EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on the objectives, progress and timelines of the revision of the ICH E6 (GCP) guideline

PCWP/HCPWP joint meeting

Presented by Milton Bonelli and Camelia Mihaescu on 1st June 2022

Overview of the revision of the ICH E6 (GCP) guideline

- E6(R3) EWG launched in Sep 19
- Concept paper and business plan agreed in Nov 19 at the ICH meeting in Singapore

- **Complete revision and reorganisation of the ICH E6(R2) Guideline:**
  - 12 Key principles of GCP
  - Annex 1: traditional interventional trials, reflecting the content of E6(R2) with updates where needed
  - Annex 2: designs such as pragmatic clinical trials, decentralized clinical trials and trials that incorporate real world data sources (e.g., electronic health records, hospital discharge summaries, claims data, patient/disease registries)

Overview of the revision of the ICH E6 (GCP) guideline (cont.)

- The principles are intended to apply across clinical trial types and settings and to remain relevant as technological and methodological advances occur;
- They can be complied with using **differing approaches** and should be interpreted to fit the intended purpose of a particular clinical trial;
- ICH E6 should be read **in conjunction with other ICH guidelines** relevant to the design and conduct of clinical trials.

Key considerations

- The guideline continues to apply to **interventional clinical trials** only;
- Re-write of the overarching principles including key elements of human subject protection and data quality/integrity of trial results;
- Link to the '**Quality by Design'** approach of ICH E8(R1);
- Consolidation of the '**Risk-based Quality Management'** approach of ICH E6(R2);
- Emphasis on **proportionality instead of unnecessary complexity** of trial-related procedures;
- Consideration of **current developments** in trial design, trial conduct and data sources to future-proof the guideline as much as possible;
- **Stakeholder engagement**

Current status of the guideline revision

- **Draft Principles** published on 19 April 2021; will undergo public consultation together with Annex-1.

- **Annex 1 development – revised sections:**
  - Section 1: Glossary (Updated Terminology – all sections)
  - Section 3: IRB/IEC
  - Section 4: Investigator Responsibilities
  - Section 5: Sponsor Responsibilities
  - Section 6: Protocol
  - Section 7: Investigator Brochure
  - **New section** on **Data Governance** describing standards and requirement for computerised systems and data throughout the data life cycle.

Expected future key milestones

Expected completion date	Deliverable
June 2022	Circulate a full draft of Annex 1 to the EWG for comments by the first half of September 2022
July-August 2022	Update Concept Paper for Annex 2
September-November 2022	Step 1 Sign-off of Technical Document (Principles and Annex 1)
October-November 2022	Step 2a/2b Endorsement of Technical Document (Principles and Annex 1)
November-December 2022	Step 3 Begin Public Consultation (Principles and Annex 1)
March 2023	Begin draft of Annex 2
May 2023	Step 3 End of Public Consultation (Principles and Annex 1)

Thank you!

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