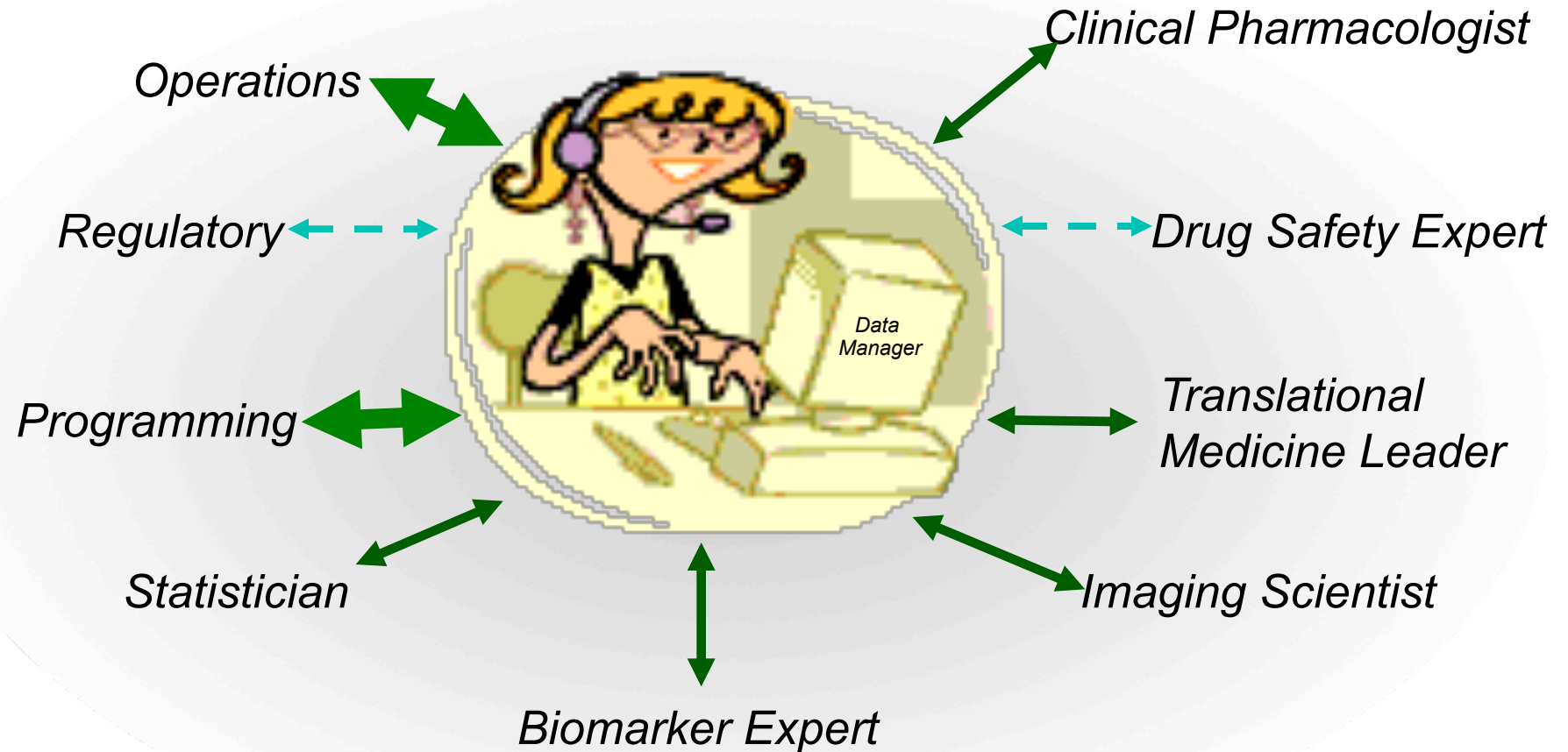


A New Era for Data Management Re-Define Collaboration

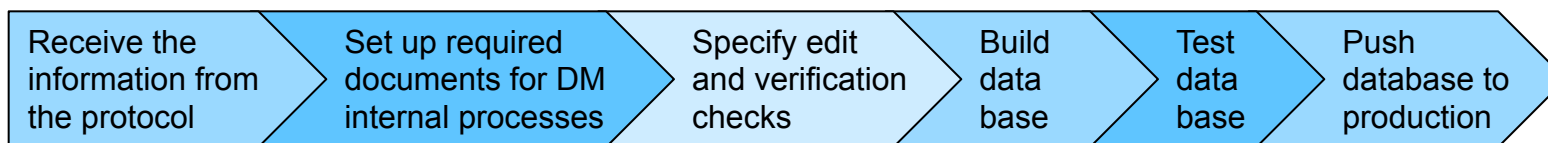
Michaela Jahn, PhUSE 2012, PD04, October 17th, 2012



Data Manager in Study Management Teams



Data Management Tasks during Study Setup



Data Management Tasks during Study Conduct

Work within EDC system

- Review query log
- Raise manual queries
- Review answers to manual queries
- Handle science queries
- Clarify errors
- Amend the database when necessary

Managing data

- Check of process regarding coding of terms
- Arrange for loading of electronically loaded data
- Reconcile serious adverse event between clinical data base and drug safety database
- Provide data listings to vendors
- Provide metrics to study management teams
- Interact with sites/monitors



Prepare for study specific decisions

- Generate dose escalation snapshots
- Prepare for database closure
- Extract data and hand over for statistical analysis

Data Management – Perception

- Receiving end
- Regarded as service provider to the organization
- Easy to outsource or off-shore



Changing Environment

Increasing pressure on organizations

- Higher cost pressure in Health Care
- Increasing costs to get to market
- A decreasing number of NDA approvals
- The traditional development model questioned

Increasing demands on departments

- The increased amount of data collection because of increased use of electronic medical records, technological advances in genomic sequencing and monitoring devices (BIG DATA)
- Higher complexity & heterogeneity of data
- Flexibility because of protocol amendments and interim data assessments
- Requests for access to data shortly after data entry has been completed
- Higher frequency of requests for early signal detection and continuous medical data review
- Faster decision making



Opportunities

Talents and skills

- Skill set within data management organization is much broader
 - Internal talents not used to its full potential
- Situation not to the benefit of the individuals, the department and the company

Adapt in a changing environment

- Broaden the scope beyond classical data management tasks
- Handle new data types
- Open to new ways of working

Implementing Opportunities

Within the department

New name

Clinical Data & Information Sciences (CDIS)

CDIS Vision

We are an agile team of Scientific Data Experts with curiosity and drive

CDIS Mission

We aim to integrate clinical, scientific and operational information at the right time to enable learning and confident decision making

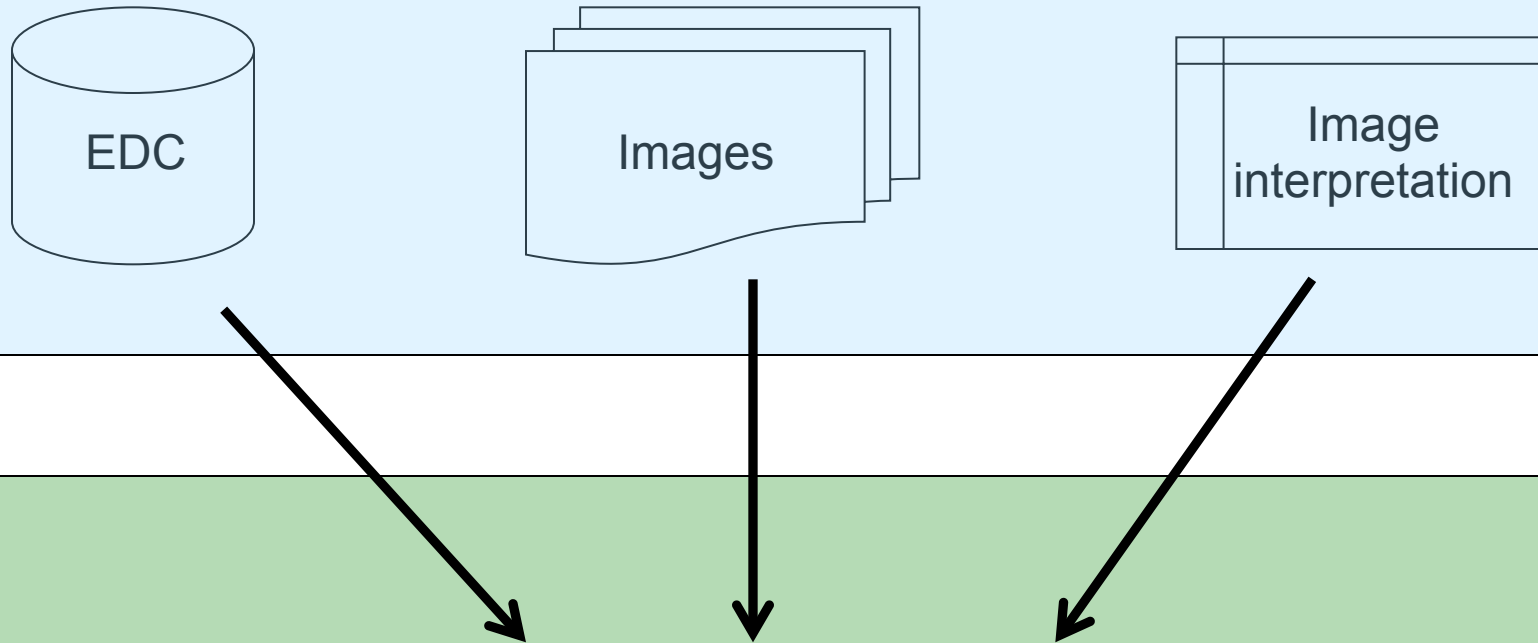
- **Broader scope** by handling further data types, engaging with science re medical data review during study conduct
- **Mindset** development focussing on communication, collaboration & teamwork, conceptual thinking
- **Change management** via global VC, local meetings, functional discussions, 1:1

Implementing Opportunities

Collaboration with other departments

- Stakeholders identified and stakeholder management plan
- Proactive communication re broader scope and more support

Examples 1 - Integrating Images into Data Flow



One system to provide an integrated view of all data related to a study

Examples 1 - Integrated Data Review (3 Systems)

Start Here

- Launch MIRA Session in Citrix
- Provide login credentials to connect to MIRA session
(Required for first request only)

MIRA Username:

MIRA Password:
(does not support paste)

Login

- Select data in Scatter Plot.
- Select option: Exclude thumbnail images
- Get list of images
- Select in the table, which images to open in MIRA.
- Select what to do in MIRA:

Add to series or

Replace series

Instructions

- Follow the instructions on the left side of the screen "Start Here"
- After "Login" is pressed, select one or multiple patients in the windows "All Patients"
- Select "Get list of images" in the left panel
- The list of images available for the selection made will be shown in the window "Images Available in MIRA"
- Select in the window "Images Available in MIRA" the images of interest and click either "Add to series" or

All Patients

Clinical Research Trial Number	Patient Number	Investigator Name	Date-Time of Birth	Age	Age Units	Sex	Race	Planned Arm Code	Desc
	1967-12-07	44.00	YEARS	M	WHITE	PADESC	ARM A: D		
	1969-12-12	41.00	YEARS	F	WHITE	PBLD	ARM B: L		
	1971-09-21	40.00	YEARS	M	WHITE	PBLD	ARM B: L		
	1941-04-08	70.00	YEARS	M	WHITE	PBLD	ARM B: L		
	1945-01-14	67.00	YEARS	M	WHITE	PBLD	ARM B: L		
	1941-05-12	71.00	YEARS	M	WHITE	PBLD	ARM B: L		
	1968-06-19	43.00	YEARS	F	WHITE	PBLD	ARM B: L		
	1951-01-18	61.00	YEARS	M	WHITE	PBLD	ARM B: L		
	1949-10-23	62.00	YEARS	M	ASIAN	PBLD	ARM B: L		
	1945-01-10	66.00	YEARS	M	WHITE	PADESC	ARM A: D		
	1949-11-07	61.00	YEARS	M	BLACK...	PADESC	ARM A: D		
	1947-05-29	64.00	YEARS	F	WHITE	PADESC	ARM A: D		
	1953-01-23	58.00	YEARS	F	WHITE	PADESC	ARM A: D		
	1957-12-09	54.00	YEARS	M	WHITE	PADESC	ARM A: D		
	1957-03-23	55.00	YEARS	F	WHITE	PADESC	ARM A: D		
	1954-02-14	58.00	YEARS	F	BLACK...	PADESC	ARM A: D		
	1940-12-29	71.00	YEARS	F	WHITE	PADESC	ARM A: D		
	1943-06-16	68.00	YEARS	F	WHITE	PADESC	ARM A: D		
	1931-10-10	80.00	YEARS	F	WHITE	PADESC	ARM A: D		
	1956-08-17	55.00	YEARS	M	WHITE	PADESC	ARM A: D		

Blocked information

Images Available in MIRA

Subject	VisitName	Modality	SeriesDescription	SeriesDateTime	Thumbnail	Series
	Cycle 1 Day 1	CT	Body-Low Dose CT	2012-03-30 06:04:48		21337
	Cycle 1 Day 1	PT	[VIB_NAC] Roche RP2K104 7r	2012-03-30 06:04:48		21339

File Edit View Insert Tools Help

Patient Selection and Visits (DM, SV) AE Tumor Ass Images Image Parameters

Instructions

- The plot provides details re the imaging parameters for the patient(s) selected in the imaging window on the previous tab ("Imaging Parameters")
- The imaging parameters presented in the plot can be specified in the filter panel on the right hand side of the screen
- All measurements for the selected patient are displayed in the window "Imaging Parameters"

Scatter Plot

Result or Finding in Standard Format

KTRANS MEAN

KTRANS MEAN

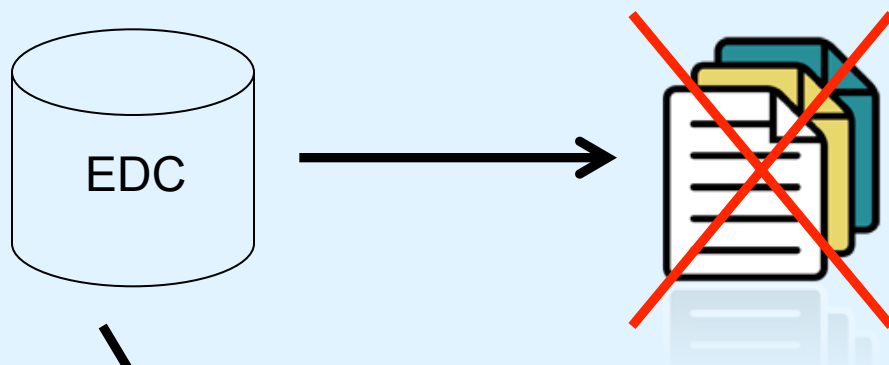
Study Day of Visit-Collection-E

Imaging Parameters

Patient Number	Group ID	Reference ID	Name of Measure	Result or Finding	Original Units	Result or Finding	Numeric Result	Standard
Q15495	701		K TRANS MEAN	0.1052		0.1052		
Q15495	701		K TRANS MEAN	0.1481		0.1481		
Q43395	702		K TRANS MEAN	0.0909		0.0909		

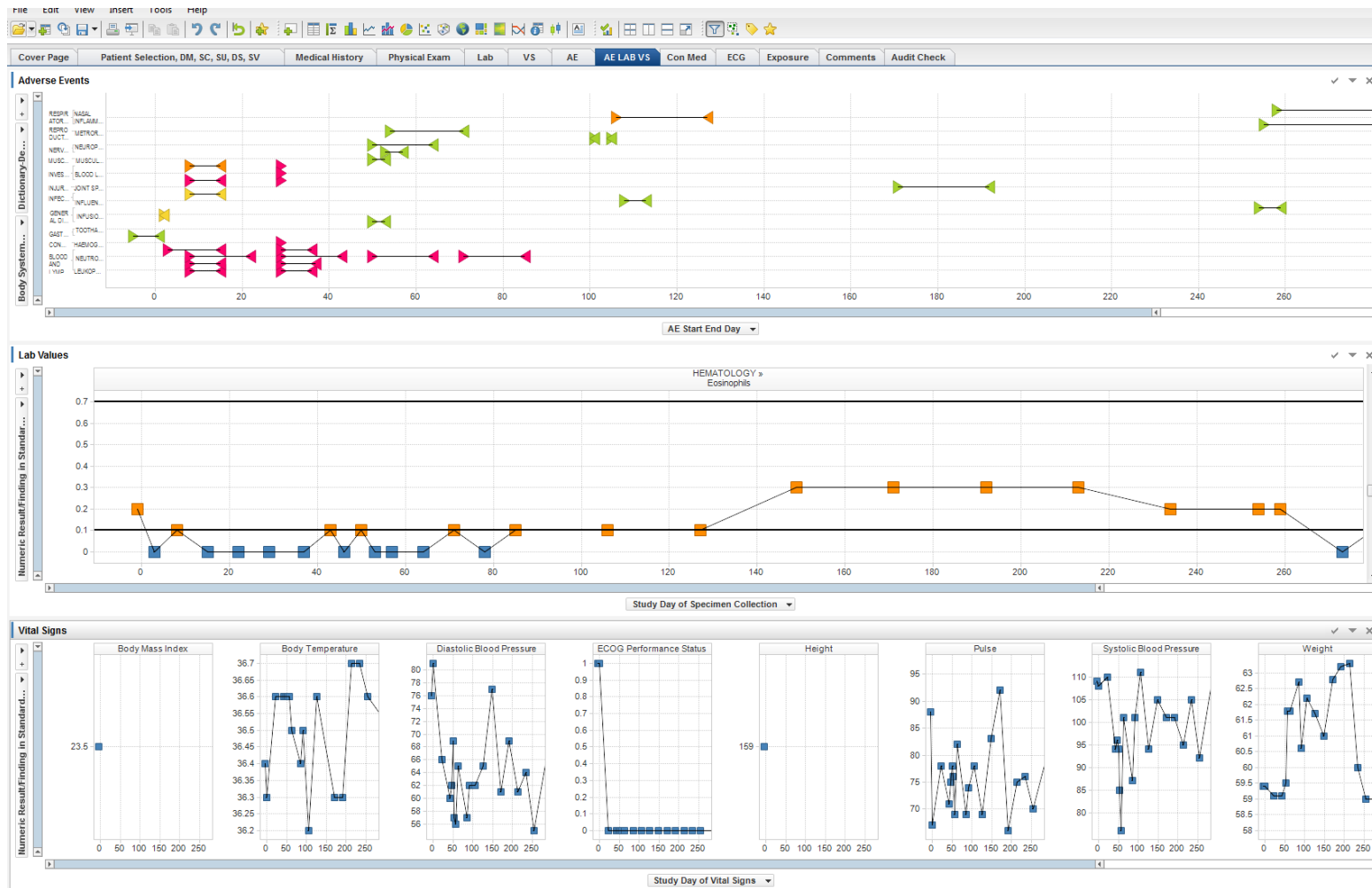


Examples 2 - Medical Data Review during Study Conduct



- Use an adequate tool and data visualization methods for state of the art medical data review
- Pair the understanding of data, data structures and technical know-how with medical/scientific questions

Examples 2 - Medical Data Review during Study Conduct



One subject
AEs
Labs
Vital signs

All on same time scale

Summary and Conclusion

- Maintaining the status quo is easy, but opportunities are not used to their full potential
- Changes in the industry and in our own organizations need to be seen and proactively addressed in order to remain in the driver's seat
- Changing is not easy but worthwhile
- Change management is vital, members of our department need to be kept on board and motivate to see WHY change is good



We Innovate Healthcare