-2 pandemic led to significant ongoing disruptive change in healthcare from 3/2020 to the present. The impact and legacy on a national clinical trials organization was assessed.

### Methods:

A review was conducted of prospectively acquired communications, team logs and time sheets, trial activation, closure, and accrual, for the period 2019-present. An online survey of the impact of the pandemic on clinical investigators was performed. During lock-down periods hospital sites closed to monitoring visits and remote visits were not always possible due to paper-based health information systems. Overall accrual to academic cancer clinical trials decreased by 49%.

### Results:

In the 9 months after the pandemic was declared clinical trial accrual fell by 54%, radiotherapy trial accrual by 90% and translational studies by 36%. Staff reassignment occurred in 60% of units. Monitoring visits by Clinical Research Associates was reduced by 42% and remote monitoring rose from 5% to 20% of monitoring visits. The opening of new trials fell by 67%. 77% of investigators experienced burnout, 71% had less time for trials and 53% reported less support for trials.

### Conclusions:

In the 9 months after the pandemic was declared clinical trial accrual fell by 54%, radiotherapy trial accrual by 90% and translational studies by 36%. Staff reassignment occurred in 60% of units. Monitoring visits by Clinical Research Associates was reduced by 42% and remote monitoring rose from 5% to 20% of monitoring visits. The opening of new trials fell by 67%. 77% of investigators experienced burnout, 71% had less time for trials and 53% reported less support for trials.

## The impact of the COVID-19 outbreaks on surgical site infections in elective colorectal cancer surgery: One potential benefit of the pandemic?

### Background:

The COVID-19 pandemic, also known as the coronavirus pandemic, has affected either directly or indirectly all medical fields. It caused a major reduction of elective surgical operations as well as overall admissions to surgical departments because of the widespread hospital fear and anxiety experienced by most patients during the peak of this outbreak. However, colorectal cancer operations were performed in large numbers also during the pandemic. In order to protect patients and health workers, hygiene and public health measures were intensified when the coronavirus pandemic began. The aim of the present study was to evaluate the rate of surgical site infections (SSIs) after the beginning of COVID-19 hygiene measures, which was in March 2020 in Greece.

### Methods:

A total of 173 patients who underwent elective colorectal cancer surgery were enrolled retrospectively. Patients were divided into two groups. Group A included 98 patients undergoing colorectal cancer surgery between January 2019-December 2019 (pre-COVID-19 era), whereas 75 patients (group B) underwent colorectal cancer procedures between April 2020-March 2021 (after the beginning of COVID-19 hygiene measures). Statistical analyses were done using Stata13. The student's t-test was used to compare results between groups.

### Results:

SSI developed in 35 of the 173 patients (20.2%). According to the results of our study, there was a statistically significant difference between the total numbers of SSIs between the 2 examined periods. 25 (25.5%) wound infections occurred in group A-patients postoperatively, whereas only 10 (13.3%) SSIs were developed in patients undergoing colorectal cancer surgery after the beginning of COVID-19 measures (P=0.048).

### Conclusions:

The current study demonstrates that COVID-19 hygiene and public health measures affect the rate of SSI after elective colorectal cancer surgery.



## Evaluation of the socio-sanitary and emotional impact caused by SARS-CoV-2 in a Spanish cohort of cancer patients after the second pandemic wave

### Background:

The Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has caused more than 120 million cases and more than 2 million deaths from its inception until March 2021, causing a great social and emotional impact. Our objective is to evaluate the emotional distress on the cancer population after the second wave and to compare it indirectly with the onset of the pandemic.

### Methods:

Observational, cross-sectional, single-center study of 102 Spanish cancer patients recruited between the months of January and March 2021. Patients of any age, with tumors of any location and in any phase of the disease were included. Socioeconomic, health care and psychological variables have been collected, using the Kessler K-10 scale for the assessment of psychological distress. The association analysis of socio-sanitary variables with emotional variables was carried out using the Chi-square test in SPSS v25.

### Results:

In our cohort, 74% of the cases were between 50 and 74 years old. The most represented tumors were breast (26%) followed by colorectal cancer (18%). 51% were retired people and 19% had temporary work disability, while around 6% were unemployed. 15% reported a change in income and around 19% lived alone without companions. Regarding health variables, 11% had presented symptoms associated with SARS CoV2 infection, 21% reported a longer waiting time for diagnostic test or initiation of oncological treatment, and 17% highlighted a shorter attention time by their medical oncologist. In relation to the emotional impact, a statistically significant relationship ( $p < 0.05$ ) was observed between the female sex and greater nervousness, retired people and less nervousness and despair, as well as the delay in health care and greater feeling of uselessness, despair, restlessness and depression, especially if this occurred more than 1 occasion.

### Conclusions:

the SARS-CoV-2 pandemic has caused a worsening of the socioeconomic and health conditions of cancer patients, persisting beyond the second pandemic wave. This is causing a chronification of the psychological impact in this population that could be improved with adequate prevention measures and better health care.

## At home androgen deprivation therapy for patients with prostate cancer during the COVID-19 pandemic. One center experience

### Background:

COVID-19 pandemic created major challenges in cancer care. Studies have shown increased risk for COVID-19 infectivity, severe disease and death in patients with cancer. Cancer centers worldwide adapted by modifying and often delaying treatment to minimize contact with patients.

### Methods:

To provide safe and uninterrupted care for patients, a home care program was created for patients with prostate cancer at Acad. F. Todua Medical center. Men with locally advanced or metastatic prostate cancer (MPC) receiving androgen deprivation therapy (ADT) were enrolled. Patients and their caretakers were instructed on gonadotropin-releasing hormone (GnRH) subcutaneous injections (SQ) for home administration. Monthly at home laboratory testing and virtual consultations with medical oncologists every 1-3 months were arranged.

### Results:

A total of 52 patients were enrolled during the period of March 2020 e March 2021. All men were White and had ECOG 0/1. The mean age was 71 [ $\pm 6.3$  y] years. Sixteen (31%) patients had stage IIIB PC and 36 (69%) patients had stage IV disease. Stage IIIB patients were receiving adjuvant ADT with SQ Goserelin Acetate 10,8mg every 8 weeks and bicalutamide 50mg daily for two weeks after definitive local treatment. Thirty-one (86%) patients had hormone sensitive metastatic PC and were receiving SQ Goserelin Acetate 10.8mg (28) every 8 weeks or SQ Leuprolide Acetate 22,5mg every 8 weeks (3) with 2 weeks of Bicalutamide 50mg daily. Five (14%) patients had castration resistant (CR) PC and were receiving SQ Goserelin Acetate 10,8mg every 8 weeks with Enzalutamide 160mg daily. Thirty-three (63%) patients had Gleason's score of 8/9. All patients were compliant with home injections, laboratory tests and virtual physician visits. Thirty-nine (75%) patients administered injections by themselves. Forty-two (80%) patients had PSA reduction  $>50\%$ . Ten (20%) patients had disease progression and required clinic visits for investigations. Median time to progression was 12 months. Only 1 (2%) patient acquired COVID-19 infection, was hospitalized and died of respiratory failure.

### Conclusions:

At home ADT with appropriate patient/caregiver education and close follow up may be safe for patients with PC during the COVID-19 pandemic.

## Why do cancer clinical trials (CT) discontinue prematurely in the era of COVID-19?

### Background:

The COVID-19 pandemic (C19P) is causing several detrimental effects on cancer care globally. CT are crucial to obtain high quality literature evidence and “poor accrual” is the most common reason for their early discontinuation (ED). At our best knowledge, no data are available on ED of cancer CT after the beginning of C19P.

### Methods:

ClinicalTrial.gov was queried for terminated (T), withdrawn (W) and suspended (S) CT for the following terms: “cancer”, “neoplasm”, and “tumor”. The search was made for all the CT available from the inception to 26th February 2021, without any restrictions. The following characteristics were extracted: reason for ED, study type (interventional [In] vs observational), sponsored (yes vs not). ED rate was compared between CT discontinued for C19P or not ( $\chi^2$ );  $p < 0.05$  was set as statistically significant. A multiple linear regression analysis was also conducted to identify independent factors of ED.

### Results:

9990 CT were identified, but 765 CT were excluded as not related to cancer. Thus, 9225 CT were included (66% was T, 23% was W and 4% was S). Among CT classified as T, W and S, the frequency of In CT was 92%, 88% and 85% respectively, while the frequency of sponsored CT was 46%, 35% and 26% respectively. The most common reasons for ED were: “poor accrual” (29%), “lack of funding” (6%) and “sponsor decision” (5%). No reason for ED was available for 15% of CT. One hundred (1%) CT were discontinued due to C19P (27% was T, 7% was W and 66% was S). Comparing CT discontinued due to C19P with those discontinued due to other reasons, a lower rate of In-CT (73% vs 91%,  $p < 0.05$ ) and sponsored CT (14% vs 42%,  $p < 0.05$ ) was found in the C19P group. At the multiple linear regression analysis, C19P was strongly positively correlated with ED (coefficient 0.59952,  $p < 0.0001$ ) whereas sponsored CT resulted as negatively correlated with ED (coefficient -0.02746,  $p < 0.0001$ ).

### Conclusions:

“Poor accrual” continues to be the main reason for ED of cancer CT, but C19P represents a new additional cause of ED. Sponsored trials showed less risk for ED. Further research is needed to maximize the expected benefit of cancer CT, reducing the anticipated risks.

## Communication specifics with cancer patients during the COVID-19 pandemic in Croatia: Can a virtual visit meet the needs of cancer patients?

### Background:

In this study, we focused on communicating with cancer patients on active treatment during the first lockdown due to the COVID-19 pandemic and the patient's main sources of pandemic information.

### Methods:

In the first wave of the pandemic, during the first lockdown, we conducted an observational study in 8 of the 13 oncology centers in Croatia. The study is based on an anonymous self-report questionnaire designed for this study. It included 422 oncology patients, older than 18 years, who were in active oncology treatment at the time. To study the correlation between the patient's perspective on communicating with medical staff during a pandemic, the preferred type of communication, and the main sources of pandemic information relative to clinical and sociodemographic data, we used univariate descriptive and bivariate analyzes.

### Results:

In the first lockdown, our respondents communicated with the oncologist and oncology nurses mostly in-person (77.7% vs. 81%), and with the general practitioner mostly virtually, most often by phone (70.6%). Regardless of the pandemic, the majority of oncology patients (76.1%) prefer to communicate with an oncologist in person, and most expressed satisfaction with communicating with medical staff during a pandemic. The choice of information sources and type of communication depends on the age, gender, income, education, and the seat of the disease of patients.

### Conclusions:

For most of our respondents, in-person visits were the basic way of communicating with oncologists and oncology nurses. On the other hand, a virtual visit was the basic way to communicate with the general practitioner. As patients stated that, regardless of the pandemic, they prefer to communicate with the oncologist in-person, we can conclude that the virtual visit does not meet the needs of cancer patients who are in active oncology treatment. In our study men showed a tendency to communicate in-person, while women, breast cancer patients, younger people, highly educated people, and people of higher income are more prone to virtual visits and are more inclined to use the Internet as a source of information about a pandemic.

## Impact of the COVID-19 pandemic on cancer care in Tunisia: Oncologists' perception

### Background:

The COVID-19 pandemic was confirmed to have reached Tunisia on March 2nd, 2020, and has therefore disrupted oncology practice ever since. We report the main difficulties encountered by oncologists across the country during the pandemic.

### Methods:

We conducted a national online survey on medical, surgical, and radiation oncologists to investigate their practice changes during the COVID-19 pandemic from March 2020 to January 2021.

### Results:

136 oncologists responded to the survey (surgical oncologists 35.8%, medical oncologists 37.8%, and radiation oncologists 26.4%); 80% were working in public hospitals. Among oncologists working in the public sector, 59% were asked to join covid-19 units. Five percent stated that their cancer care units were requisitioned for the management of COVID-19 patients and therefore, their patients were referred to other hospitals to pursue their treatment. Moreover, when comparing the number of new cancer cases diagnosed during and before covid-19, 63% of the surveyed oncologists reported a decrease in the number of new cases while 27% stated that the number was stable. During the lockdown, 45% of the participants noted that only 25 to 50% of their patients attended the follow-up visits and that 83% of them missed their CT imaging appointments. On the other hand, 62% of the surveyed oncologists stated that their patients experienced delayed curative surgeries, and 41% had chemotherapy delays. Decreased consultations at the emergency oncology departments were reported by 88% of the oncologists. Besides, 40% of oncologists reported that they adopted telemedicine to monitor patients during the lockdown, and, 48 % stated that they participated in videoconferences to learn about patients' management during the pandemic. Finally, 46% of the surveyed oncologists reported losing patients due to the COVID-19 infection, which was a trigger for anxiety symptoms in 35% of the participants.

### Conclusions:

Oncologists reported deleterious effects of COVID-19 on oncology practice and patients' management. Establishing standardized practice guidelines during the pandemic may help to decrease oncologists' distress and reassure them about the appropriateness of their treatment policies.



## Health behavior of cancer patients during COVID-19 pandemic. Focus head neck cancer

### Background:

During pandemic coping strategies become very important for for each individual cancer patient. Are there any changes in health behavior of our patients due to pandemic?

### Methods:

We have analyzed questionnaire data of 575 patients, among them 171 head neck cancer patients. 246+84 questionnaires were filled in May 2020 (wave 1) and 158+87 questionnaires were filled in October 2020 (wave 2). We asked for alcohol consumption (5-point Likert scale), sportive activities, meditation, praying, and drug abuse (all 4-point Likert scale). We compared each item at both time points (t-test, 2-fold, inhomogeneous variance). Sub-analysis was performed for head and neck cancer patients.

### Results:

Comparing between both time points, we see a stable alcohol consumption ( $1.700 \pm 1.463$  vs.  $1.66 \pm 1.428$ ), a significant decreased in sportive activities ( $1.789 \pm 1.013$  vs.  $1.557 \pm 0.995$ ,  $p=0.013$ ), a trend to less meditation ( $0.571 \pm 0.951$  vs.  $0.408 \pm 0.873$ ,  $p=0.056$ ), a significant decrease in praying ( $0.938 \pm 1.225$  vs.  $0.650 \pm 1.126$ ,  $p=0.009$ ) and an unchanged drug abuse ( $0.366 \pm 0.891$  vs.  $0.392 \pm 0.942$ ). Comparing head neck cancer patients with cancer patients of other tumor localizations, they show a significant stronger reduction of praying ( $p=0.002$ ). During wave 2 head neck cancer patients reported about more alcohol consumption ( $1.473 \pm 1.491$  versus  $1.697 \pm 1.427$ ) and drug abuse ( $0.333 \pm 0.875$  versus  $0.48 \pm 1.044$ ).

### Conclusions:

During pandemic we see a reduction of individual coping strategies and changes in physical and mental health behavior. Societal activities are necessary to encourage coping strategies as sports or spiritual care.

## Unintended consequences for an integrated oncology ecosystem from COVID adaptations

### Background:

Cancer services had to adapt for social distancing to minimize risk of COVID spread between staff, persons with cancer attending and those supporting them. Prior to COVID patients attended a large combined outpatient clinic (OPC) once a week (12.30-7pm). This allowed optimal staffing of the day unit and inpatient service for the majority of the week. A separate outpatient facility at a removed location, though still on the Hospital campus, was created for OPC assessments with the intent of dispersing the large clinic across 4 days during COVID outbreak. An analysis of the impact on staff availability throughout the service as a consequence of an increased frequency / reduced patient volume OPC is outlined below.

### Methods:

The numbers of non-consultant hospital doctors (NCHDs), their assigned location (day unit or OPC), allowances for full staff and also allowing for vacation time were gathered for 1) pre-COVID clinic and 2) modified COVID clinics. Activity levels within the day unit treatment facility was also assessed using the hospital information system. The number of NCHDs multiplied by the hours available to the day unit were calculated per week for both clinic structures to produce the "available NCHD hours".

### Results:

From Jan. 2nd to Dec. 31st 2020 there were 11089-day oncology treatment unit by 1304 patients, alongside 4045 OPC visits. To adjust for COVID social distancing the large OPC (7 hours) was dispersed across 4 mornings (18 hours). This change resulted in the reduction of available NCHDs to the day oncology unit from 247 available NCHD hours to 158 available NCHD hours once vacation and study leave are factored into the equation. This represents a 36% reduction in available staff yet no planned reduction in patient activity.

### Conclusions:

While dividing clinical activity in the OPC over several days allowed patients attend with a family member, allowing better insight and support, it reduced the numbers of doctors available for a significant part of the day, placing more strain on those doctors trying to manage a similar number of patients in a safe and patient focused manner. Changes within the outpatient clinic setup adjusting to COVID restrictions has inadvertently had knock-on effects on the "Oncology Ecosystem" and may impact on future service quality.

## Experience with telemedicine during COVID-19 pandemic

### Background:

Since the beginning of COVID19 pandemic, cancer patients were considered to be more susceptible to contract SARCOV2 due to their underlying disease, greater immunosuppression and comorbidities. This higher risk forced oncologist on March 2020 to switch to telehealth without previous knowledge on this field. The aim of this study is to review our experience with telemedicine during the COVID-19 pandemic.

### Methods:

Patients attended by a telephonic and/or an in-person visit in the Medical Oncology Service at Parc Taulí Hospital Universitario between March 13 to April 30 2020 were included. Characteristics of recruited patients were summarized using descriptive analysis. The study was approved by the Research Ethic Committee.

### Results:

855 patients were attended. 24.4 % had an in-person visit, 63.2 % had a phone call visit and 12.4 % both types. Median age was 65,48 [26-94] years old. 48.7% were male. 65.4% ECOG 0. Cancer types were: 41,8 % Colorectal, 12,7% Gastrointestinal non-colorectal, 12% Lung, 21,3 % Breast and 12.2 % Others. Most patients (52.4%) had a follow-up visit. 26.4 % were receiving palliative treatment and the most frequent administered drug was chemotherapy (51.2%). Telephonic appointments were mainly follow-up visits (63.7%), used for older patients (median age 66 years) with colorectal and breast cancers (42.7 % and 24.3% respectively), ECOG 0 (65.4%) and stage I, II and III disease (73.9%). In contrast, in-person appointments were mostly treatment visits (84.1%), for younger patients (median age 63.4 years) with stage IV disease (60%), ECOG 1 (51.7%) and colorectal cancer (35,9%). The proportion of patients with non-colorectal and thoracic cancers was higher when compared to telephonic assistance (40.6 % vs 19.4% respectively). The differences between the two types of visits were statistically significant ( $p < 0.0001$ ).

### Conclusions:

Without a robust scientific basis or previous experience, it seems that during the first period of COVID-19 pandemic oncologist felt more comfortable with face-to-face appointments when visiting patients with stage IV disease and/or ECOG  $\geq 1$  that were receiving palliative treatment. These patients attended more to the hospital despite having a higher mortality for COVID19.

## Impact of COVID-19 on ongoing oncological and hematological treatment strategy

### Background:

Outcomes and risk factors associated with COVID-19 worsening among cancer patients have previously been reported. However, the actual impact of SARS-CoV-2 infection on the cancer treatment strategy remains unknown. Here, we report the Gustave Roussy (GR) experience, one year after the onset of the pandemic focusing on the impact of COVID-19 in patients with ongoing management of oncohematological disease.

### Methods:

All patients positively tested for SARS-CoV-2 and managed at GR between Mar 14th 2020 and Feb 15th 2021 (data cut-off) have been included. Patients underlying oncohematological disease and COVID-19 characteristics have been collected. Cancer and COVID-19 management and outcomes have been assessed. Primary endpoint was the overall impact of COVID-19 on oncological and hematological treatment strategy assessed at 1, 3, 6 and 12 months.

### Results:

At the time of the analysis, 423 patients (median age: 62 years) were found positive for SARS-CoV-2 and managed at GR with a median follow up of 5.6 months (0-13 months). Among them, 284 (67%) were admitted due to COVID-19. Clinical deterioration occurred in 87 patients (21%), 43 patients (10%) were transferred in intensive care unit and 123 (29%) patients died, among which 47 (11%) died from COVID-19. Overall, 329 (78%) patients were on active treatment for underlying oncohematological disease at time of COVID diagnosis. Impact of COVID-19 on cancer treatment strategy in those patients is presented in the Table. The majority (N=268, 81%) had no change in oncological strategy. For those who experienced a delay, median delay in treatment was 21 days (N=99, [1-77]), 30 days (N=15, [15-56]), 7 days (N=8, [3-35]) for systemic treatment, surgery and radiotherapy respectively.

**Table: 1639P** Impact of COVID-19 on cancer treatment strategy in patients with active oncohaematological treatment at time of COVID-19 diagnosis

	N = 329
<b>Death from COVID-19</b>	<b>36 (11%)</b>
<b>No change in strategy</b>	<b>268</b>
Without delay	136 (41%)
With Delay	132 (40%)
<b>Change in strategy</b>	<b>22</b>
End of treatment – Surveillance	8 (2%)
End of treatment – Palliative care	7 (2%)
Change of treatment modality	6 (2%)
Change of systemic therapy	1 (<1%)
<b>NA</b>	<b>3 (&lt;1%)</b>

### Conclusions:

COVID-19 outbreak is associated with a significant mortality in patients with cancer. However, for patients who did not die from COVID-19, we provide the first report supporting that ongoing treatment was maintained or could be resumed in the majority of cases in a timely manner.

## Impact of COVID-19 vaccination campaign on psychological status in cancer patients (pts)

### Background:

The health emergency caused by the SarS-Cov-2 pandemic has been strongly impacting on oncological patients' (pts). The purpose of this study was to explore the emotional impact and perception of cancer pts who received the vaccine against COVID-19 at the University Hospital and Trust of Verona (Italy).

### Methods:

After the first dose of COVID-19 vaccine an anonymously questionnaire was proposed to cancer pts (March-May 2021). The survey investigated anxiety and depression levels using the Hospital Anxiety and Depression Scale (HADS), psychological distress with the Distress Thermometer (DT). Additionally, four specific items regarding the awareness about: i) infection risks, ii) interference with chemotherapy treatment, and iii) adverse effects, were developed. Descriptive analyses were performed.

### Results:

A total of 736 patients (mean age 63 yrs) completed the questionnaire. Breast (23%) and gastrointestinal (40%) were the most represented cancer sites. The majority of pts (65%) reported mild levels of distress ( $DT \leq 4$ ), while moderate ( $DT 5-7$ ) and severe ( $DT \geq 8$ ) levels were identified in 26% and 9% of participants, respectively. A total of 11% and 8% of pts experienced clinically significant symptoms of anxiety and depression ( $HADS \geq 11$ ), whereas 15% were borderline ( $HADS$  score 8-10). Two thirds of pts (67%) thought that the vaccination may reduce the infection risks and 56% felt safer. Overall, 59% of pts did not believe that vaccine-related side effects may interfere with the oncological treatment and 49% considered the vaccination safe.

### Conclusions:

Most cancer pts undergoing COVID-19 vaccination presented mild levels of anxiety, depression and distress. Oncological pts undergoing vaccination felt safe and judged the benefits of COVID-19 vaccination to overweight the potential side effects.



## Patient preferences towards the application of telemedicine on cancer care during Coronavirus disease 2019 (COVID-19) pandemic. ONCOTELEMED STUDY

### Background:

COVID-19 became a worldwide pandemic in March 2020. To reduce virus spread and ensure continuity of cancer care, the use of telehealth was rapidly implemented. Currently, there is no mature data on patient's perception about the use of telemedicine during this period, so we sought to evaluate the opinion of patients with cancer who were attended telematically in Hospital Parc Taulí.

### Methods:

COVID-19 became a worldwide pandemic in March 2020. To reduce virus spread and ensure continuity of cancer care, the use of telehealth was rapidly implemented. Currently, there is no mature data on patient's perception about the use of telemedicine during this period, so we sought to evaluate the opinion of patients with cancer who were attended telematically in Hospital Parc Taulí.

### Results:

487 patients (75.4%) responded; 57% by phone call. Median age was 68 years [27-90]. 65.7% of patients had a follow-up visit and 34.3% were receiving treatment. Most patients (>80%) were satisfied with the telephonic visit and believed that it was useful to solve their concerns. Around 60% said that they would agree to continue with some virtual visits following the COVID-19 pandemic. 62% of patients would agree to be informed telematically of radiological results while 82% would agree for analytical results. 52% would agree to be visited virtually if they were receiving an oral treatment whereas only 33.5% would agree if the treatment was endovenous. In general, younger patients (<50 years old) feel more comfortable with virtual visits than older ones (>70 y) (77.4% vs 62%,  $p=0.07$ ). Only 20% of patients older than 50 believe that they can handle new technologies as opposed to 58.5% of younger ones ( $p=0.001$ ). 60.4% of the younger patients would like to have different technological tools to contact their oncologist whereas most patients (47.6%) older than 70 prefer only phone calls ( $p=0.001$ ). Regardless of the type of visit (treatment or follow-up) patients felt comfortable with virtual attendance (58.7% and 65.6% respectively,  $p=0.2$ ).

### Conclusions:

As a whole, patients surveyed believed that telehealth could have a role following the COVID-19 pandemic. However, telemedicine is not applicable in all cases. Visits to older patients, to inform about radiological results and to patients receiving treatment should be assessed case by case.

## Improve the conditions of lockdown may decrease anxiety among cancer patients during the COVID-19 pandemic

### Background:

The COVID-19 pandemic is a highly traumatic event that may lead to a greater risk of developing psychological disorders, especially in cancer patients who are more likely to be infected with the virus and to develop complications. The objective of this study was to measure anxiety levels among cancer patient during COVID-19 pandemic and the associated factors including patients' conditions of lockdown.

### Methods:

A cross-sectional study was conducted among adult cancer patients (hematological and solid tumors) receiving outpatient treatment or during follow-up in a French Comprehensive Cancer Centre. A postal self-administered questionnaire was sent to 4000 patients in June 2020, including Anxiety (Stait Trait), Fear of a cancer recurrence (FCR) as well as questions relative to socio-demographics, management of cancer care during the pandemic and the conditions of lockdown.

### Results:

A total of 1097 patients completed the questionnaire (63.2% female; mean age 64.7 years  $\pm$ 2.3 years, 24.3% haematological cancers). Mean IES-R score was 15.7 ([0-81]) and 14.7% of patients had moderate or severe post-traumatic stress (score  $\geq$ 33). Mean anxiety score was 39.0 (SD=13.6, range: [20-80]) with 30.5% of patients having anxiety symptoms. In the multivariate analysis we found that anxiety level was significantly increased for younger patients (OR=1.69, 95%IC [1.01-2.82]), female (OR=1.65, 95%IC [1.05-2.59]), patients with a high FCR score (OR=4.90, 95%IC [2.84-8.44]), patients unsatisfied with the current management of their cancer (OR=2.4, 95%IC [1.58-3.66]) and patients afraid of coming to hospital for fear of COVID (OR=2.10, 95%IC [1.32-3.35]). Protective factors against anxiety were staying busy during the lockdown period (OR=0.46, 95%IC [0.300.72]) and seeing the positive aspects of lockdown (OR=0.43, 95%IC [0.28-0.66]).

### Conclusions:

These results contribute to a better understanding of the psychological consequences of COVID-19 pandemic in the context of cancer and highlight the need to better support patients at high risk of developing high anxiety levels. Conditions of lockdown are important to contain anxiety among cancer patients.

## Knowledge and attitude of cancer patients towards COVID-19 pandemic: A study from Pakistan

### Background:

Pandemic spread, rapid transmissibility and currently incurable status has made COVID-19 a major concern of today. Old age and weak immunity make cancer patients highly susceptible to get infected.

### Methods:

A questionnaire-based study was conducted to determine knowledge of cancer patients about COVID-19 and resulting response in terms of preventive measures, delays in scheduled cancer management and impact of delay on cancer. Data was analyzed using SPSS version.23. Descriptive variables were reported as means and frequencies. Intergroup analysis was done using Chi square test with  $p < 0.05$  taken as significant.

### Results:

Of 269 enrolled patients, the majority had advanced/metastatic disease (82.4%) and were being treated on an outpatient basis (71.6%). Almost all (99.6%) were aware of COVID, electronic/print being the most common source of information (62.7%). Though having different views, 81.5% took it as a natural calamity. 71.3% considered themselves among the high-risk population. During first and second wave, 22.4% had delayed their investigations while treatment interruptions were seen in 34.7% patients, with average duration of delay being  $55 \pm 27$  days and traveling difficulties due to lockdown commonest reason of delay (54.8%). During this period 62.4% either noted worsening of symptoms or new symptoms. Despite all the chaos, 89.9% selected for treatment continuation if provided with a chance and appropriate facilities. Correlation of delay in therapy with high level of education ( $p=0.013$ ) and perception about COVID-19 as a natural calamity ( $p=0.041$ ) was found to be statistically significant. receiving an oral treatment whereas only 33.5% would agree if the treatment was endovenous. In general, younger patients (<50 years old) feel more comfortable with virtual visits than older ones (>70 y) (77.4% vs 62%,  $p=0.07$ ). Only 20% of patients older than 50 believe that they can handle new technologies as opposed to 58.5% of younger ones ( $p=0.001$ ). 60.4% of the younger patients would like to have different technological tools to contact their oncologist whereas most patients (47.6%) older than 70 prefer only phone calls ( $p=0.001$ ). Regardless of the type of visit (treatment or follow-up) patients felt comfortable with virtual attendance (58.7% and 65.6% respectively,  $p=0.2$ ).

**Table: 1643P Knowledge of cancer patients towards COVID-19**

	Number	%age
<b>Source of Information:</b>		
Electronic/print media	168	62.7
Social media	29	10.8
Relatives/friends	66	24.6
Health care worker	4	1.5
<b>View about COVID-19</b>		
Natural calamity	212	81.5
Plot by government	12	4.6
Man-made virus	17	6.5
It has no existence	16	6.2
<b>Is it a threat to life?</b>		
Major threat	123	45.9
Mild threat	86	32.1
No threat at all	20	7.5
<b>Mode of transmission</b>		
Via droplets	153	57.1
Air borne transmission	21	7.8
Person to person	68	25.4
Via contaminated food	12	4.5
<b>COVID case in friends/relatives</b>		
Yes	69	25.7
No	200	74.3
<b>Death due to COVID in friends/family</b>		
Yes	16	6
No	253	94.05

**Conclusions:**

As a whole, patients surveyed believed that telehealth could have a role following the COVID-19 pandemic. However, telemedicine is not applicable in all cases. Visits to older patients, to inform about radiological results and to patients receiving treatment should be assessed case by case.



## Improve the conditions of lockdown may decrease anxiety among cancer patients during the COVID-19 pandemic

### Background:

The COVID-19 pandemic is a highly traumatic event that may lead to a greater risk of developing psychological disorders, especially in cancer patients who are more likely to be infected with the virus and to develop complications. The objective of this study was to measure anxiety levels among cancer patient during COVID-19 pandemic and the associated factors including patients' conditions of lockdown.

### Methods:

A cross-sectional study was conducted among adult cancer patients (hematological and solid tumors) receiving outpatient treatment or during follow-up in a French Comprehensive Cancer Centre. A postal self-administered questionnaire was sent to 4000 patients in June 2020, including Anxiety (Stait Trait), Fear of a cancer recurrence (FCR) as well as questions relative to socio-demographics, management of cancer care during the pandemic and the conditions of lockdown.

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Death due to COVID in friends/family		
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No	253	94.05

**Conclusions:**

Patient's perspective is an important factor in management of a disease especially under unusual circumstances like COVID-19. It should be taken into account to help in making efficient management planning in future.



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## What is the attitude to new vaccines against COVID-19 in cancer patients?

### Background:

Since January 2021 new vaccines against COVID-19 have been available in Italy. After the first step reserved for medical staff other categories have been involved in vaccination. Now we are going to vaccinate cancer patients in our Oncologic Department. Vaccine efficacy has been already proved and frail patients are considered at high risk for COVID-19 mortality, but are patients inclined to vaccination? Are they afraid? We proposed our patients a survey to understand their stance on vaccination and whether they would accept it.

### Methods:

From 3rd to 30th March, 2021, we submitted a survey to consecutive cancer patients in chemotherapy or immunotherapy for metastatic or neo/adjuvant treatment in order to know their attitude towards anti-COVID-19 vaccine.

### Results:

We have collected 213 answers to the survey. Many solid cancers were represented. The mean age was 64 years. 46% were male, 54% female. 9.8% of patients had a COVID-19 infection, 62% of them being symptomatic. Half of the participants took the anti-influenza vaccine during the last vaccination campaign, compared with 47% that vaccinate regularly every year. Most of the patients (90%) had drawn information about vaccines from the media, although only 20% consider these clear and exhaustive. 182 pts (85%) were ready to be vaccinated. 23 pts refused vaccine. On 15th April AIFA announced the suspension of AstraZeneca vaccine because of a suspected correlation between it and some deaths. We noted an increase of vaccination refusal after this event: 15% vs the previous 6%.

### Conclusions:

Adherence to anti-COVID-19 vaccine is high in cancer patients, higher than to anti-influenza vaccine. It could be related to a high perception of risk and fear that cancer care might be interrupted. The media had probably a significant contribution on that adherence as well as on the so called “vaccine hesitancy”.

## Group psychotherapy in young female cancer patients during COVID-19 pandemic

### Background:

Cancer patients are particularly vulnerable to the deleterious consequences of lockdown and social distancing. The psychosocial effects of the COVID-19 pandemic on this group are still unknown. Young female cancer patients need extra support in this unique situation. We want to explore if their quality of life could be affected by online group psychotherapy during the Covid-19 pandemic.

### Methods:

An online survey, EORTC QLQ-C30 was administered to a cohort of young gynecologic cancer patients. The questionnaire also incorporated questions about their specific diagnoses and current treatment. Inclusion criteria included female patients aged 18-45 who were diagnosed with cancer during the last 5 years. We asked selected patients to fill the survey twice, before and after group psychotherapy sessions. Online group psychotherapy was conducted for 3 consecutive months, three times per week, using the interactive ZOOM platform.

### Results:

Total of 25 patients aged 18-45 were included in the study, 17 patients were breast and 8 were cervical cancer patients. 52% were receiving hormonal therapy, remaining patients were receiving chemotherapy, radiation therapy targeted treatment, or was on follow-up. The scores of physical (82 vs 79.5) role (47.5 vs 51.6) emotional (73.8 vs 80) cognitive (47.5 vs 51.6) social functioning (47.5 vs 51.6) were different between pre and post psychotherapy sessions. In breast cancer group pre and post group psychotherapy results were significantly different with PF - $p=0.0035$ , RF -  $p=0.0035$ , EF -  $p=0.0073$ , CF -  $p=0.0035$ , SF  $p=0.0035$  symptom scales/items  $p=0.0035$ . In cervical cancer group pre and post group psychotherapy results were not significantly different; PF - $p=0.4435$ , RF -  $p=0.3394$ , EF -  $p=0.4435$ , CF  $p=0.3394$ , SF -  $p=0.3394$  symptom scales/items -  $p=0.4435$ .

### Conclusions:

Our results show that young breast cancer patients' QoL can be positively affected by online group psychotherapy, but outcomes were not the same in the cervical cancer group. More research and larger sample size are needed for a better interpretation of results.

## Efficacy of SARS-CoV-2 vaccination in cancer patients during treatment: A prospective observational study (ANTICOV trial)

### Background:

Cancer patients (pts) have higher risk of serious COVID-19 symptoms, morbidity and mortality than general population. SARS-CoV-2 vaccine trials excluded patients with metastatic cancer or undergoing immunosuppressive therapies; therefore, the effectiveness of vaccines is unknown in this population. Hence, there is an urgent need to understand the correlation between cancer type, its treatment and vaccine efficacy.

### Trial design:

**Methods:** This is a prospective study conducted by the Oncology Unit of Cremona (Cr) Hospital, enrolling pts from Oncology, Hematology, Radiotherapy (RT) and Palliative Care divisions. The trial aims to evaluate effectiveness of mRNA vaccines [BNT162b2 (Pfizer) and mRNA-1273 (Moderna)], incidence of symptomatic COVID-19 infection, antibodies (Abs) response and onset of adverse events (AEs) in a consecutive population of 300 cancer pts, undergoing antineoplastic therapies, starting from March 2021. A vaccination point was set up by Cr Hospital, dedicated to cancer pts treated with chemotherapy (CT), TKIs, RT, hormones. Only pts in follow-up or treated with adjuvant hormone are excluded. CT was suspended at least 5 days before and 3 days after vaccination; targeted therapy, immunotherapy and RT are not interrupted.

**Primary endpoint:** Number of symptomatic pts affected by COVID-19, diagnosed 7-60 days after the 2<sup>nd</sup> dose of vaccines. The infection is defined according to the FDA criteria combined with a positive nasopharyngeal swab. Secondary endpoints: Abs variation at different timepoints compared to baseline; vaccine-related adverse events; duration of abs, up to 12 months after 2<sup>nd</sup> dose; correlation between effectiveness of vaccines and antineoplastic treatments, tumor burden, PS ECOG. **Statistical analysis:** The primary objective will be tested by non-inferiority one-sample proportion test, compared with the value of 95% observed in the vaccine registration trials. The hypothesis of vaccine inferiority in the trial population is rejected if a rate of protection conferred by the vaccine is observed in 89% of the sample size. **Results:** Preliminary results will be available in July 2021.

### Clinical trial identification:

NCT04878796.