ADDRESSING INDUSTRY PAIN POINTS

BACKGROUND

ACRO directly engages regulators, customers and other stakeholders to facilitate our collective input on issues and initiatives such as the 21st Century Cures Act and the EU Clinical Trial Regulation. ACRO's Board of Directors established a committee to develop a proactive agenda focused on policy outcomes that would advance specific operational interests of ACRO members.

OBJECTIVE

Identify and prioritize industry "pain points" that affect members and that could be addressed via ACRO's primary audiences of regulators, customers and policymakers.

PROCESS

- Representatives from each member company worked through their respective organizations to identify industry issues and pain points.
- Committee consolidated input, proposed priority issues and desired outcomes to the ACRO Board of Directors at the 2018 Q1 meeting.
- ACRO's Board of Directors selected projects to focus on and charged the Committee and ACRO staff with making and progressing project plans for those priorities.

PAIN POINT	DESIRED STATE	STATUS / NEXT STEP
FDA's insufficient notice for routine BIMO inspections in the U.S. creates burdens and causes delays for both the CRO and FDA inspector	FDA provides reasonable notice (akin to that given in Europe) for these routine inspections and provides focus/scope so that CROs can assemble proper materials and staff ahead of the inspector's arrival	Member data collected, to be used in early-2019 meeting with FDA representatives
EMA/MHRA inspectors varying definitions of "contemporaneous" filing, expectations for drafts in the Trial Master File	Clear expectations from EMA/MHRA regarding TMF filing requirements for essential documents as per ICH E6, and clarity regarding draft vs. final essential documents	Awaiting final guidance and MHRA response in Q1 2019. Board guidance will determine priority and subsequent committee response
MHRA's GxP Data Integrity Guidance on Audit Trail Review, justification of data collection and second party verification are causing confusion or redundant activities that do not add to – and possibly detract from – ensuring data integrity	While guidance on this matter has been finalized, it would be beneficial to gain clarity on alternative processes and controls that may be deemed acceptable by the regulator	ACRO has presented a proposed Q&A document overing 3 key concerns in the Final Guidance. Publishing options are under consideration
ICH E6 (R2) Sec. 5.2.1-2: Ambiguity from sponsors on how to "ensure oversight of all trial-related duties," leading to redundant audits	Common expectations from sponsors and sponsor acceptance of CRO audits of vendors	ACRO's CRO Forum developing a member agreement as to what constitutes "adequate oversight." White paper draft in progress