Research, Development, and Regulatory Roundtable

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

ROPES & GRAY

OUR VISION

To provide a periodic forum wherein academia, industry and regulators may openly discuss pre-competitive issues in drug and device development, regulatory oversight of clinical trials, and human subjects research.

OUR MISSION

To foster a broader understanding of the laws and regulations that influence therapeutic innovation, product approval, and the protection of human research subjects on the global stage.

Frequency and Conduct of Meetings

- Three half-day meetings per year
- Location rotates between Boston, Chicago, New York City, San Francisco, and Washington, DC
- Discussion topics are non-proprietary and pre-competitive
- Chatham House Rule: participation without attribution

Attendance and Sponsorship

- Meetings open to sponsoring institutions and selected guest speakers
- We welcome sponsors from industry, regulatory agencies, non-profits, academia, and law firms

July 2018

Application of the General Data Protection Regulation to Research: Legal, Practical, and Strategic Implications

- Boston, MA
- In light of the limited guidance available to date from EU authorities, attendees explored the impact of the EU GDPR on human subjects research. Panelists highlighted the challenges posed by the GDPR to clinical research, biobanking and data banking, and big data research.
- Outcome: Workgroup assembled to develop voluntary EU GDPR Code of Conduct for U.S. trial sites and research sponsors

Nov. 2018

Right to Try vs. Expanded Access: Practical, Legal, and Regulatory Considerations

- New York, NY
- Attendees considered the advantages and drawbacks of the two pathways by which patients may request access to pre-approval therapies. Participants explored the impact of each pathway on long-term drug development, the resources necessary for handling requests consistently and ethically, and the optimal contents of organizational policies.
- Outcome: The MRCT Center and Ropes & Gray LLP are developing a survey on frequency and outcomes of pre-approval requests, which will be administered to Sponsors, IRBs, and Academic Medical Centers. Aggregate results will be shared to increase awareness of pre-approval pathways.

Nov. 2018

Developing a Code of Conduct for the EU GDPR: Mapping the Commitments of U.S. Trial Sites and Research Sponsors

- New York, NY
- Building on previous efforts from the July 2018 meeting, attendees discussed
    - Requirements for Codes of Conduct
    - Potential benefits of Code of Conduct for U.S.-based researchers
    - Ongoing efforts to develop Codes of Conduct
    - Anticipated timeline for issuance of guidance on EU GDPR Code of Conduct
- Outcome: The MRCT Center and Ropes & Gray LLP are compiling case vignettes highlighting the challenges of international data transfer for submission to the European Data Commission

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