



On the other side of the fence: When two skill areas join forces and boundaries dissolve

Stine Ross

Senior Statistical Programmer
Obesity & Metabolism

Mette Krogh Beyer

Principal Data Management Specialist
Insulin & Devices

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Agenda

1. How the **journey** began
2. Two skill areas – **one goal**
3. **Differences** – the key to succes (if used wisely)
4. The **shared** journey continues...

1. How the **journey** began

A *Biostatistics* resource
at *Data Management's*
disposal for 8 weeks

Two roles:
**Clinical Trial Data
Managers** and SDTM
programmers



Automated
checks

Input to
Risk-Based data
management

Share knowledge & ideas

A Short Term Assignment can turn out to be so much more....

1. How the **journey** began



2. Two skill areas – *one* goal

High data quality



~~(perfectly)~~
clean data...



2. Two skill areas – **one** goal

consistent and **reliable** data
that ensure
solid statistical results and
optimal **usage**



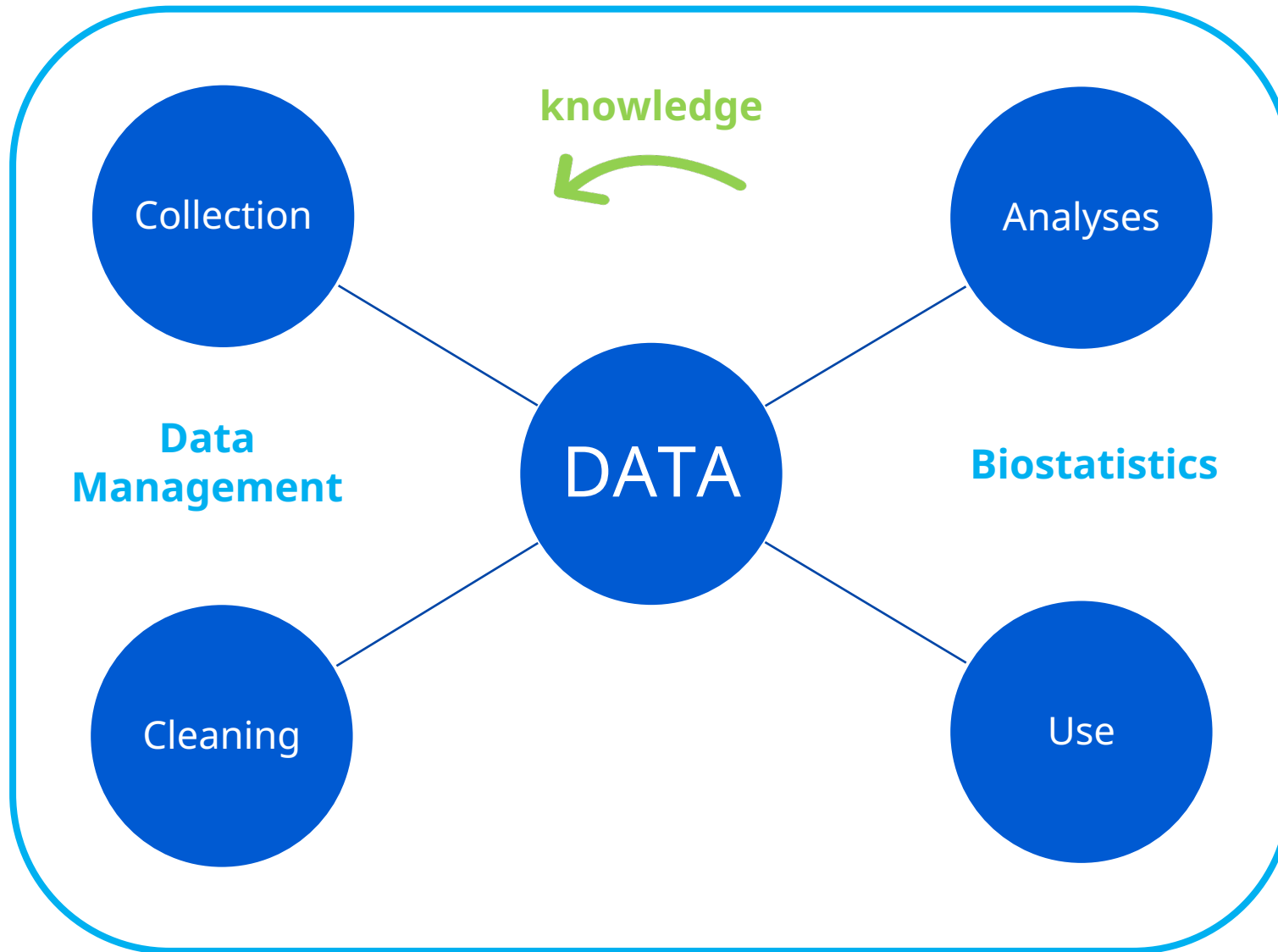
All data equally important

**Risk Based
Monitoring**



Specific data and time points

2. Two skill areas – **one goal**



2. Two skill areas – **one goal**

	DATA MANAGEMENT*	BIOSTATISTICS
Data view	Prespecified data cleaning	Review and explore data
Language	eCRFs, clinical database, lab, vendors, other	CDISC (SDTM**, ADaM)
Knowledge	Clinical setup, design, communication	Statistics, programming

*Clinical Trial Data Managers

**Generated by the SDTM programmers

2. Two skill areas – **one** goal

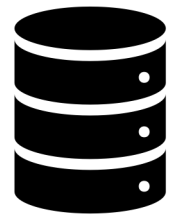
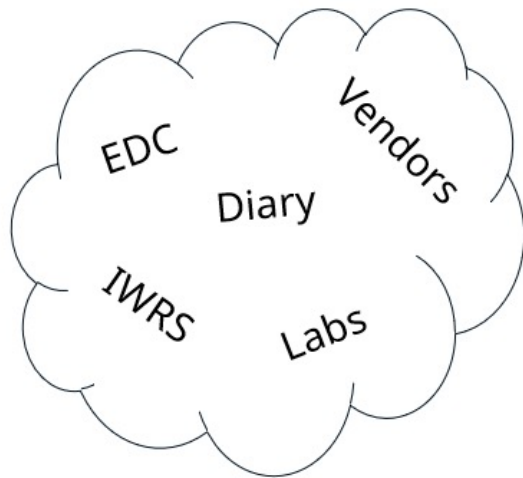


We need to **speak the same language**.....

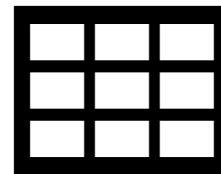
(both **literally** and **figuratively**)

2. Two skill areas – *one* goal

CDISC terminology



ADaM



SDTM

3. **Differences** – the key to succes (if used wisely)

How can we work **smarter together** to reach our common goal: High data quality?



By **dissolving the boundaries** between us and moving from stakeholders to **close colleagues**

3. **Differences** – the key to succes (if used wisely)

Close **collaboration** *early* in the process

- Share ***knowledge*** (data flow, analyses, usage)
- ***Bridge*** between different data systems (language, mappings)
- Bring ***ideas*** to the table (cleaning strategy, processes)

3. **Differences** – the key to succes (if used wisely)

Communicate regularly

- Work ***agile*** (reach out when needed)
- Ask questions and be ***curious***
- Build ***trust***

4. The **shared** journey continues...



4. The **shared** journey continues...

Let's bridge the gaps and work less in silos

We're all in the same boat

