Day 1

Tuesday, Dec. 1, 2020

10:00 AM **Welcome, Verification of Attendee Workshop Tools. Session Overview**

10:00 AM – 10:30 AM EST

- Review of connectivity and interactive tools
- Session agenda overview
- What to do in case of connectivity issues

10:30 AM **Clinical Data Integrity — Requirements and Realities**

10:30 AM - 11:30 AM EST

- Core regulatory requirements — regulatory health agencies
- Practical elements of data integrity characteristics (ALCOA+) — how this looks in the "real-world" of clinical development, trial conduct and post-trial analysis
- Overlooked guidance documents that can help define expectations (including what FDA and EMA inspect for and why)
- *Interactive Q&A on this section* — Attendees have the chance to ask questions and have them answered by the instructor

11:30 AM **Morning Break** *(offline)*

11:30 AM - 12:00 PM EST

12:00 PM **Suppliers and Data Integrity**
12:00 PM - 1:00 PM EST

- Accountability v. responsibility (the legal view)
- Data integrity chain-of-custody in the clinical space
- Digital data record keeping challenges for clinical data
- Typical clinical supplier red flags — cloud providers, IT data hosting, etc. — that FDA and other regulatory health agencies look for
- Dealing with critical suppliers who collect, handle and store clinical digital data (i.e., Medidata, et al) who are NOT regulated
- Qualifying record/archival storage vendors (e.g., Iron Mountain, et al)
- *Interactive Q&A on this section* — Attendees have the chance to ask questions and have them answered by the instructor

1:00 PM **Lunch** *(offline)*
1:00 PM - 2:00 PM EST

2:00 PM **Risk-Based Data Integrity and Operationalizing DI Controls**
2:00 PM - 3:00 PM EST

- Basics of computerized system assurance as a risk-based approach
- Monitoring data integrity controls with CROs and investigator sites
- Putting it all together from trial planning to pre-approval inspection (PAI) readiness to long-term data retention
- Documenting your data integrity controls — what, where, how, and why
- *Interactive Q&A on this section* — Attendees have the chance to ask questions and have them answered by the instructor

3:00 PM **Afternoon Break** *(offline)*
3:00 PM - 3:30 PM EST

3:30 PM **Open, Emerging Issues with Digital Data Integrity and Control**

3:30 PM - 4:00 PM EST

- Long-term archival especially for digital photos, videos and imagery
- Cloud-based technology and data reliability
- Wearables data and patient submitted digital data
- Impact on inspectional changes in the clinical arena

4:00 PM **Wrap Up and Review**

4:00 PM - 4:30 PM EST

4:30 PM **Adjournment of Day One**

Day 2

Thursday, Dec. 3, 2020

10:00 AM **Welcome, Verification of Attendee Workshop Tools. Session Overview**

10:00 AM – 10:30 AM EST

- Review of connectivity and interactive tools
- Session agenda overview
- What to do in case of connectivity issues

10:30 AM **GCP Data Integrity Enforcement**

10:30 AM – 11:00 AM EST

- Examples and statistics from regulatory agencies
- Recent updates to FDA's Pre-Approval Inspection methodology
- *Interactive Q&A on this section* — Attendees have the chance to ask questions and have them answered by the instructor

11:00 AM **Morning Break** *(offline)*

11:00 AM – 11:30 AM EST

11:30 AM **Clinical Digital Data Inspectional Tactics — Onsite v Remote**

11:30 AM – 12:30 PM EST

- Example regulatory agency inspection questions to prepare for — sponsor v. CRO v. clinical investigator
- Example regulatory agency tactics during clinical inspections — how the new inspection protocol program (NIPP) plays into finding data integrity issues at the sponsor, at clinical sites, and with the CRO
- *Interactive Q&A on this section* — Attendees have the chance to ask questions and have them answered by the instructor

12:30 PM **Lunch** *(offline)*
12:30 PM – 1:30 PM EST

1:30 PM **True and Certified Copies with Digital Records — Risks and Realities**
1:30 PM – 2:00 PM EST

- Basics of the true/certified copy and legal admissibility
- True copy requirements from submission guidances
- Putting together a true-copy scanning process for clinical trial usage
- *Interactive Q&A on this section* — Attendees have the chance to ask questions and have them answered by the instructor

2:00 PM **Afternoon Break** *(offline)*
2:00 PM – 2:30 PM EST

2:30 PM **Preparing for and Handling GCP Data Integrity Inspections** 2:30 PM – 3:30 PM EST

- Challenges to address with remote inspection handling
- Sponsor-specific activities — pre-submission vs. PAI handling
- CRO-specific — during trial conduct vs. PAI handling
- Clinical investigator site — sponsor and CRO preparation activities for a PAI whether remote, onsite or combination
- Points to remember for responding to allegations of untrustworthy data

3:30 PM **Wrap Up and Review**
3:30 PM – 4:00 PM EST

Attendees have time to ask any final questions for the day

4:00 PM **Adjournment of Day Two**