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# ICH GCP Stakeholder workshop June 3, 2020

European Organisation for Research and Treatment of Cancer

# High level remarks

- Clinical research is a component of medical and health research intended to produce knowledge valuable for understanding human disease, preventing and treating illness, and promoting health
  - Having GCP limited to regulatory /drug trials is a reductive approach.
- From (early) drug development into applied clinical trials
  - Re-engineer a holistic continuum of research from innovation into therapeutic strategy

**2-TIERED RESEARCH AS IT HAS BEEN ESTABLISHED NEEDS TO BE REVISITED**

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# High level remarks

- Science and methodology evolve very fast,
- Therefore ICH is to become a guideline which is :
  - Agile
  - Proportionate
  - Risk based
  - Evolutive
- Ultimate goal is adaptation to:
  - Changing environments,
  - New types of trials collecting multidimensional data
  - Reaching all patients

**ICH SHOULD CONSIDER TAKING THE CHALLENGES FROM THE PATIENT ANGLE, NOT FROM THE TRIAL CONTENT ANGLE**

In a transformative  society, we, actors in the field should “unlearn” what we have done, so that we can learn how to do things differently and create completely new concepts

Reach a process to perform efficiently widely applicable clinical research in the best interest of therapeutic progress while preserving patient interests and rights

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# Areas of attention

- **Place all stakeholders around the table at ICH level**
  - Academia
  - Patients
- **Focus resources on raising quality, not documentation**
- **Elevate the process of PIS/IC:**
  - Opt out; one time-consent; short focused document
  - Flexibility for multifaceted protocols
  - Focus on what is new and deserves attention, not what is known
  - Privilege qualitative over quantitative and variable information
- **Shape up amendment procedures:**
  - Group changes over time when possible
  - Live process of amendments which impact on protocol and patient

# Areas of attention

- **Digital transformation to serve the process**
  - Required document upload
  - Remote and proportionate monitoring
  - QA programs: upload of imaging
- **Protocol recommendation is not data collection**
  - Limit data collection to what is needed by SAP
- **Not all tested agents are created equal**
  - Agents part of the standard armamentarium, not registered based on specific sequence: de-escalation, sequence etc…
  - De-regulate provisions related to tested agents
- **Obsolete definitions for site and principal investigator**
  - Remote trial, histology agnostic trials etc…adapt for multiple PIs reaching to patients where they are.

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# The ultimate question……

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## Clinical research in Europe: Who do we do all that for?

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ABSTRACT

Independent applied clinical research addresses questions which are centered on optimization of treatments and patient management. It often finds itself confronted to policies and regulations implemented more specifically with pharmaceutical research and drug development in mind but which in practice apply throughout all clinical research programs. We report herein a specific case illustrating such challenges. We question how far legal constraints overshoot their initial objectives, leading to opposite effects for which they were set up. In an era where independent evaluation of cancer treatments is becoming so critical due to complexity, duplication and costs, comprehensive and pragmatic reform of our frameworks appears critical.

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# Thank you