FDA Draft Guidance on Update to ICH GCP E6(R2)

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In September, FDA proposed adopting an updated ICH GCP for international clinical trials. The guidance is entitled, "E6(R2) Good Clinical Practice."

This revised ICH E6 GCP comes from the working group on the International Conference on Harmonisation (ICH). FDA explains that the ICH GCP guidance is intended to provide a unified standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions. The working group considered current good clinical practices of the EU, Japan, U.S., Australia, Canada, the Nordic countries, and the World Health Organization. R2 should be followed when generating clinical trial data for submission to regulatory authorities.

The draft guidance is in marked (essentially redlined) format and, when finalized, would integrate an addendum into the FDA E6 Good Clinical Practice: Consolidated Guidance . The latter has provided a uniform ICH standard since 1996 for acceptable clinical trial data.

Many revisions in this integrated addendum (draft guidance) focus on electronic data and computerized systems in clinical investigations, similar to what is found in FDA's September 2013 guidance on Electronic Source Data in Clinical Investigations. The draft guidance also addresses clinical monitoring.

If you have any questions or would like more information about these developing issues, please contact the following:

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