

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 a constantly evolving clinical trial regulation, the Hospital Pharmacist is more and more involved in clinical trials [1]. In the current context of deep economic crisis, clinical trials represent an important aspect of health care, especially for access to the latest generation therapies.

AIM AND OBJECTIVES

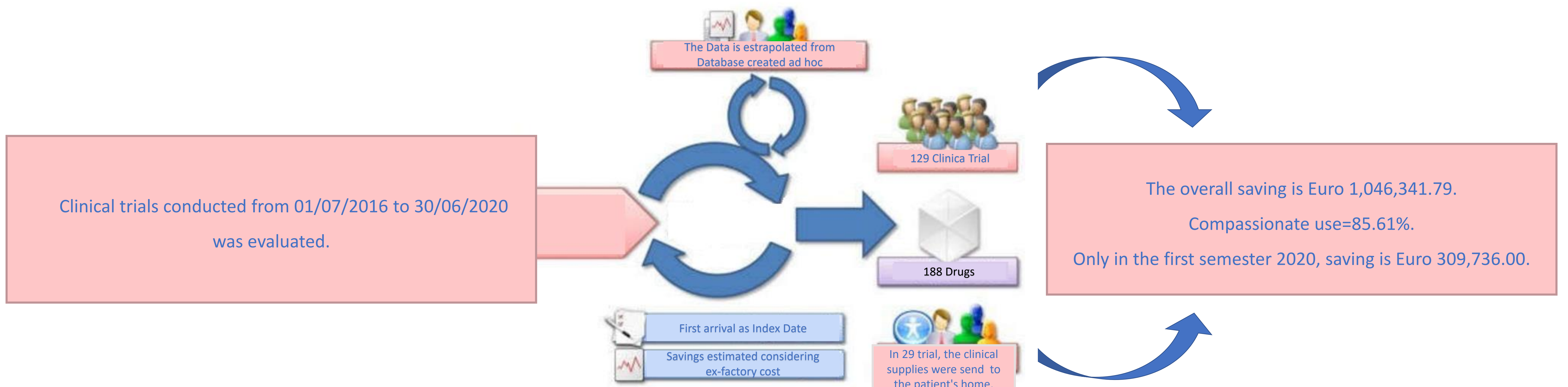
Aims of the study were to provide an overview of the clinical trials governance and to estimate the cost savings generated by unused resources, attributable to the provision of drugs used in Phase IV trial and to "compassionate use".

MATERIAL AND METHODS

A retrospective study was conducted on clinical trials started from 01/07/2016 to 30/06/2020 in hospital setting.

Characteristics analysed phase and type of study, drug (according to anatomical chemical-therapeutic classification (ATC)), method of storage, route of administration. The first arrival of supplies was considered as index date.

The savings were calculated by monetizing supplies for Phase IV and "compassionate use". Costs estimated considering the ex-factory cost (excluding VAT), net of temporary legal reductions, where applicable.



RESULTS

In the study period were evaluated 129 clinical trials (Phase I (1.2%), Phase II (16.7%) Phase III (54.9%) Phase IV (10.9%) and "Compassionate use" (16.3%)): 44.44% international multicenter trial, 92.6% randomized blinded (double-blind=22.4%). 188 different drugs involved (70.5% stored at 2-8°C); solid oral formulation (11.78%). Phase IV trials involved 8 drugs (ATC: A10A; B01A; J05A; L01C; L01X; N02C; N07X); "compassionate use" involved 12 drugs (ATC:L01XC=93%; L01XE=5%; other=2%).

The overall saving is Euro 1,046,341.79 (compassionate use=85.61%). In the first semester 2020, saving is Euro 309736.00. In particular, saving is related to use of ATC:L01X(93.81%) and ATC:N02C(6.19%).

In the first semester 2020, following 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.

CONCLUSIONS

Clinical research generates not only an economic value for the Health System, but also clinical benefits related to the availability of innovative therapies. This study shows that the care system of clinical trials has worked even during an unprecedented health emergency. Thanks to the collaboration of all the health professionals involved, no "lockdown effect" fortunately resulted in a detriment to the patients enrolled in clinical trials.