



EXPERTISE

SAFETY

SOLUTIONS

Onboarding a Junior Clinical Data Manager in an Early Phase Team: My Story from University to First Database Lock

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WHEN YOU NEED TO BE SURE

SGS

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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the opinions of PHUSE members, respective companies or organizations.*





Data
Management

- Background
- Role of CDM
- Hurdles for a Junior CDM
- Personal experience
- Tackling challenges
 - Onboarding program
 - Extensive training
 - Mentorship
 - Multiple POCs
 - Synergy with CPU and CDP
- Conclusions

Data
Management

Background

- Studied Biology at University of Antwerp, Belgium
- Obtained Bachelor and Master
- Finished PhD in Biology in 2019
- Started working at SGS Health Science in June 2019
- First job in Clinical Research

Data
Management

Role of CDM

ROLE OF CDM

- SGS CDM role is diverse

Data collection design and implementation
Adherence to data standards (SDTM)
Problem-solving and issue resolution
External vendor data reconciliation

ROLE OF CDM

■ SGS CDM role is diverse

Data collection design and implementation
Adherence to data standards (SDTM)
Problem-solving and issue resolution
External vendor data reconciliation

Project and stakeholder management
Documentation (eTMF)
Medical coding and SAE reconciliation

Challenges

Hurdles for a Junior CDM

HURDLES FOR A JUNIOR CDM

Lack of clinical
research
experience

Short duration
of EP studies

Increasing
complexity of
EP studies

Flexibility & broad
knowledge

- ICH-GCP
- SDTM
- CTP
- Up- & downstream
Data knowledge

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Short duration of EP studies

- EDC set-up
- SDTM set-up
- Define checks
- Data cleaning
- Database lock process

Increasing complexity of EP studies

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Increasing complexity of EP studies

- SAD and MAD
- Adaptive design
- Randomized and open label
- Combination of healthy subjects and patients

Flexibility & broad knowledge

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Increasing complexity of EP studies

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Flexibility & broad knowledge

- Working on 2 or 3 studies
- Protocol amendments
- Fast & frequent switch in study timelines
- Different EDC systems (eSource, eCRF)
- Different requirements or IGs per client

Challenges

Personal experience

- Learning to work with SDTM standards
- Multiple studies at start
- Data reconciliation for blinded external vendor data
- Documentation and filing



Challenges

Tackling challenges



TACKLING CHALLENGES

Onboarding program

SHINE

EMPLOYEE CHECKLIST TO ONBOARDING

Use the information and resources in this checklist to help you reach full performance in your role and better understand SGS over your first three months. Some content is available via SGS Campus, our Learning Management Platform, therefore ensure to log-in in SGS Campus



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SECTION 1 WELCOME AND IMMERSION

First week. Meet your new colleagues and get to know your work environment, the SGS culture and values.



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First week. Meet your new colleagues and get to know your work environment, the SGS culture and values.

SECTION 2 EXPLORATION, DISCOVERY AND ENGAGEMENT

First three months. Coach & support – ensure working knowledge of SGS Two way feedback – follow-up on progress.

TACKLING CHALLENGES

Extensive training

- SGS SOPs & WIs
- ICH-GCP
- CDISC & SGS SDTM IG
- In-house developed data management tools

Different training environments:
Quality Management System (EtQ)
SGS Campus
Face to face

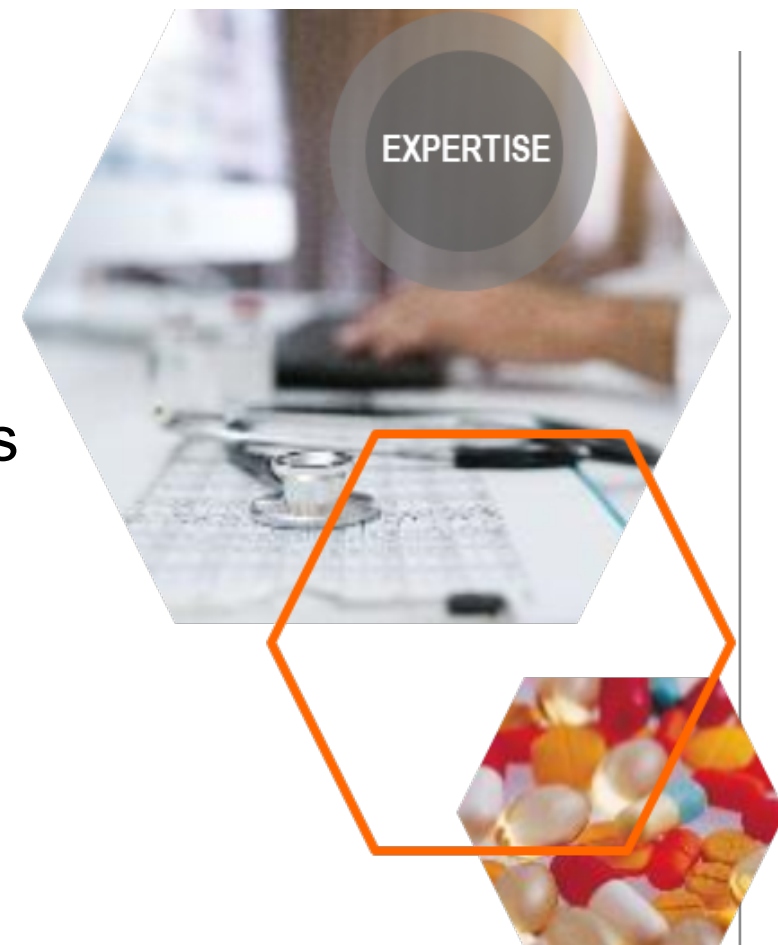


TACKLING CHALLENGES

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On average 100 hours in the first year
80h in the first 3 months



Study
set-up

Study
conduct

DB lock

TACKLING CHALLENGES

Mentorship

- Assigned a senior CDM as a mentor
- Hands-on supervision
- Work together on clinical studies



Study
set-up

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conduct

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TACKLING CHALLENGES

Multiple POCs

- Line Manager
- Coordinator
- Subject Matter Expert
- Direct colleagues



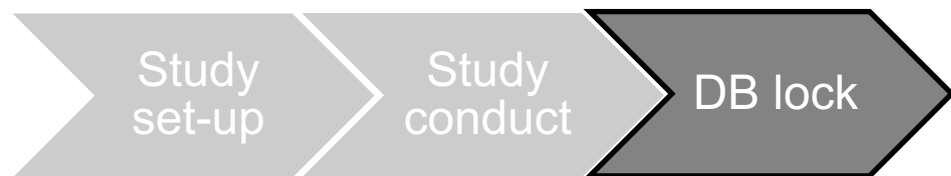
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TACKLING CHALLENGES

Synergy with CPU and CDP



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Conclusions

- Onboarding is intensive for junior profiles
- Knowledge of the entire study flow is gathered in a short period in EP teams

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 - Providing training environments and structure
 - Varied, extensive and well-documented training
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- Key success factors
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 - Multiple POCs
- Lead CDM after ± 6 months with mentor follow-up
- Future studies as lead CDM



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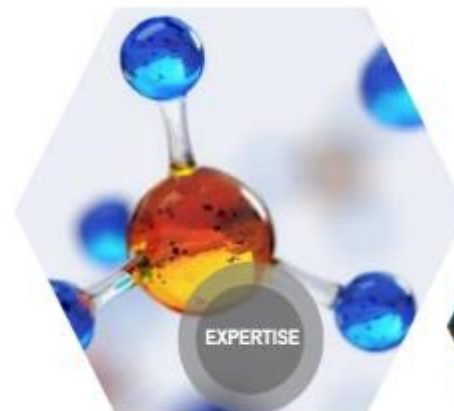
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