Overview of TriTiCon's training program

Theme A
Clinical Data Management

A1: Introduction to clinical development and clinical data
- Clinical development stages, objectives and outcomes
- The basics of clinical trial design and statistics
- Clinical data collection & the role of clinical data

A2: Data management in context
- Clinical development functions
- The role and objectives of clinical data management
- Clinical data management ABC

A3: Data management process introduction
- Set-up (planning, eCRF Set-up and UAT, handling of external data)
- Conduct (data review and cleaning, status management)
- Close out and delivery (database lock, data management deliveries,archiving)

A4: Data management in depth - Setup
- Planning, start-up activities and timelines
- Typical data management documents
- eCRF design and set-up
- ePRO / eCOA, handling of external data
- System specifications and UAT

A5: Data management in depth - Conduct
- Data cleaning and query management
- Data review and monitoring
- Handling of external data, reconciliation
- Residual data issues, protocol deviations
- Status management

A6: Data management in depth – Close out and delivery
- Clean file" checkpoints
- Database lock and release
- Data management deliverables
- Archiving and close out

Theme B
Managing Data Management

B1: The current & future of clinical data management
- Changes, trends and challenges in clinical data management, including topics like, distributed/virtual clinical trials, dynamic/adaptive trials, new types of data sources, sourcing and oversight, and from data management to data science.

B2: Sourcing and vendor strategies
- Sourcing models (services and systems)
- Sourcing options and key considerations for sourcing data management services and systems
- Vendor contracting and oversight basics
- Oversight in data management

B3: Data quality and risk management
- Definitions of clinical data quality
- Data quality risks management
- Data quality planning and responsibilities.
- Data quality monitoring, quality controls
- Bias and fraud

B4: Standards and standards management
- Overview of industry standards
- Standards management/governance
- Standards in action. Getting standards to work in your favour and as an enabler rather than a constraint

B5: Managing Data Managers
- The changing role of the data manager. Future responsibilities and key skills.
- Data management within the organization (from sponsor and CRO perspective).
- Ownerships and responsibilities
- Stakeholder and expectations management

B6: Data management business planning - Optimizing data management
- The role of a department/team business plan. Suggested components and considerations
- Processes monitoring and continuous improvement methods

Theme C
Clinical Systems and clinical data handling

C1: Introduction to clinical trial systems
- Overview of clinical systems (role, scope, key functionalities, handled data, users)
- Typical data flow and data/information touch-points (related / redundant data)
- The basics of system validation

C2: Dataflows and handling of different data-sources
- Overview of clinical data sources and data flow
- System data/information "touch-points"
- Data flow models and key considerations
- Specific cases: SAE-data, lab-data, ePRO, IRT vs EDC
- Consolidated data for medical monitoring, oversight and trial management

C3: Introduction to EDC/eCRF systems
- Basic and "2nd level" system modules
- System and vendor categories
- Key considerations and differentiators
- Best practice for EDC/eCRF configurations and trial set-up

C4: Introduction to ePRO/eCOA
- Introduction to patient/observer reported data (Validated instruments, regulatory requirements)
- Set-up process and timelines, requirements for CTA/EC/IRB submissions, translations and instrument validity
- Monitoring and compliance management

C5: ePRO/eCOA – In depth
- Technology and Vendor categories and considerations
- Real life challenges and pit-falls
- Set-up activities, best practice design, UAT
- Data handling, deviation handlings.
- Close out / archiving

C6: System selection, implementation and validation
- System (and vendor) selection, recommended methodology/steps
- System implementation, recommended approach and key considerations
- System validation in practice

Theme D
Leadership, Strategy and Organisation

D1: Clinical trial systems strategy
- Clinical systems choices and strategies - for *your* company needs.
- System vs service selection
- Own versus trial-by-trial sourcing considerations

D2: Oversight
- Definitions and regulatory requirements
- The oversight process
- Structuring and planning your oversight
- Oversight conduct and documentation
- Do's and don'ts: practical recommendations

D3: Risk Management
- Definitions, regulatory requirements
- Risk Management in practice: making regulatory requirements and business benefits meet.
- Suggested risk assessment areas, methods and processes

D4: TriTiCon's 2 cents on leadership in clinical development
- Navigating the cross-functional world
- The benefits and challenge of "responsibility splitting"
- Leading specialists
- Training and learning in the 2020's