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SCIENCE MEDICINES HEALTH

Clinical Trials and COVID-19

PCWP and HCPWP Joint Meeting 2 June 2020

Presented by Fergus Sweeney 2 June 2020

International coordination needed to encourage conduct of large, decision-relevant COVID-19 clinical trials

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Press release 15/05/2020

Regulators are highlighting the need for a comprehensive international coordination mechanism to allow the conduct of adequately powered, randomised controlled trials, which can generate sound evidence on the effects of therapeutics or vaccines against COVID-19. This follows a call made by EMA's Human Medicines Committee (CHMP) for the research community to pool resources into large, well-designed, multi-arm clinical trials to determine which investigational or repurposed medicines would be safe and effective for the treatment or prevention of COVID-19.

Although the scientific community has responded to the COVID-19 challenge in an unprecedented manner, there are concerns about the growing number of COVID-19 stand-alone clinical trials with a small number of participants and observational studies, which might not generate the data required for regulatory decision-making.

Clinical Pharmacology & Therapeutics

REVIEW | Open Access

Clinical trials for Covid-19: can we better use the short window of opportunity?

Hans-Georg Eichler, Marco Cavaleri, Harald Enzmann, Francesca Scotti, Bruno Sepodes, Fergus Sweeney, Spiros Vamvakas, Guido Rasi

First published:14 May 2020 | https://doi.org/10.1002/cpt.1891

GUIDANCE ON THE MANAGEMENT OF CLINICAL TRIALS DURING THE COVID-19 (CORONAVIRUS) PANDEMIC

Protection of clinical trial participants.

Enable continuation of their treatment where possible and in particular for important therapies.

Mitigating burden on clinical site staff and facilities.

Enable management of clinical trials whilst maintain social distancing.

Prioritising clinical trials for treatment of COVID-19, and or treatment of other life-threatening or seriously debilitating conditions.

Ensure reliability of trial results, enable trials to continue to the extent possible

Guidance on the management of clinical trials during COVID-19

The safety of the trial participants is of primary importance, and risks of involvement in the trial, in particular with added challenges due to COVID-19, should be weighed against anticipated benefit for the trial participants and society

- Initiating new trials
- Changes to ongoing trials
- Safety reporting
- Risk assessment
- Communication with authorities
- Agreement between sponsors, sites and participants
- Changes to informed consent
- Changes in distribution of IMP
- Changes in distribution of diagnostics and devices
- Changes to monitoring
- Changes to auditing
- Protocol deviations
- Reimbursement of exceptional expenses
- Initiation of new trials aiming to test new treatments for COVID-19

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25 March 2020
EMA/158330/2020
Committee for Human Medicinal Products (CHMP)

Points to consider on implications of Coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials

Actions for sponsors of ongoing clinical trials affected by the pandemic to help ensure the integrity of their studies and interpretation of study results while safeguarding the safety of trial participants as a first priority. Complements the guidance on how sponsors should adjust the management of clinical trials .

EMA's Biostatistics Working Party encourages clinical trial sponsors to seek scientific advice on these matters.

In line with this guidance, EMA will be flexible and pragmatic during the assessment of affected clinical trial data submitted to the Agency as part of marketing authorisation applications.

Trials uploaded and approved in EudraCT – as of 26/5/2020

303 trials were uploaded in EudraCT, of which:

- 193 Approved by National Competent Authorities and Ethics Committees
- 101 Currently under assessment
- 9 Withdrawn/refused by NCA

Among the approved ones:

- 2 trials were already ongoing before 2020, and now include COVID-19 patients
- 34 were approved in March, 114 in April, 43 in May

Sponsors types and number of member states involved

Considering all trials uploaded, and excluding the 9 trials withdrawn/refused:

- 238 trials are from non commercial sponsors
- 56 trials are from commercial sponsors

- 257 trials are conducted in only 1 member state (33 commercial, 224 non commercial)
- 13 trials in 2 member states (8 non commercial, 5 commercial)
- 14 trials in 3 to 5 member states (all commercial)
- 9 trials in more than 5 member states (3 non commercial, 6 commercial)

Categories of therapies

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Number of trials per therapeutic category:

- 63 Antimalarial (of those, 25 in combination with antibiotic, antivirals or anti arthritis)
- 41 Monoclonal antibodies (mainly Tocilizumab)
- 18 Cardiovascular (of those, 6 on Heparin/LMWH)
- 17 Combination of several therapies (antivirals, antibiotics, antimalarial, anti-arthritis, anti-inflammatory medicines)
- 17 Anti-inflammatory medicines
- 14 Antivirals (mainly Remdesivir)
- 11 Vaccines
- 9 Antibiotic therapy (not in combination)
- 5 Plasma therapy
- 100 Other treatments (e.g.: camostat, nitric oxide, interferon, protein kinase inhibitors, recombinant proteins, stem cells, calcifediol, anti-asthmatic medicines, vitamin D)

European Commission website on corona response (research and innovation):

https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/coronavirus-research-and-innovation_en

14 May 2020

Coronavirus: Commission launches one-stop shop for coronavirus research and innovation funding

Mariya Gabriel, Commissioner for Innovation, Research, Culture, Education and Youth, said:

"During this challenging period, it is important to stand united and coordinate our response to the coronavirus pandemic. The new ERA corona platform, a one-stop shop for coronavirus related information on research and innovation funding, marks an important step in strengthening this coordination and testifies to what we can achieve when we work together across Europe."

Any questions?

Further information

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