Ethics support and lessons learnt from COVID-19
Perspective EC Research UZ / KU Leuven

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Organisation in UZ Leuven: unique in Belgium

Ethics Committee Research UZ/KU Leuven

EC Care

EC Research

Ethical questions and advices
  • EC Care UZ/KU Leuven
  • Chair: Prof. Martin Hiele

Clinical Research
  • EC Research UZ/KU Leuven
  • Coordinator: Ruth Storme
  • Chair: Prof. Minne Casteels
Scope of the Belgian Law 7/5/2004

Any experiment, study or research carried out on the human person with a view to developing knowledge specific to the health care professions.

No experiment can be started before a positive advice from EC is obtained.
Studies evaluated by EC Research

Initial studies

- Data for years 2006 to 2019
- Initial studies evaluated by EC Research
Modifications evaluated by EC Research

What this curve does not represent is the large increase in complexity (and evaluation difficulty): adaptive / flexible design, basket trials, seamless design....
Statistics

• 82 new COVID-related initial studies submitted to EC since 02 March 2020 (up to now)

• Already approved studies by EC Research:
  • 9 retrospective studies
  • 30 observational studies (including registries and surveys)
  • 7 studies on residual human body material
  • 11 interventional studies

• More than 400 COVID-related modifications

• As of 16 March, the meetings of EC Research continued at the same frequency (3 per month) via Skype for business/zoom.
“Urgent safety measures taken in the context of coronavirus, this may be taken without prior notification to FAMHP and the EC. The sponsor must inform as soon as possible the FAMHP and the EC of the measures taken and the plan for further action and a substantial amendment must be submitted afterwards.”

“A protocol deviation (control of visits,...) should be considered as an USM if the change has to be directly implemented for the patient’s safety and if it is considered as a substantial amendment”
Modifications: examples

• Recruitment / studie on hold
  • A temporary halt (recruitment/trial; globally/locally) should be submitted to the FAMHP and to the EC’s of the participating sites within 15 days of the decision. A temporary halt is not a substantial amendment. A notification is sufficient.

• Face-to-face interviews replaced by tele-visits

• Shipping study medication (by courier) (in Belgium: not via the commercial sponsor)

• Home nursing

• Restart of study put on hold: **substantial amendment** (= approval) necessary for restart

• When only recruitment has been put on hold, only **notification** is required.
Restart

We check a number of elements (in consultation with the groups) to make researchers more aware/responsible about the impact of the current problems. When we get a request for restart, we reply with questions below:

• Will it be possible to respect the federal and institutional rules, e.g. social distancing, protective measures..?
  
  Yes □  No □  NA □

• Is additional protective material needed in order to execute the study? Please specify.
  
  Yes □  No □  NA □

• How many additional persons (researchers/observers) are envisaged in the interaction with the participants?

• In which room/building will the study take place?

• If the study takes place in another institution, has this institution approved the re-start in writing?
  
  Yes □  No □  NA □

• Is there a need for modifying the ICF, and if so, please provide a changed version with track changes.
  
  Yes □  No □  NA □

• Is there a need for modifying the protocol, and if so, please provide a changed version with track changes.
  
  Yes □  No □
Support EC for (academic) COVID-studies

• Informed consent forms
  • Writing ICF’s of interventional clinical studies with medicines
  • Creating a Standard Operating Procedure for obtaining informed consent in COVID-units

• Flexible way of submitting studies

• Very fast registration and administration
  • Federal Agency for Medicines and Health Products (FAMHP) commits to validate and review in four working days, as will do the evaluating EC

• Up to date website

• Contribute to set out national guidelines

• We should guarantee that the same rules are applied in the evaluation of studies, even when pressure is very high
Challenges

• EC should apply the same high quality framework in these exceptional circumstances but so should researchers

• Time pressure

• Law 07/05/2004 in international studies

• Ensure continuity of non-COVID studies

“We are in a pandemic situation, not in a panic situation”
Thank you

Questions?

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