



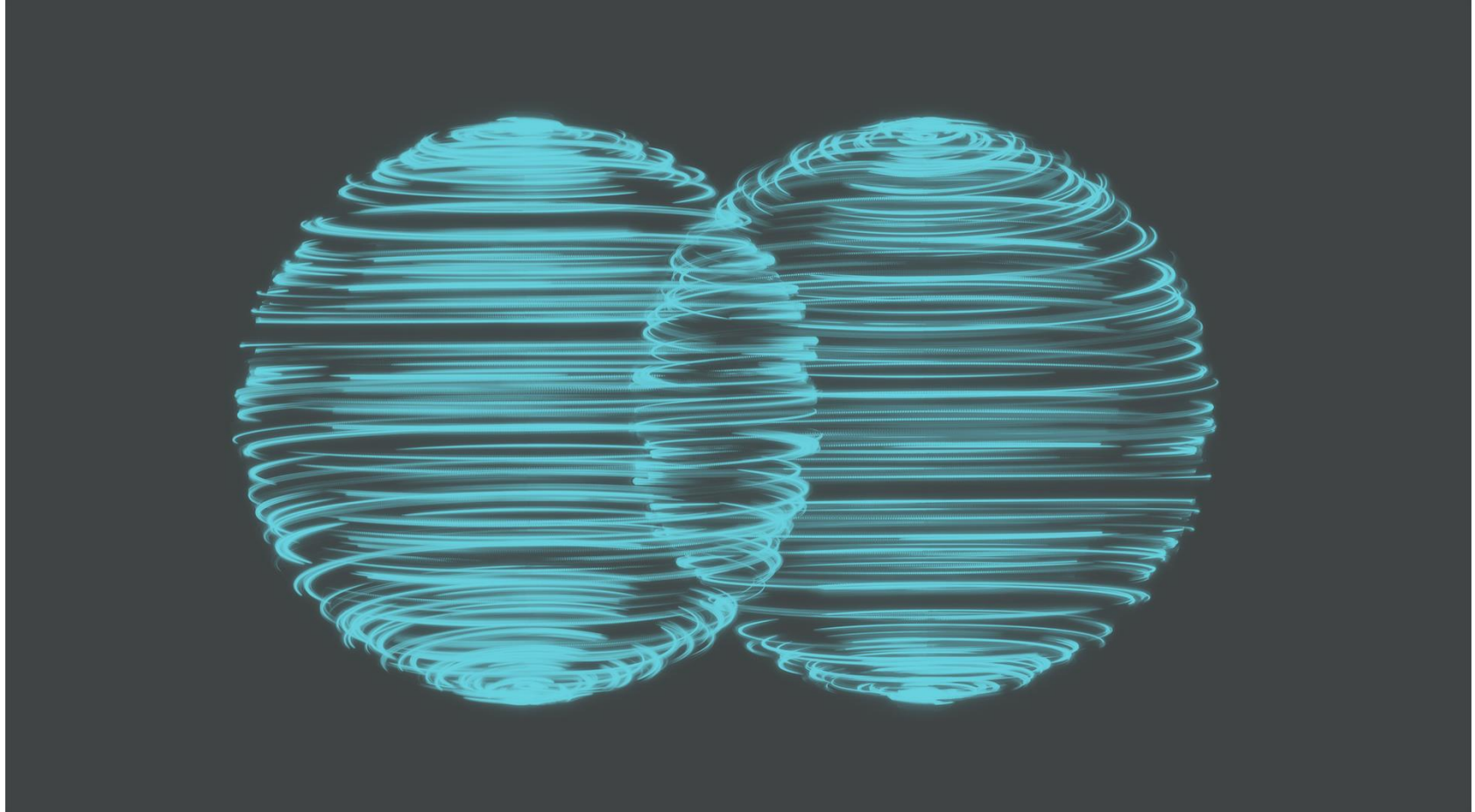
Society for Clinical Data Management
DATA DRIVEN

Theme:
Capabilities | Collaboration |
Change on the way to Clinical Data Science

SCDM Live

India conference

2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru



Site Exposure Program (SEP)

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Associate Director, AstraZeneca

Mission

To bridge the knowledge & practical gaps between Data management, Central monitoring and Site personnel to gain insights on improved ways of working and implement innovative approach in process, tools and technologies.



SITE PERSONNEL



Site Management & Monitoring



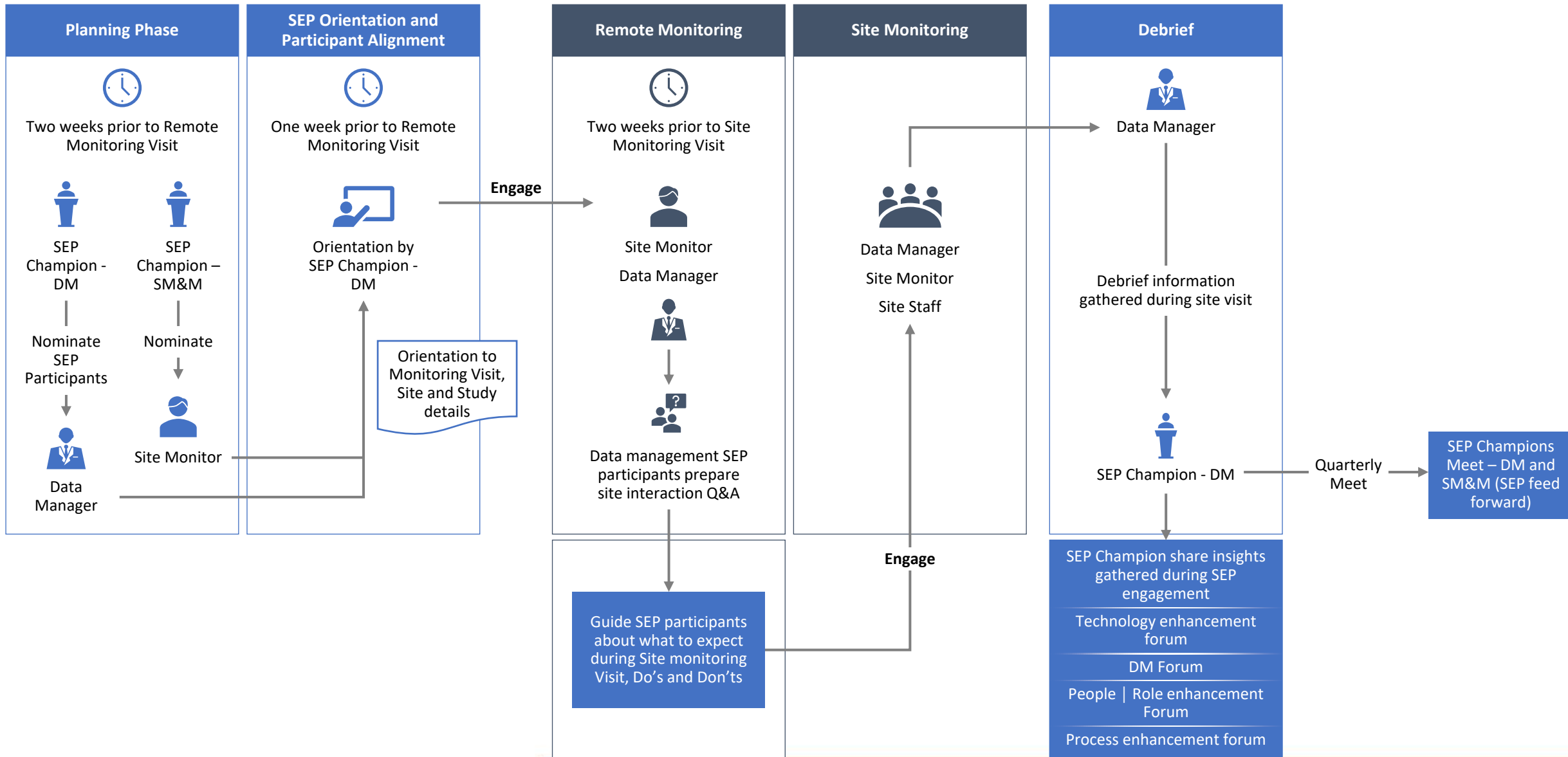
Clinical Data Insights

Reimagining our DM & RBQM role to adopt to ever changing landscapes of data trending and patient safety signalling.

Skill enhancement for sustainable delivery with Site Management and Monitoring, Clinical data insights engagement.

Scale up leadership capabilities through Exposure and Learning.

Overall Process



Business Benefits

Company

- Reputation build by Data Management with Site staff.
- Skill enhancement of staff
- Art of story telling and listening
- Engagement of staff patient stories
- Integrated quality risk management plan
- Building site user experience on evolving and adoptive study designs and decentralized trials
- Embrace the patient centric data revolution

People | Role

- Quality of engagement with site staff- Send issue precise queries to site (reduction in re queries, cancelled queries)
- People engagement through different types of site visits (SDV, SDR, RMV and MV)
- Better manage sample tracking and reconciliation by having insights on biological sample management at site
- Lean the validation process like ECO (edit check optimization)

Process | Technology

- Unit cost reduction by understanding end user requirement
- Design eCRFs where information collection flow is similar in way data is entered in medical records [using CRF labels with close resemblance to medical source records]
- Elevate information presentation in existing dashboards and study metrics platforms

Apply Cross Functional Strengths

- CtQ (critical to Quality) data acquisition strategy
- Align data cleaning strategy with monitoring visit strategy to prevent end loading (eg: data entry, PI Signature)
- Functional efficiencies through impactful data insights
- Engagement through patient stories
- Reflection of site risk quality management strategy in eCRF and tSDV build



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AFFILIATIONS