

#### 4CPS-389 GOVERNANCE OF CLINICAL TRIALS BETWEEN HEALTH NEEDS, ACCESS TO CARE, INNOVATION AND SUSTAINABILITY IN THE COVID-19 PANDEMIC ERA

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**Background and importance** In the constantly evolving new regulations for clinical trials, the hospital pharmacist is more and more involved in clinical trials.<sup>1</sup> In the current context of a deep economic crisis, clinical trials represent an important aspect of healthcare, especially for access to the latest generation therapies.

**Aim and objectives** The aims of the study were to provide an overview of the governance of clinical trials and to estimate the cost savings generated by unused resources, attributable to the provision of drugs used in phase IV trials and for 'compassionate use'.

**Material and methods** A retrospective study was conducted on clinical trials started between 1 July 2016 and 30 June 2020 in hospital settings. Characteristics analysed were phase and type of study, drug (according to anatomical chemical therapeutic classification (ATC)), method of storage and route of administration. The first arrival of supplies was considered as the index date. The savings were calculated by monetising supplies for phase IV and 'compassionate use'. Costs estimated considered the ex-factory cost (excluding VAT), net of temporary legal reductions, where applicable.

**Results** During the study period, 129 clinical trials were evaluated (phase I (1.2%), phase II (16.7%) phase III (54.9%), phase IV (10.9%) and 'compassionate use' (16.3%)): 44.44% were international multicentre trials and 92.6% were randomised blinded trials (double blind=22.4%). 188 different drugs were involved (70.5% stored at 2–8°C); solid oral formulations (11.78%). Phase IV trials involved eight drugs (ATC: A10A; B01A; J05A; L01C; L01X; N02C; N07X); 'compassionate use' involved 12 drugs (ATC: L01XC=93%; L01XE=5%; other=2%). The overall savings was 1 046 341.79€ (compassionate use=85.61%). In the first semester of 2020, savings were 309 736.00€. In particular, savings were related to use of ATC:L01X (93.81%) and ATC:N02C (6.19%). In the first semester of 2020, with the pandemic in progress, 2.48% of trials in the digestive pathophysiology area (29/129) saw at least one referral to the patient's home.

**Conclusion and relevance** Clinical research generates not only economic value for the health system, but also clinical benefits related to the availability of innovative therapies. This study showed that the care system for clinical trials worked even during an unprecedented health emergency. Thanks to the collaboration of all the health professionals involved, no 'lockdown effect' resulted in detriment to the patients enrolled in clinical trials.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

1. De Fina, et al. *IJMSBR* 2020;07:01–08.

**Conflict of interest** No conflict of interest

#### 4CPS-390 DISPENSING OF ANTICANCER INVESTIGATIONAL DRUGS DURING LOCKDOWN FOR THE SARS-COV-2 PANDEMIC: EXPERIENCE IN AN ONCOLOGICAL CENTRE

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**Background and importance** Patients enrolled in oncology clinical trials are frequently at risk and often live far from the oncology centre. Starting from 21 February 2020, during the lockdown caused by SARS-CoV-2, oncological patients were allowed to travel for health reasons, but their clinical conditions, organisational difficulties and the risk of COVID-19 suggested adopting prudential solutions.

**Aim and objectives** The AIFA and EMA authorised centres to adopt exceptional measures, promoting the dispensation of more cycles and the delivery of therapies to patients at home. This work aims to verify the impact of these solutions in an oncological centre.

**Material and methods** The number of experimental drugs dispensed from January to 3 June were analysed using an Excel database. Dispensations were divided in three periods to evaluate the trend: daily intravenous (IV) and oral (PO) dispensations before 21 February 2020 (P1), between 22 February and 3 March (P2) and from 19 March (start of shipments) until the end of lockdown (P3), analysing the main issues noticed and the percentage of therapies shipped.

**Results** Therapies in the entire period were 4154; mean daily dispensations in P1 was 39.46 (16.03 PO, 23.43 IV), in P2 40.06 (16.12 PO, 23.94 IV) and in P3 38.71 (14.71 PO, 24.00 IV). During P3, 109 shipments of PO medications were delivered, representing 13.72% of the total therapies. The slight increase in dispensations in P2 was due to the anticipation of visits due to the fear of an imminent closure; the subsequent decrease was due to a higher drug quantity dispensed/shipped per single dispensation. PO therapies decreased slightly (–8.23%) compared with the pre-lockdown period, while IV therapies remained steady over the three periods. Seven transport issues occurred, leading to therapeutic discontinuity in 4 of 109 cases. No therapeutic error was detected during the period analysed, probably due to telephone feedback on the arrival of the drugs.

**Conclusion and relevance** Investigational drug shipment was effective in lowering the impact of the pandemic on the therapeutic continuity, without however becoming the most frequently used model. Logistical difficulties produced four cases of therapeutic discontinuity and the telephone feedback mechanism limited the risk of errors in therapy.

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