SCDM Live
EMEA conference
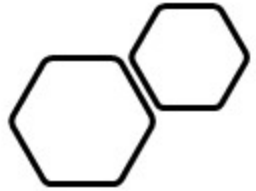
SCDM 2023 EMEA CONFERENCE

The Human Behind CDM in Different Working Models

GOTHENBURG

April 26-28, 2023

Introduction

The human behind CDM
in different
Working Models
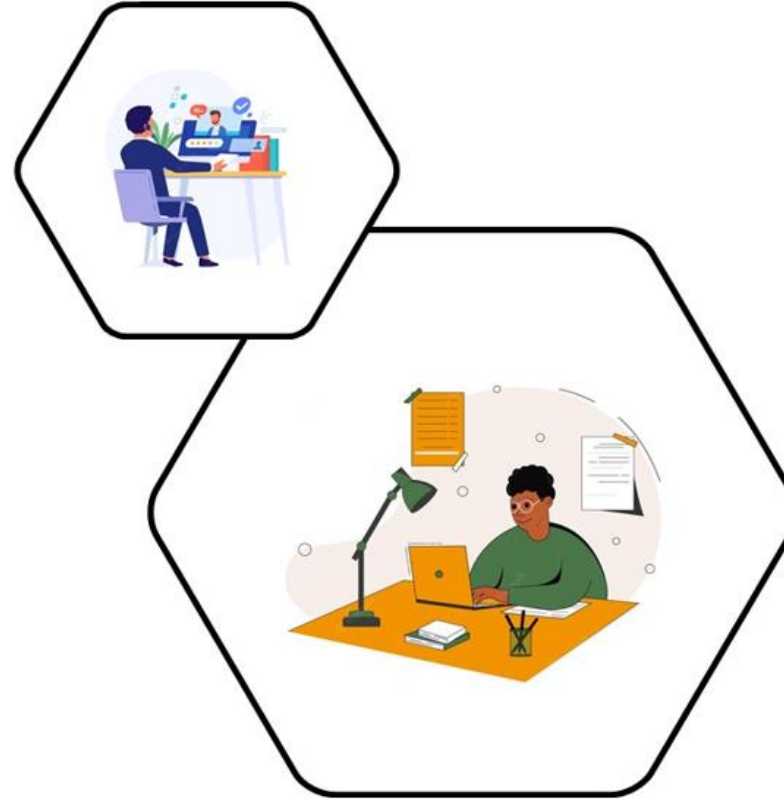
Session Agenda

Engineering

Manager

Data Management Lead

Manager behind clinical
Data Management

Engineering

Manager

Data Management Lead

Presenter Biography

Céline Frily is a Senior Manager of Clinical Data Management for ICON plc with almost 20 years of Clinical Data Management experience. Céline joined ICON plc in August 2008 as part of an FSP team, with currently 8+ years with the same Sponsor

Agenda

Defining the Role

- Education (degree)
- Specific skills (be organized, Strong written and oral communication skill (English))
- Experience (Phase I/II or III studies, Therapeutic Area)
- DM tasks and documents
- Documents from other teams (protocol, SAP, Medical Review Plan)

Selection of Candidates

Candidate Identification

- Advertise the position

- CRO Talent Acquisition screen the Candidates

- Interview with the CRO manager

- Potential Meet and Greet with the Sponsor

- Candidate offer

Initiation of Training

- Onboarding plan
  - CRO learning (TA, EDC system)
  - Sponsor SOPs and guidances

- Sponsor Mentoring -> Initial training
  - Get familiair with the different tools
  - Get familiar with the different DM documents
  - Get familiar with the vocabulary
  - Create bonds, collaboration

- From initiation to long-term partnership
  - Regular Meetings with mentors
  - Workload meetings between managers

Evolve Team

- Team Growth -> many countries, different cultures, different educations and strenghts

- Communication, open-minded team, adaptability, flexibility

- Evolution (COVID-19, RBQM, DCT, eSource)

INCREASE ⬇ TRUST

Long-term relationship

Driving Success

Identify and Retaining Best talents

Good Team Spirit

Training Experience

TEAMWORK

Motivation

Trust Collaboration

Team Strengths

SCDM Live
EMEA conference

My Journey as Manager

- 2014: started with 5 Data Managers (2 in the US, 3 in France)

- End of 2022: 34 individuals (Data Managers, Data Coordinators, Medical Affairs) from the US, France, the UK South Africa and China

- Longest serving team members on program
    - 2 team members with almost 9 years
    - 5 team members (> 7 years)
    - Average for team (4.3 years)
    - All team members (> 1 year on program)

- Longest serving team members with CRO
    - 2 team members (over 20 Years)
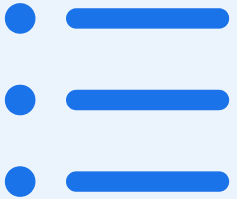   - Average for Team (6.9 years)

Sharing Experience

Communication

Teamwork

Trust

SCDM Live
EMEA conference

Thank you

SCDM Live
EMEA conference

Which working model do you think of as more efficient in managing project delivery and Sponsor expectations?

ⓘ Start presenting to display the poll results on this slide.

DML behind Clinical Data Management

Client/Vendor

Manager

Data Management Lead

The Human Behind Clinical Data Management in FSP Environment

26-28 April 2023, GOTHENBURG

Agenda

- ➢ FSP Explained

- ➢ Relationship vs Partnership

- ➢ Adaptive and Diverse Working Culture

- ➢ Attributes of an Efficient FSP Team

- ➢ Conquering FSP Challenges

FSP Explained

➢ **Functional Service Provider in a nutshell**

　➢ Partnership between CRO and a sponsor

　➢ Tailored advantages

　➢ Time and cost efficiencies

　➢ Integrity and quality

➢ **Why selecting FSP model**

　➢ Relationship over coincide
　➢ Trust
　➢ Mutually beneficial

FSP Explained

> Advantages of established FSP Partnership

> Tailor made service

> Innovative thinking

> Cost effective resourcing
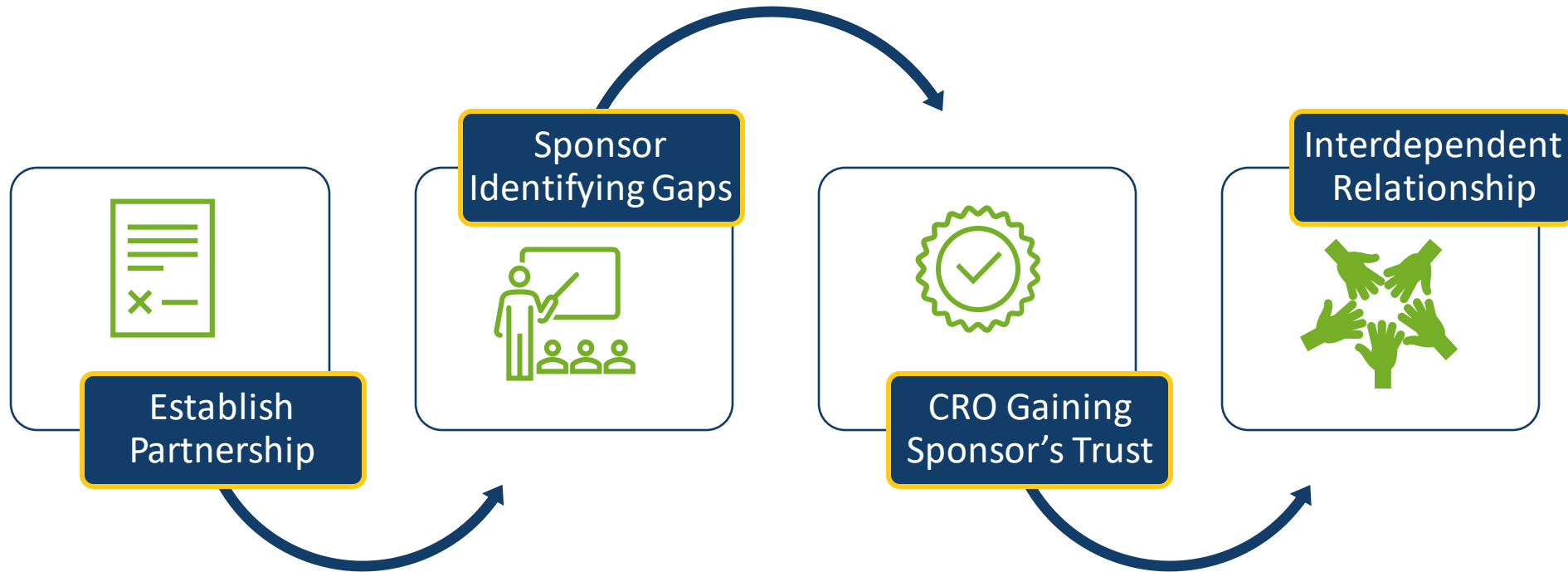
> Streamlined compliance

> Flexibility and adaptability

> Cumulative experience and growth

Partnership vs Relationship

Establish Partnership → Sponsor Identifying Gaps → CRO Gaining Sponsor's Trust → Interdependent Relationship

Adaptive and Diverse Working Culture

- ➢ **Adaptive Team**

  - ➢ Resilient to sponsor updates

  - ➢ Continuous development on industry technology

- ➢ **Diverse Working Culture**

  - ➢ Location consideration
  - ➢ Interchangeable role allocation

Attributes of an Efficient FSP Team

➢ The substance of a FSP team lead

➢ **Behavioral skills**

- ➢ Building respect with respect
- ➢ Concrete communication
- ➢ Constructive conflict

➢ **Technical skills**

- ➢ Problem solving recognized
- ➢ Critical thinking as a team
- ➢ Jack of all trades and master of all

SCDM Live
EMEA conference

Conquering FSP Challenges

➢ Common issues in a FSP.

Establishing Ownership

➢ Document who is accountable vs responsible for each task

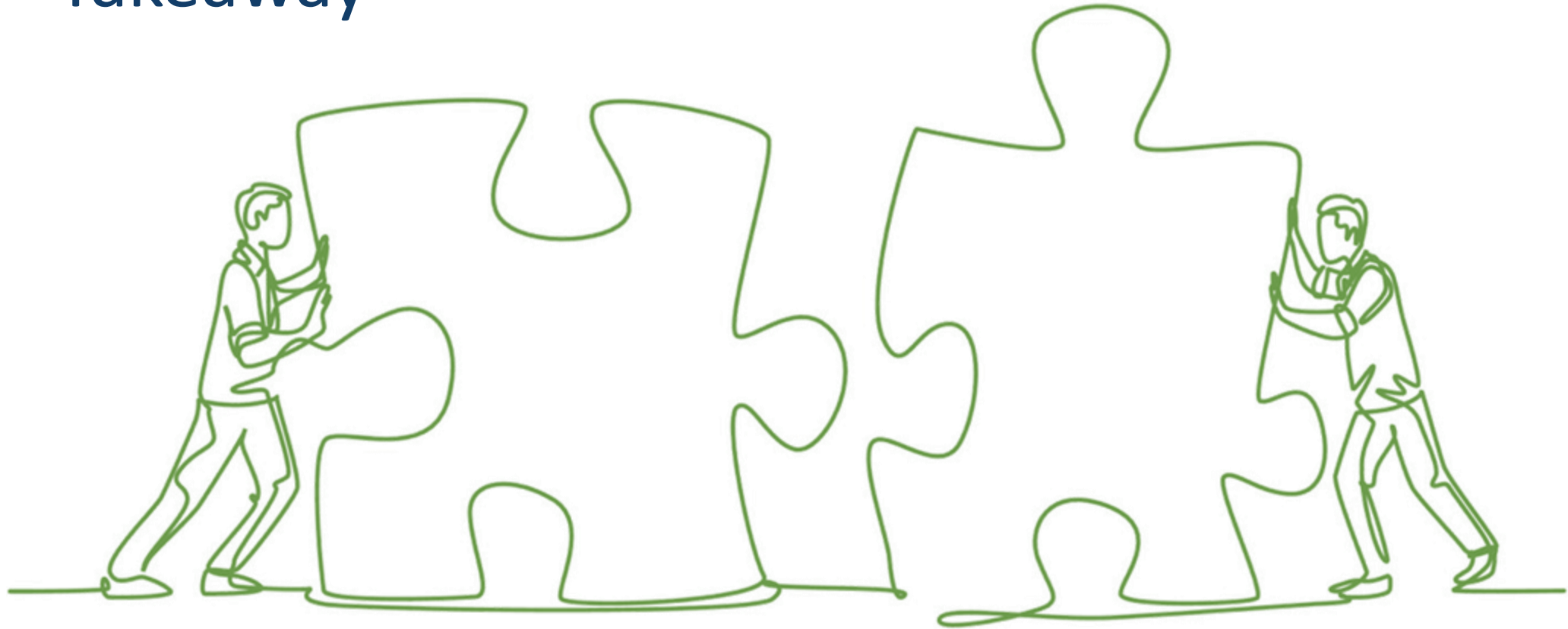**Opportunity for Growth**

➢ Adjustment window for CRO to familiarize

Management Style Conflicts

➢ The Data management lead vs sponsor counterpart

Takeaway

"Those who have learned to collaborate most effectively have prevailed."

Charles Darwin

Thank you

SCDM Live
EMEA conference

Engineering the Human Behind Data Management

Engineering

Manager

Data Management Lead

Agenda

- Understanding the New World

- Engineering an Entertaining DM
  - DM as Data Collectors
  - Capitalizing on the Science
  - Concept of Shared Boundaries

Understanding the New World

By 2025, **72% of all Internet users** will solely use **smart phones** to access the web

6.92 Billion SmartPhone users

86.29% of people in the world have smartphones today

By 2026, mobile device users will increase to 7.57 Billion
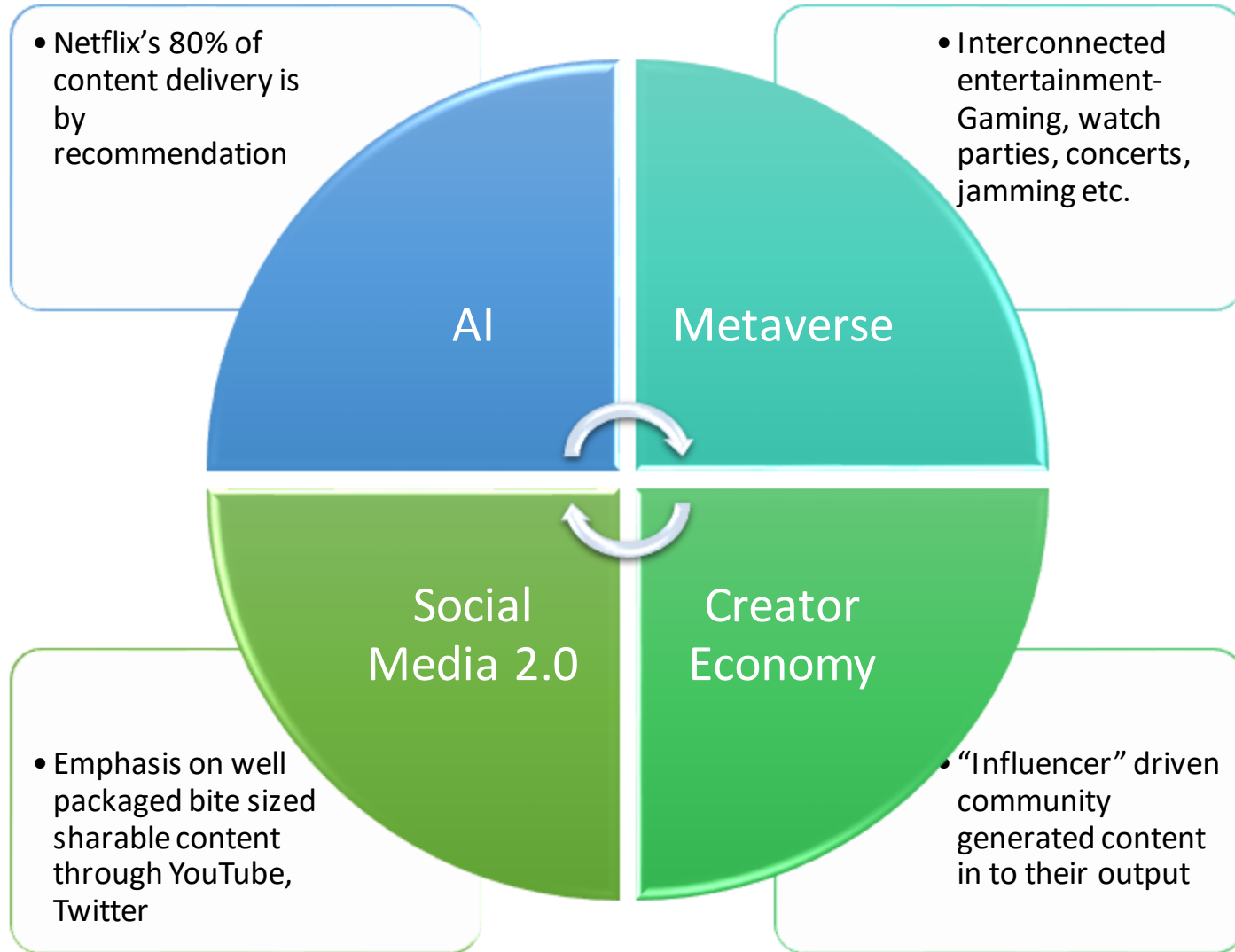
49.89% Increase SmartPhone users from 2017-22

A study found 23% with behaviour consistent to Smartphone addiction
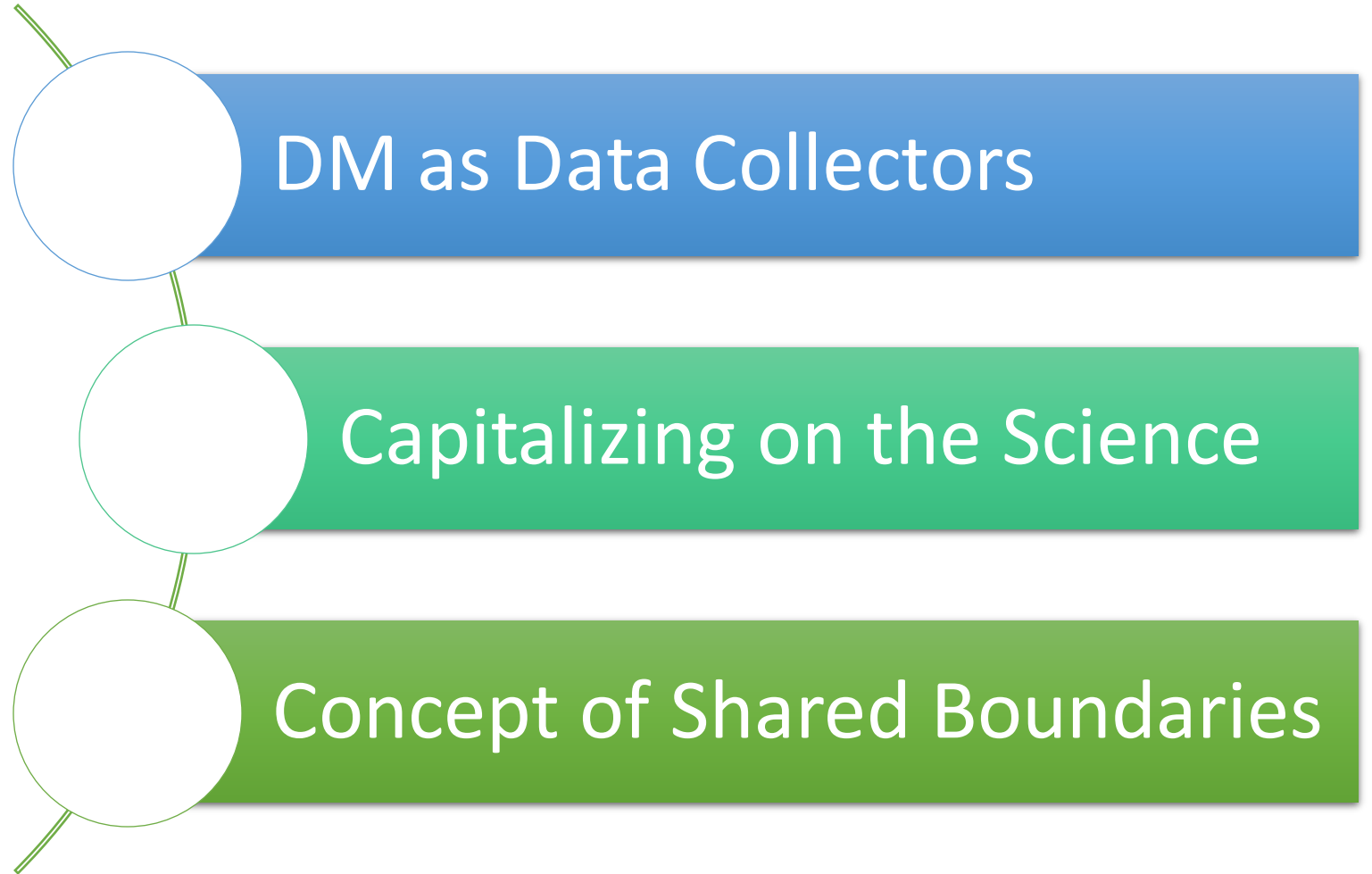
Research published by BMC Psychiatry in 42000 young people

26-28 April 2023, GOTHENBURG

Technology Trends which are most influencing

- Netflix's 80% of content delivery is by recommendation

AI

- Interconnected entertainment- Gaming, watch parties, concerts, jamming etc.

Metaverse

Social Media 2.0

Creator Economy

- Emphasis on well packaged bite sized sharable content through YouTube, Twitter

- "Influencer" driven community generated content in to their output

SCDM Live
EMEA conference

26-28 April 2023, GOTHENBURG
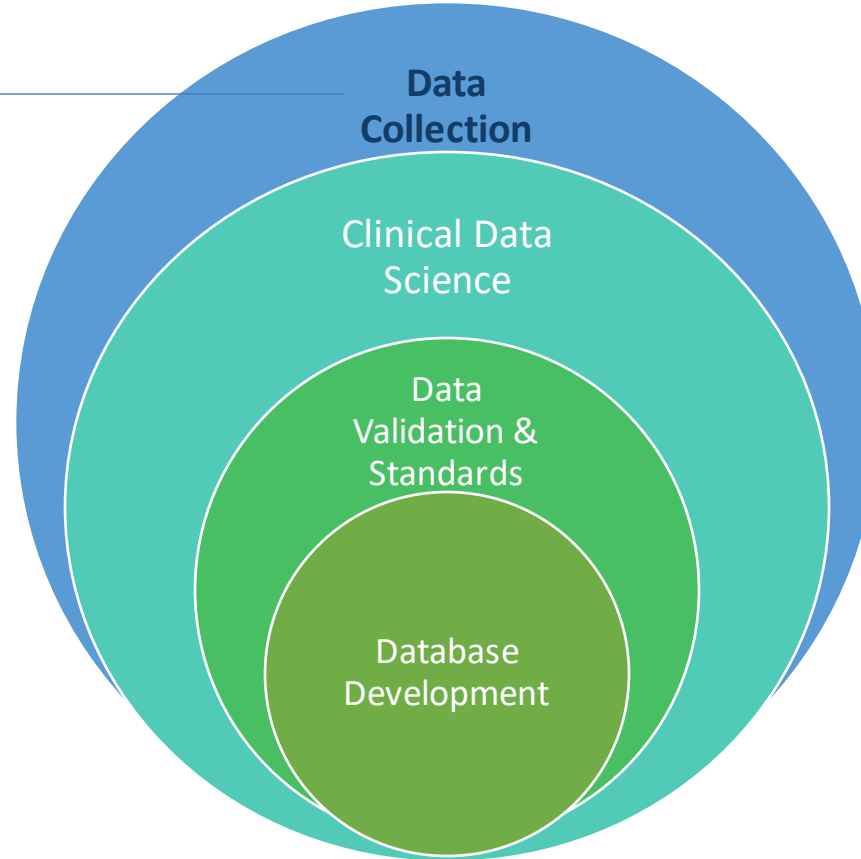
Possible "**Collection**" Oriented Quality Assessments

Sl no	Quality Metrics	Measure	Description
1	Data Completeness	Measure of data collected v/s expected volume	This metric describe the level of completeness of the data collected
2	Data Correction Metrics	% of data corrected after first collection	This describes efficiency of data collection process; RCA of this could throw light on effectiveness on EDC build, site training & data validation
3	Comparative Cleanness	% data clean in comparison with related other data collected	This metric would provide a clear understanding of how clean the data is after collection.

SCDM Live EMEA conference
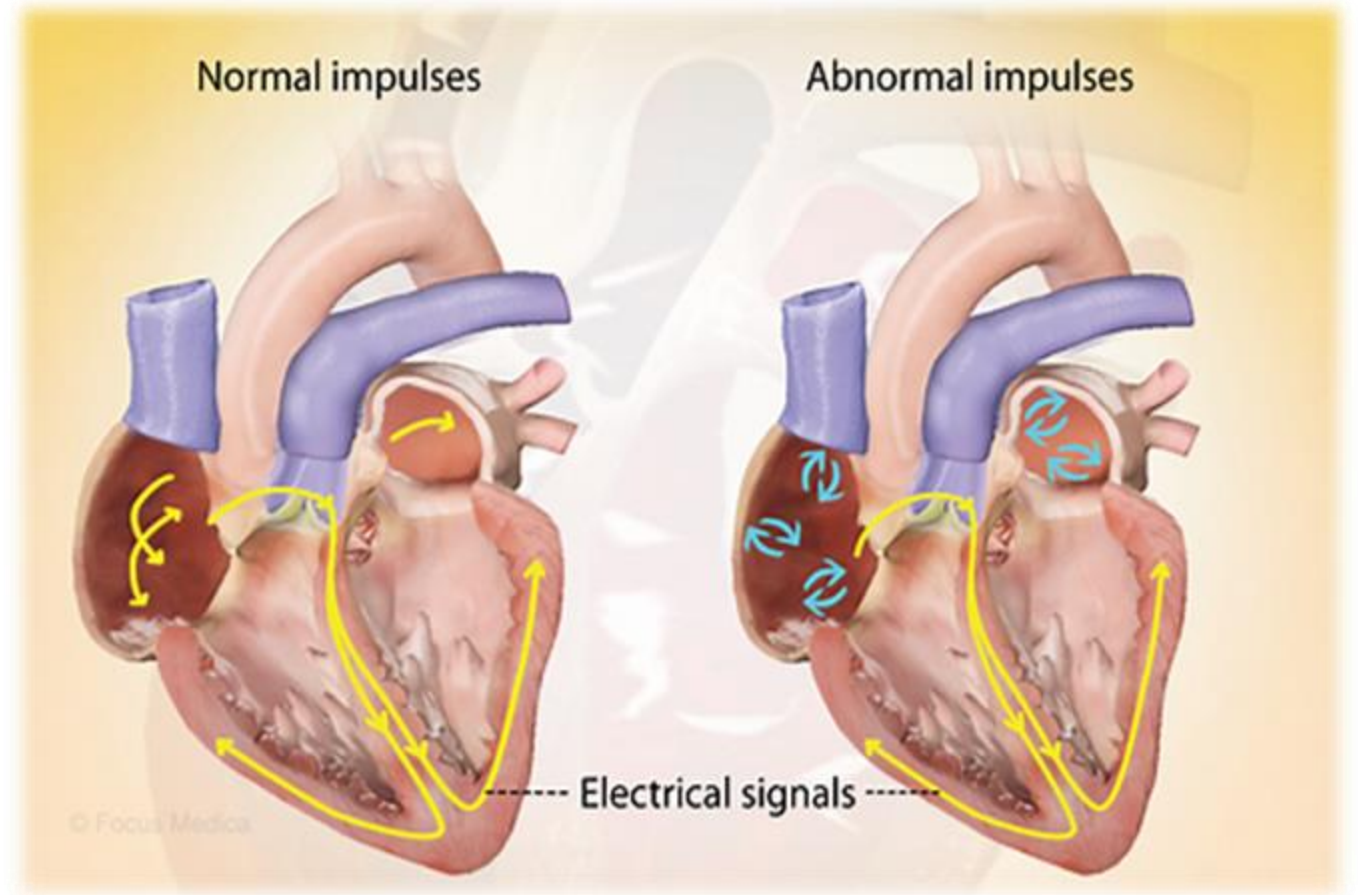
Open-Label non-superiority study on **AFib** Patients comparing Warfarin & Study drug
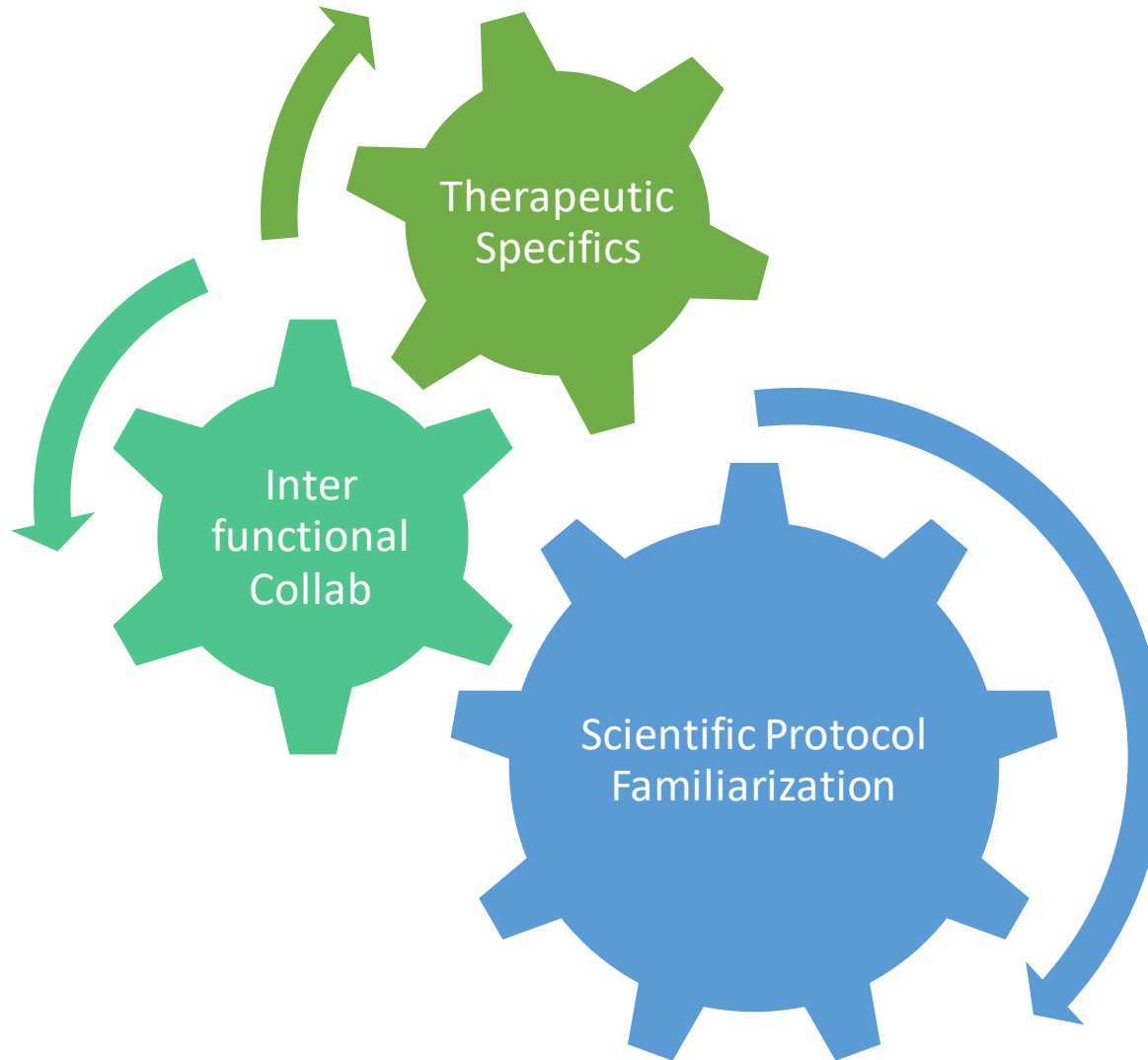
Why Warfarin for Afib?	Why specific data is collected?
• Why treat irregular impulses with anti-coagulant?	• Suspected events & adjudication

Normal impulses

Abnormal impulses

---- Electrical signals ----

© Focus Medica

Capitalizing on the Science

Therapeutic Specifics

Inter functional Collab

Scientific Protocol Familiarization

Other Areas in similar direction:
- Promoting Certifications
- Promoting Participation in Industry forums
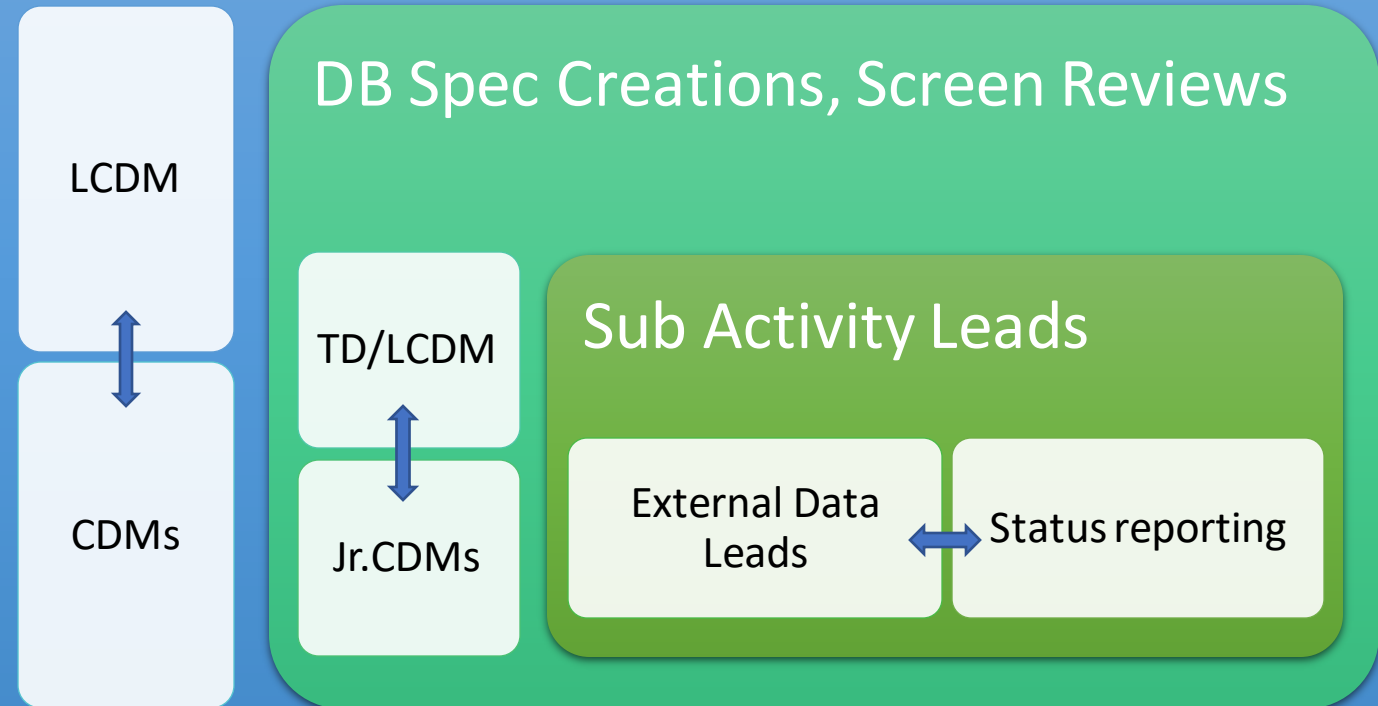- Organize scientific discussions, KT sessions across functions

26-28 April 2023, GOTHENBURG

RACI v/s Shared Boundaries

- Improved study ownership

- Enhanced Team engagement

- Feeling of higher importance

- Larger representative ideation

- Possible meaningful recognition

Creation & Maintenance of DMP & Study Docs

LCDM

CDMs

DB Spec Creations, Screen Reviews

TD/LCDM

Jr.CDMs

Sub Activity Leads

External Data Leads

Status reporting

SCDM Live
EMEA conference

Thank you

SCDM Live
EMEA conference

Which of the below can generate more enthusiasm and focus for Data Managers in data management deliverables?

ⓘ Start presenting to display the poll results on this slide.

Q&A

SCDM Live
EMEA conference

26-28 April 2023, GOTHENBURG