Azienda Ospedaliera
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How to close the gap?

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Clinical research and clinical trials: main critical issues from the researchers' point of view

Time for trial approval/start:

-Lag time from submission to approval at the EC

-Lag time from EC approval to contract definition and signing

-HSP 2012/2013 TRIALS: 2-6 months for EC approval, 2 more months for final contract signature and trial start (total of 8 mo.s!)

-HSP 2014 TRIALS (Centralized EC): 4-6 months for EC approval, 1 to +3 months for final contract signature and trial start (total of +9 mo.s!)

-Often the changes required relate to several sentences in the patient information sheet, with no impact on patient's defense.

-NO CHANCES TO COMPETE WITH OTHER COUNTRIES

-COMPETITIVE ENROLMENT THAT OFTEN CLOSES IN THE MEANWHILE

-NO IMPROVEMENT BUT WORSENING WITH CENTRALIZED EC

Clinical research and clinical trials: main critical issues from the researcher point of view

Funding and human resourses:

- No dedicated personnel (research nurses, technicians,on site datamonitors)
  - Temporary, less qualified personnel paid by the center
- No dedicated sites (for blood collection, visiting, explaining study rules etc)
- No investment (45% of profits go to the hospital with no return to the clinical unit)
- No culture on the importance of clinical trials among personnel

Clinical research and clinical trials: main critical issues from the researcher point of view

Possible implementation:

-Cultural improvement (courses, meetings)

-EC implementation and simplification

-Common contract template

-Dedicated personnel (research nurses, technicians, datamonitors) shared with researchers from different areas

-Dedicated sites within the hospital

-Wide information and recruitment of the patients

-Implementation of independent investigators' driven clinical research