Global Medical Technology Alliance

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New Work Item Proposal

Harmonization of Good Clinical Practices

IMDRF

September 16, 2014

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Background for ISO 14155 *

- International standard
- Good clinical practice for design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes.
- General requirements
  - protect rights, safety and well-being of human subjects
  - ensure scientific conduct of clinical investigation/credibility of results
  - define responsibilities of sponsor and principal investigator, and assist sponsors, investigators, ethics committees

*Does not apply to IVDs

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Specific areas for harmonized approach

- Definition of a "qualified" Independent Ethics Committee (IEC) or Institutional Review Board (IRB)
- Audits – potential MOUs among regulators
- Need common Medical Device Clinical Trial Classification scheme (e.g., Significant Risk/Non-Significant Risk)
- Agreement that approval should not be denied if one or more studies were not GCP-compliant unless data from the study(ies) essential for determination of safety & effectiveness/performance
- Ensure use of de-identified specimens critical to IVD development as IVDs have unique considerations for good study practices guidance)
- Any harmonized agreement should be prospective and should allow adequate transition timeframe.

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Purpose for GCP harmonization

- Ensure efficient, appropriate conduct of trials
- Ensure regulator acceptance of clinical trial data conducted according to ISO 14155 independent of where trial was conducted
- Reduce costs of clinical trials
- Eliminate need to repeat trials
- Fewer studies leads to more ethical conduct overall (i.e., need for less experimentation/fewer human subjects)
- Allow faster introduction of safe and beneficial technologies for patients

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New Working Group

- Industry experts on working group essential
- Other clinical experts as needed (e.g., ISO 14155 and academic representatives)
- 18 months to complete work