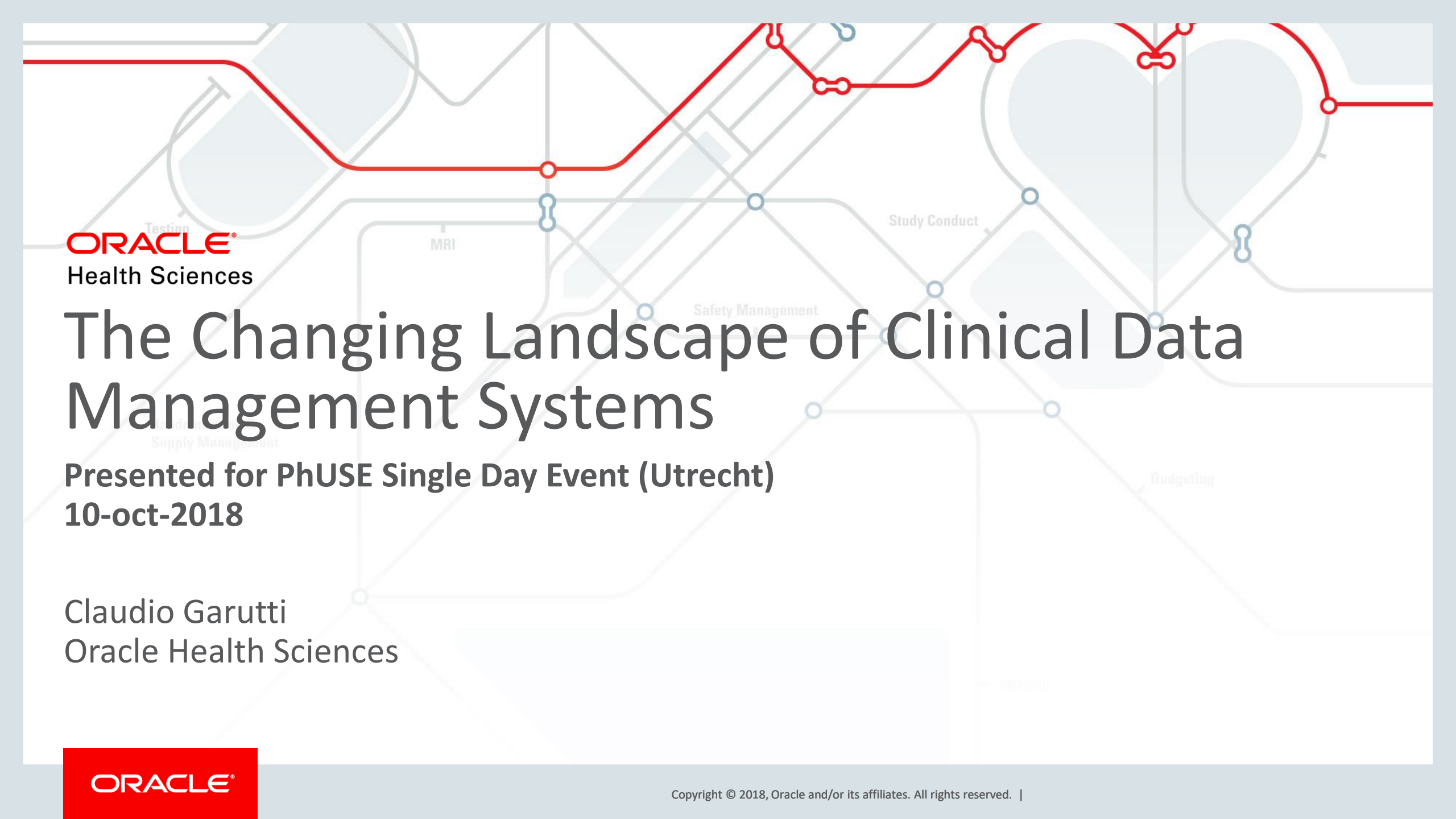




ORACLE®
Health Sciences

The Changing Landscape of Clinical Data Management Systems

Presented for PhUSE Single Day Event (Utrecht)
10-oct-2018

Claudio Garutti
Oracle Health Sciences

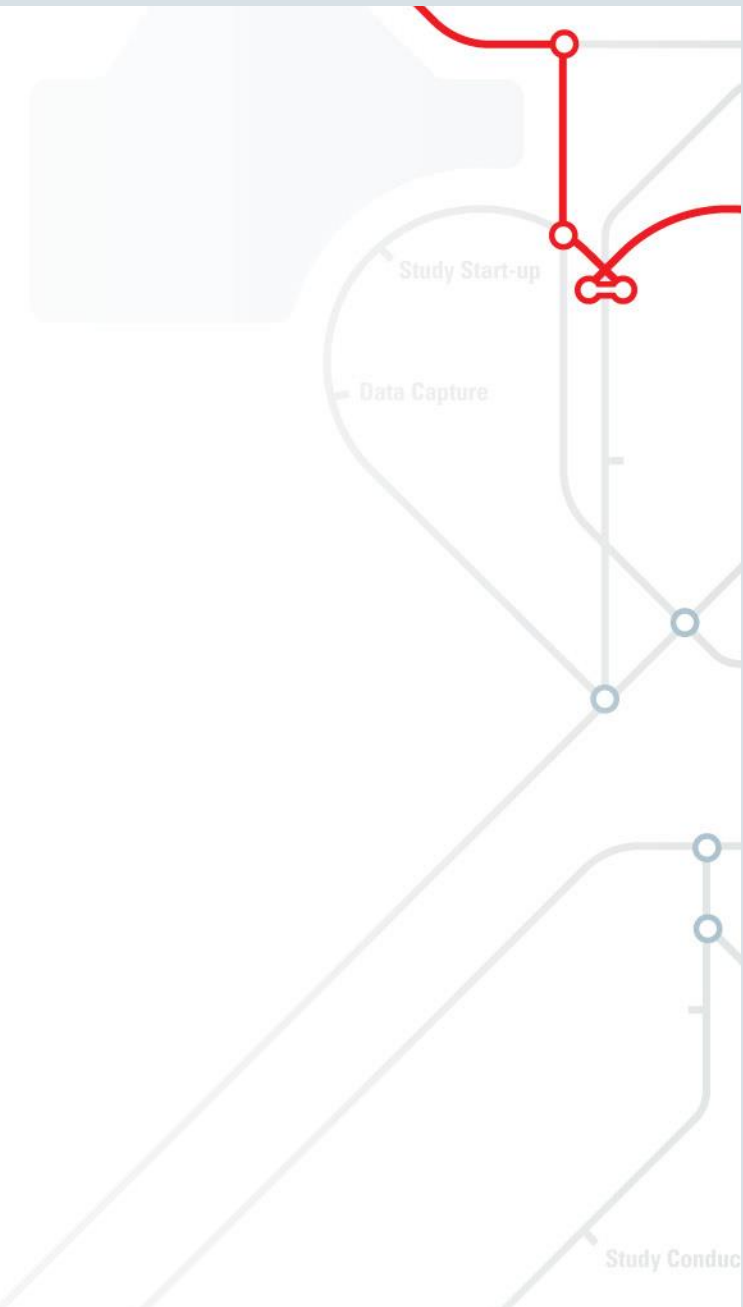
ORACLE®

Safe Harbor Statement

The following is intended to outline our general product direction. It is intended for information purposes only, and may not be incorporated into any contract. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decisions. The development, release, and timing of any features or functionality described for Oracle's products remains at the sole discretion of Oracle.

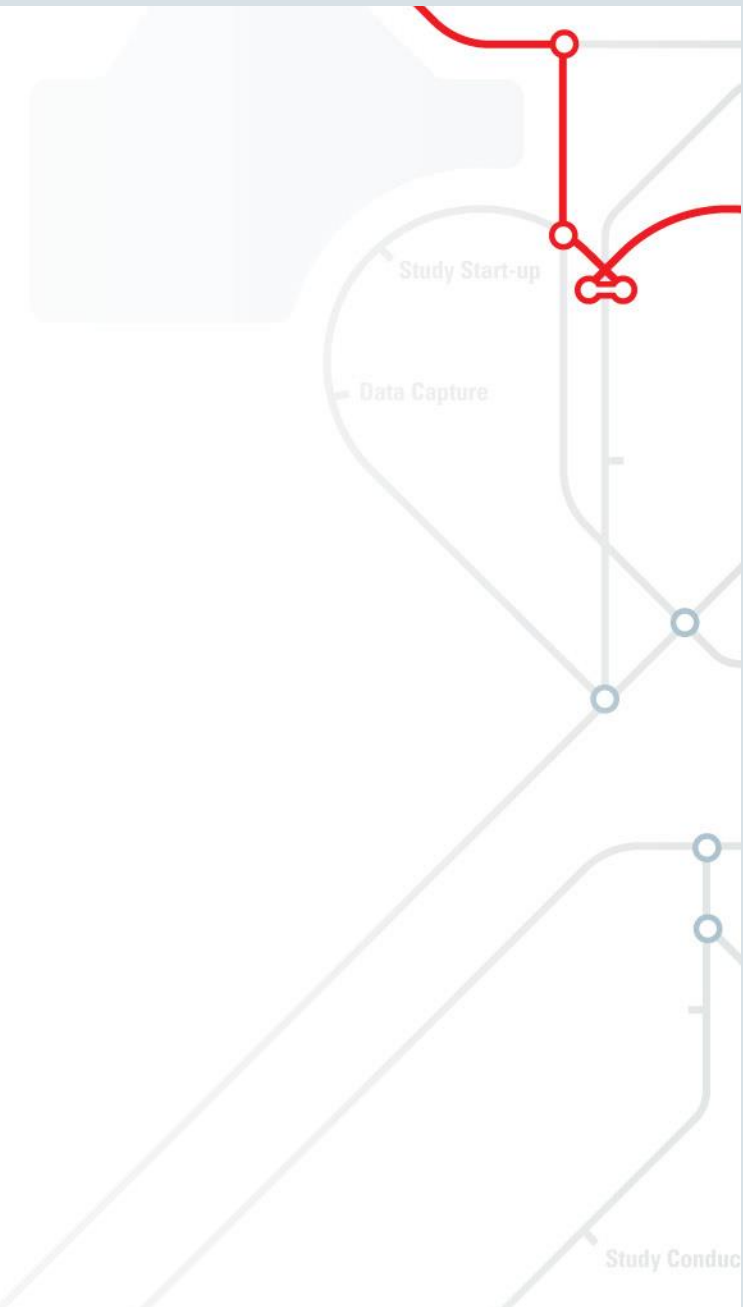
Program Agenda

- 1 ➤ Where did we come from?
- 2 ➤ Where are we now?
- 3 ➤ Where are we going?
- 4 ➤ Conclusion



Program Agenda

- 1 Where did we come from?
- 2 Where are we now?
- 3 Where are we going?
- 4 Conclusion





Where did we come from?

(Chemist Lee Geismer looking over an NDA in the 1960s)

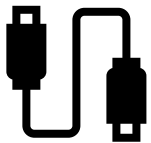
1961 - Hospital Computer Project



In 1961, BBN lead by Jordan J. Baruch, an MIT professor of electrical engineering, started the **Hospital Computer Project** at the **Massachusetts General Hospital**.



The modules included **admissions/discharge**, **medication** ordering and listing at the nursing station, and clinical chemistry **laboratory test** ordering and result **reporting**.



BBN had developed Time Sharing technology. This gave way to real-time access and modification data. The project was implemented in systems with **18bit memory and 5 simultaneous users**.



Problems: High cost, Difficulty in usage of teletype input, Slow Speed of communication, Limited Functions

Clinical Data Management System

Example #1: Clintrial



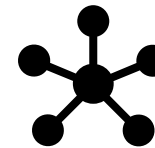
Built by BBN in the late 1970s, by the name of RS/1. Spin-off to **BBN Solutions**, rebranded **Domain Solutions**, spin-off to **Domain Pharma**, rebranded **ClinSoft**, acquired by **PhaseForward**, acquired by **Oracle**.

SUBJECT	COUNTRY	SEX	AGE
001-001	INDIA	M	45
002-002	INDIA	M	37
003-003	U.S.	F	55
004-004	U.S.	F	28

DB design is **fat tables**, e.g. one table with Demographics with one column for each field. Optimized for **data extracts**. Closer to the **data manager** and **statistician**.



Capabilities include **double data entry**, **data cleaning** on collected data, **coding**, data structure **design**, **controlled** environment with full **audit trail**, data **repository**.



Client server architecture, with deployment **on premise**.

Clinical Data Management System

Example #2: Oracle Clinical



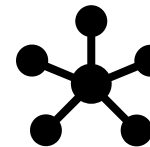
Oracle product, the first version was "Rx/Clinical". Later this turned into Oracle Clinical. Later added RDC for data capture.

NAME	SEX	AGE
JOHN DOE	M	45
JANE SMITH	F	32
JOHN DOE	M	45
JANE SMITH	F	32
JOHN DOE	M	45
JANE SMITH	F	32
JOHN DOE	M	45
JANE SMITH	F	32
JOHN DOE	M	45
JANE SMITH	F	32

DB design is “hyper-normalized”, **skinny tables**, e.g. one column with Field name, one with Field value. Optimized for **data entry**: normalized data in, denormalized data out.



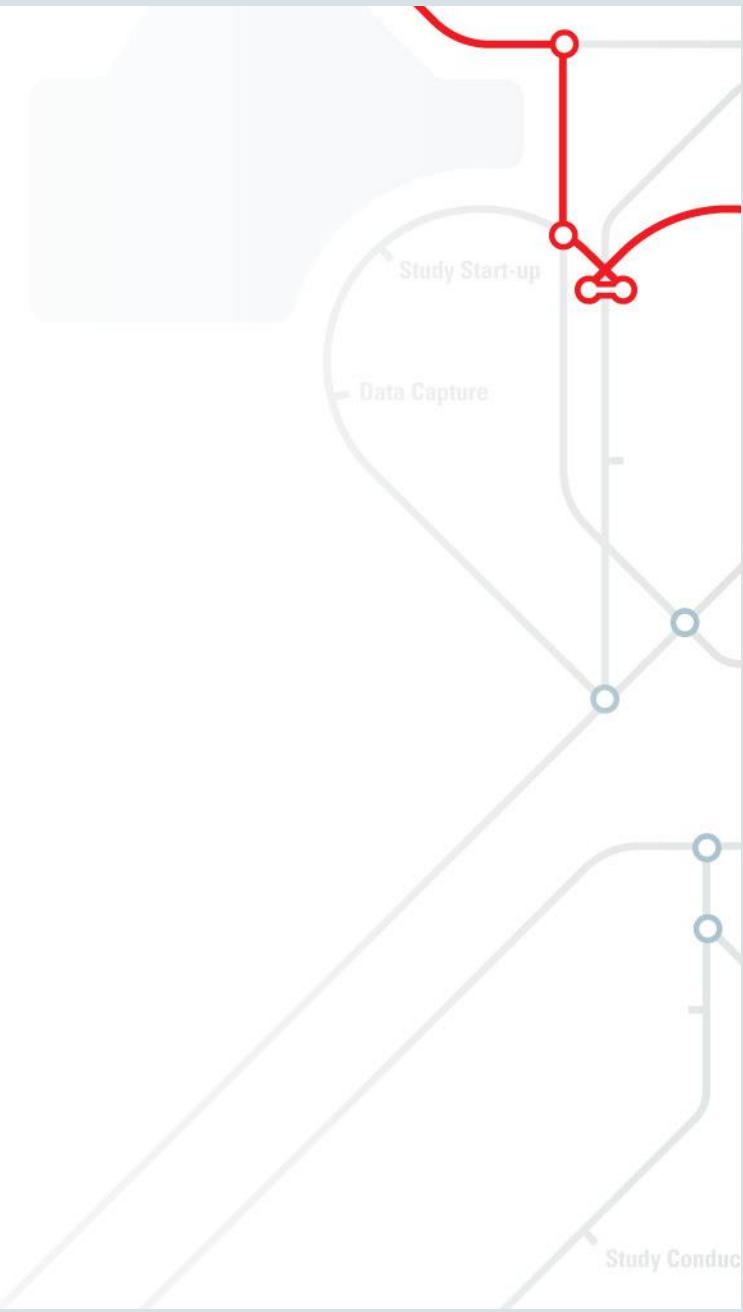
Capabilities include **double data entry**, **data cleaning** on collected data, **coding**, data structure **design**, **controlled** environment with full **audit trail**, data **repository**.



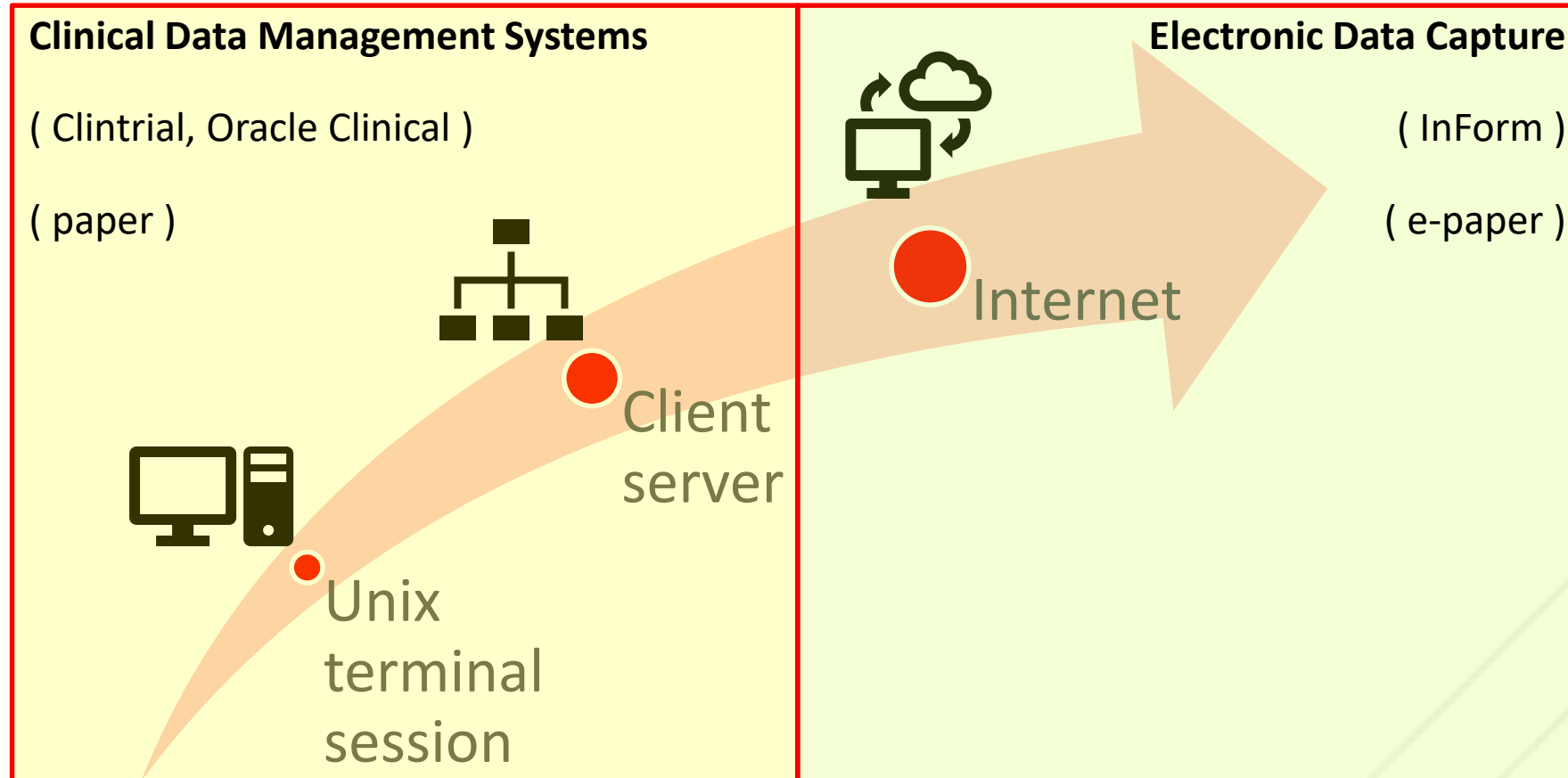
Client server architecture, with deployment **on premise**.

Program Agenda

- 1 Where did we come from?
- 2 Where are we now?
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- 4 Conclusion



Technical Intermezzo



Electronic Data Capture

Example: InForm



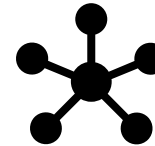
Phase Forward product, started in 1998. Acquired by Oracle in 2010. **Continues to be enhanced.**

SURID	COUNTRY	SEX	AGE
001-001	INDIA	M	45
001-002	INDIA	M	37
001-003	INDIA	F	67
001-004	INDIA	F	28

DB design has both **skinny tables**, and **fat tables** for data entry. Needs additional programming to use extracted data. Closer to **investigators, study coordinators, monitors, data managers.**

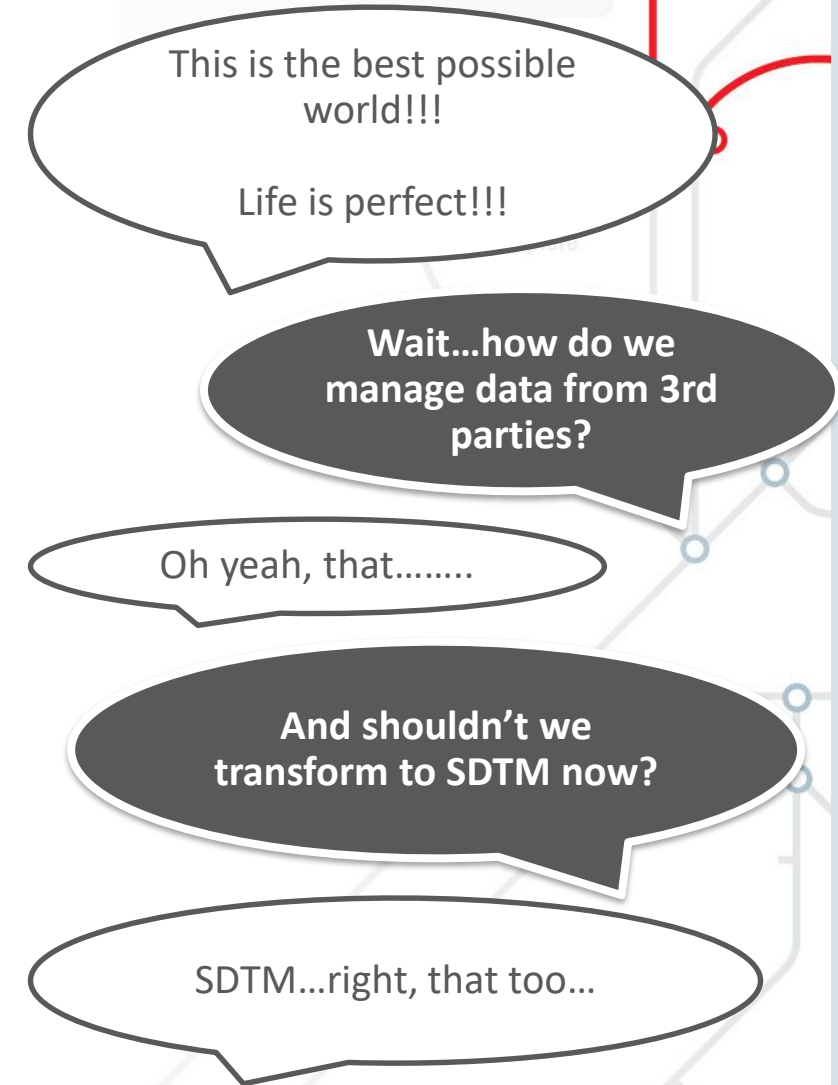
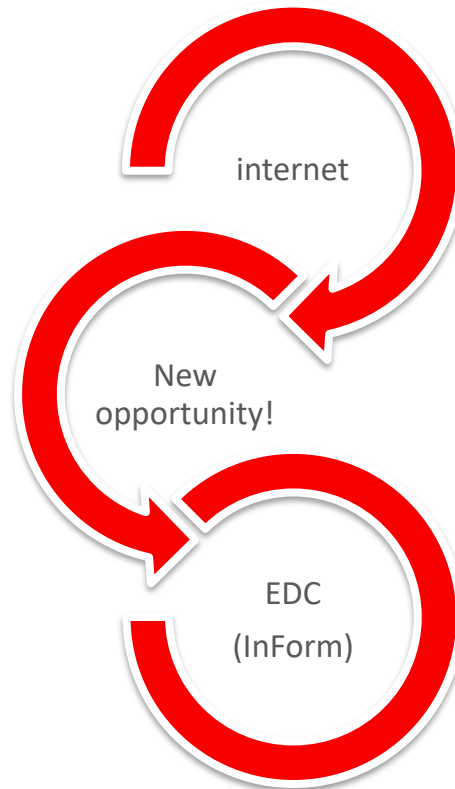
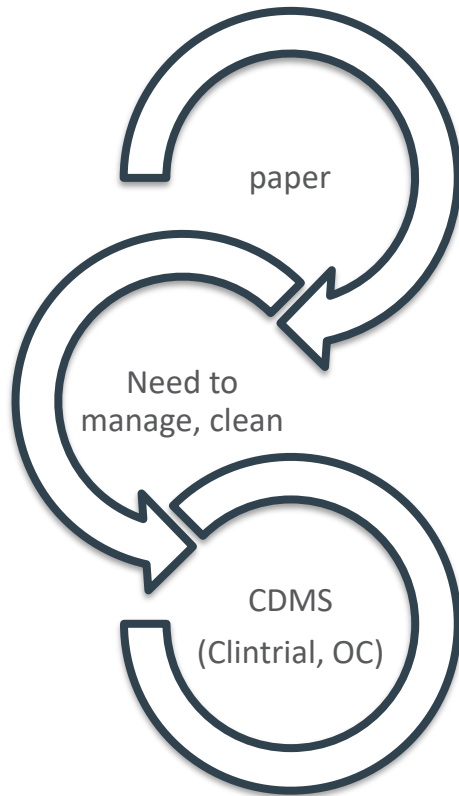


Capabilities include **data entry**, **data cleaning** on collected data, **coding**, data structure **design**, **controlled** environment with full **audit trail**. **Faster** data collection and cleaning.



Internet (3-tiers) architecture, with deployment (mostly) **on cloud**.

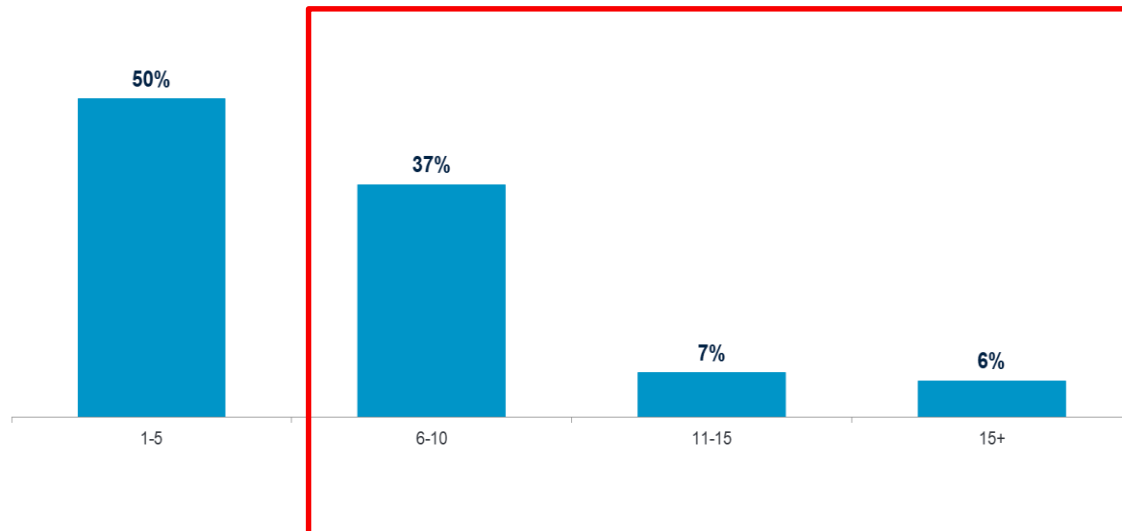
Why try harder?



Data Aggregation Challenges

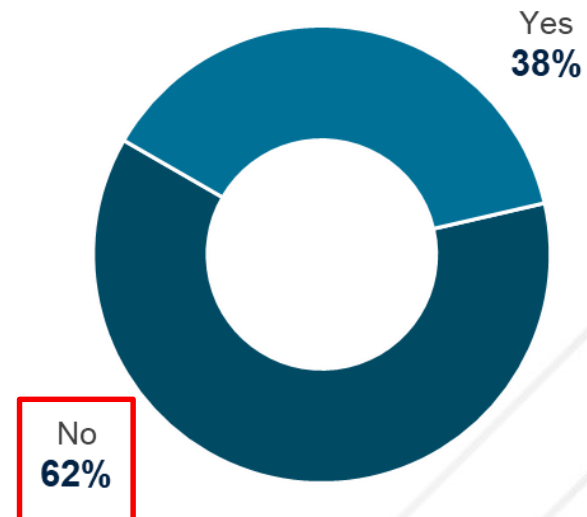
Number and complexity of data sources

How many different data sources do you have for a typical clinical trial?



Timely access to the data

Do you have real-time access to ALL of your clinical trial data?



<http://pharma.intelligence.informa.com/Challenges-Opportunities-In-Clinical-Data-Management?code=OraclePodcast>

Data Aggregation Platform

Example: Data Management Workbench



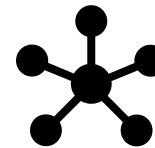
Oracle product, started in 2013.
Continues to be enhanced.

SURID	COUNTRY	SEX	AGE
001-001	INDIA	M	45
001-002	INDIA	M	37
001-003	INDIA	F	67
001-004	INDIA	F	28

DB design supports any data structure of source and target data. Closer to **data managers, medical reviewers, statistical programmers.**



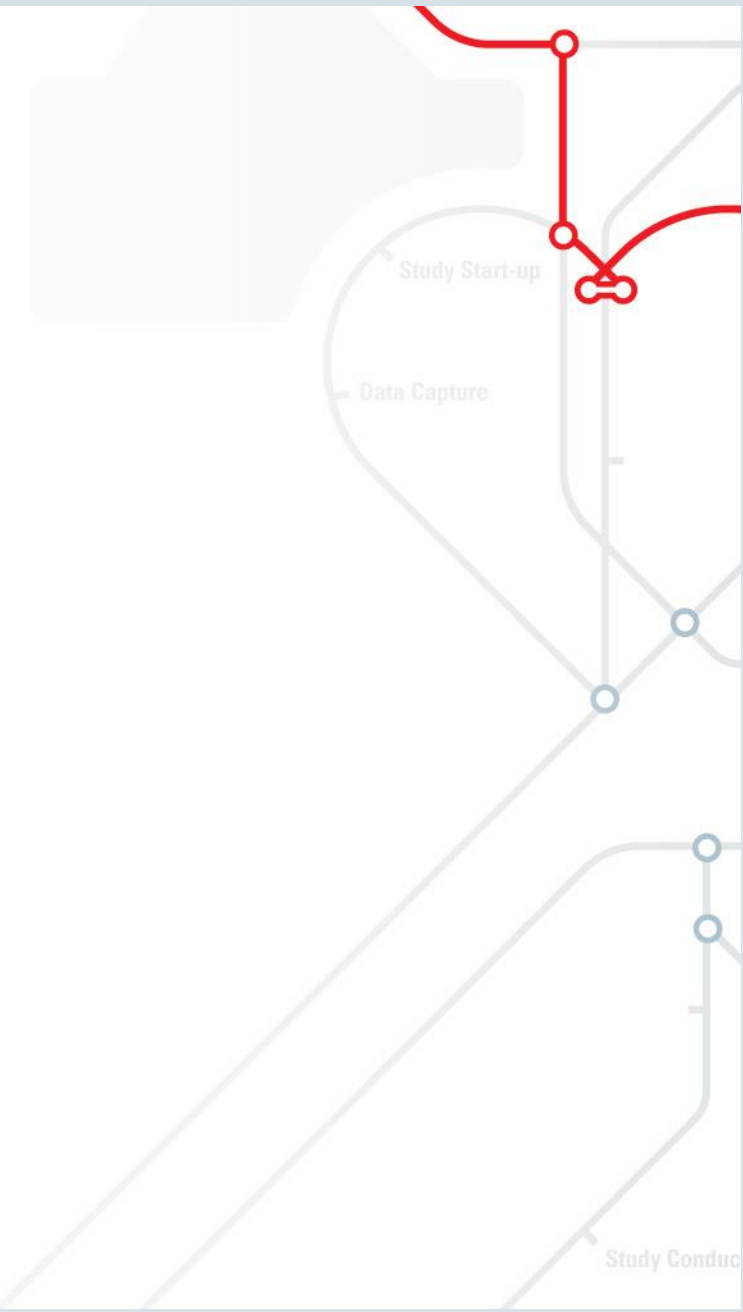
Capabilities include **data load**, integration with EDC, **data cleaning**, data aggregation, data transformation, **coding**, data structure **design**, **controlled** environment with full **audit trail**. **Faster** to clean and get to SDTM across **multiple sources**.



Internet (3-tiers) architecture, with deployment (mostly) **on cloud**.

Program Agenda

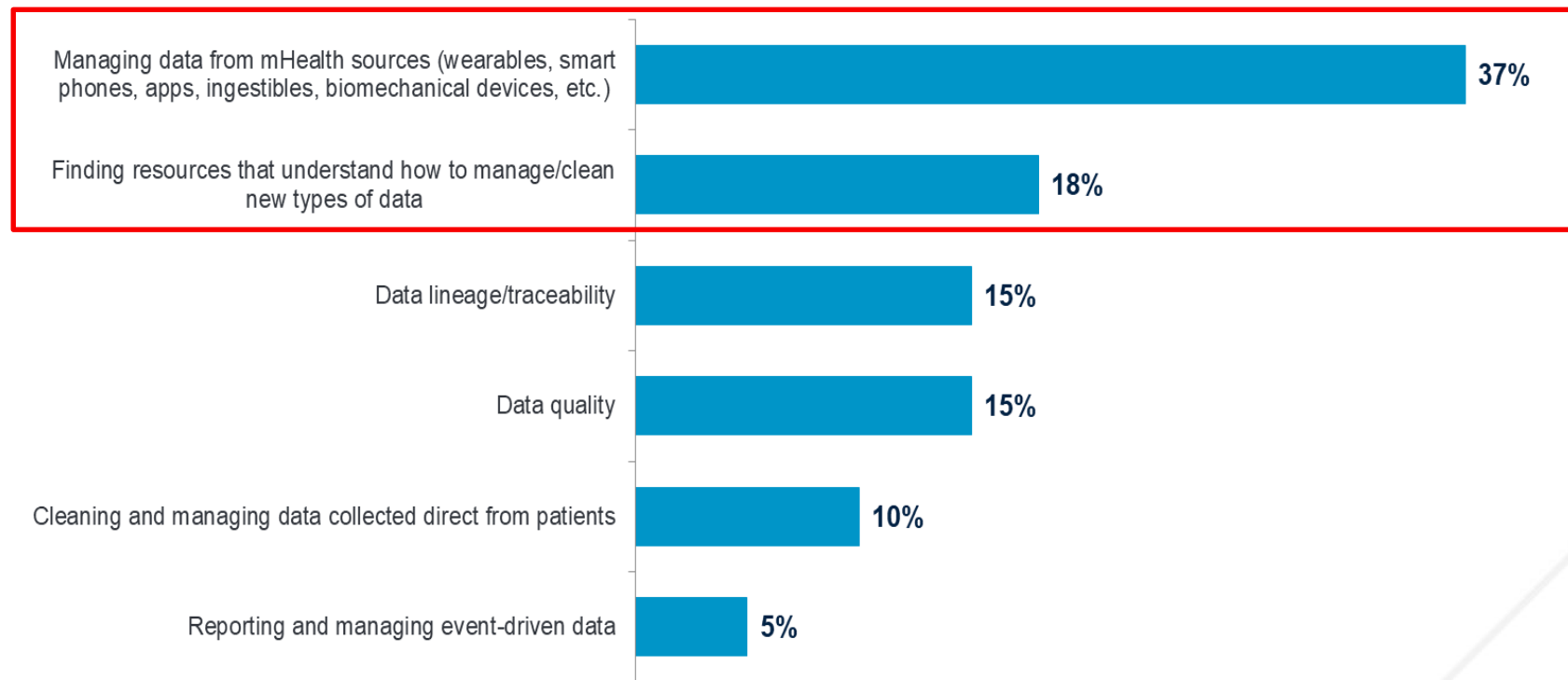
- 1 Where did we come from?
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Future Outlook #1

New data sources

Five years from now, what do you think will be the most urgent challenge, when it comes to clinical trial data?



<http://pharma.intelligence.informa.com/Challenges-Opportunities-In-Clinical-Data-Management?code=OraclePodcast>

Future Outlook #1

Data management may change too

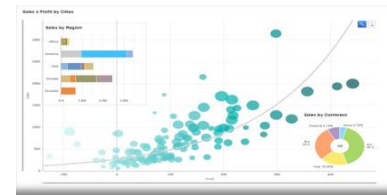
ACQUIRE

Internet of Things



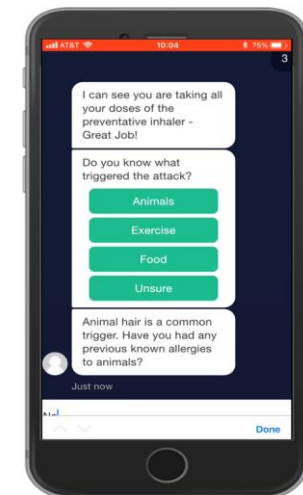
EXPLORE & MONITOR

Integrated Analytics



ADAPT & LEARN

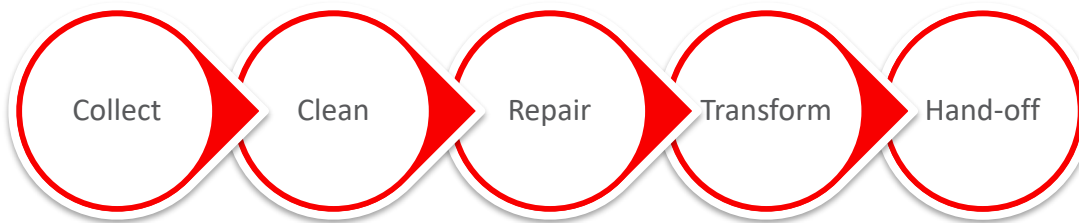
Machine Learning and AI



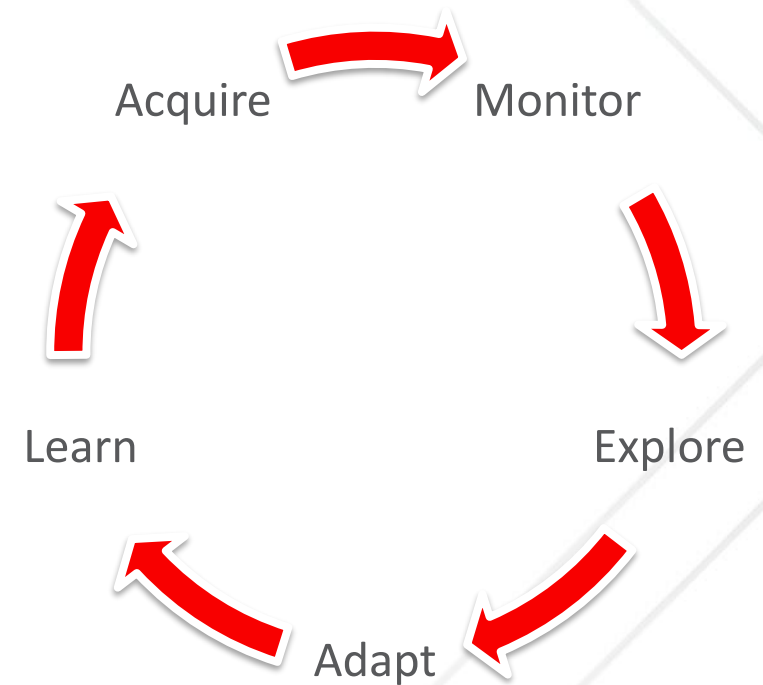
Future Outlook #1

Data management may change too

From Clinical Data Management....



...to Clinical Data Science

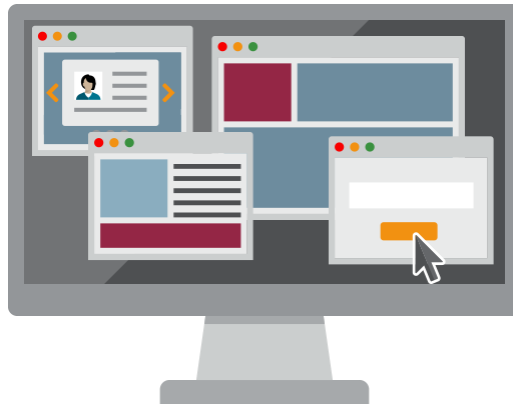


Future Outlook #2

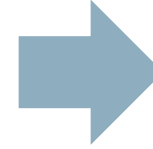
Addressing complexity



First, there was
paper...



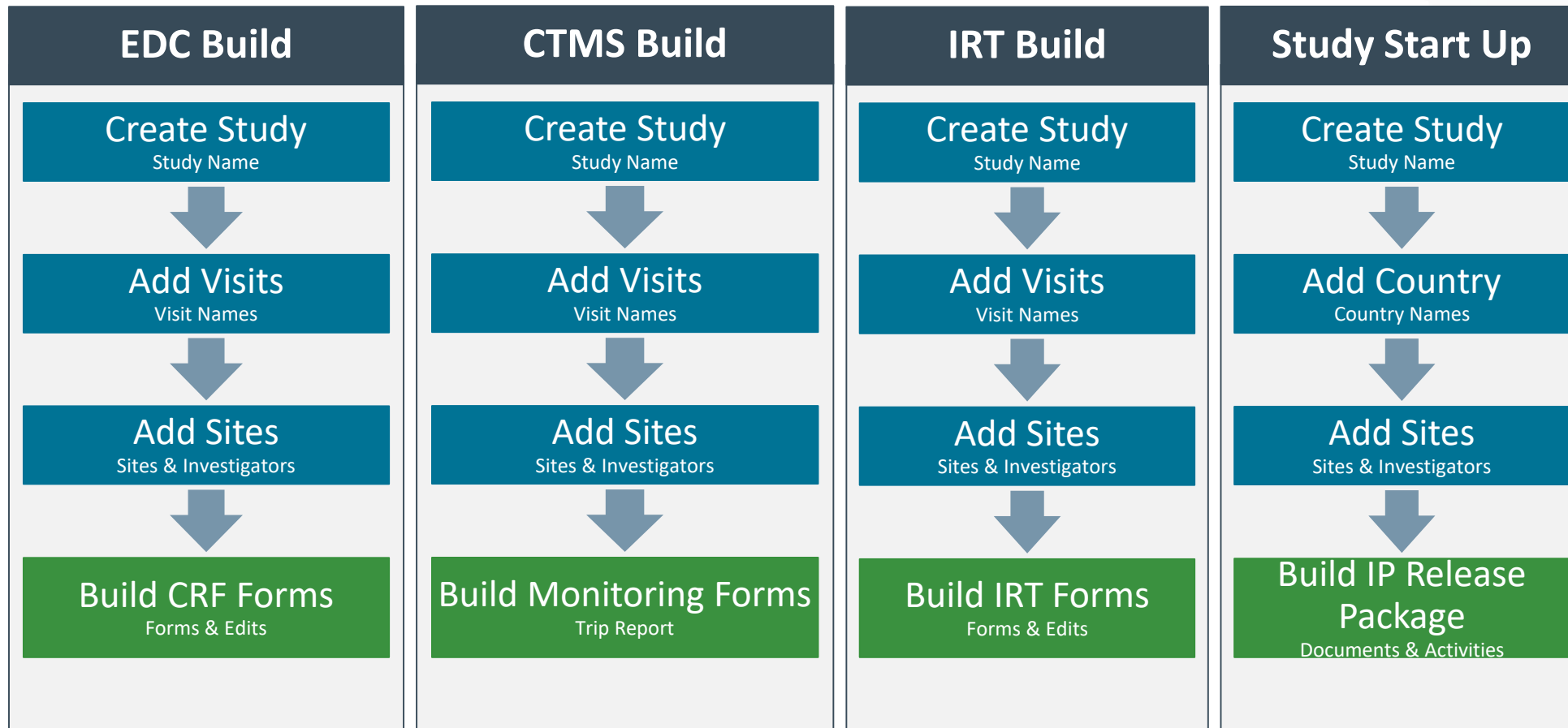
Then, there were
point solutions...



Now, there's
a mess...

Future Outlook #2

Addressing complexity

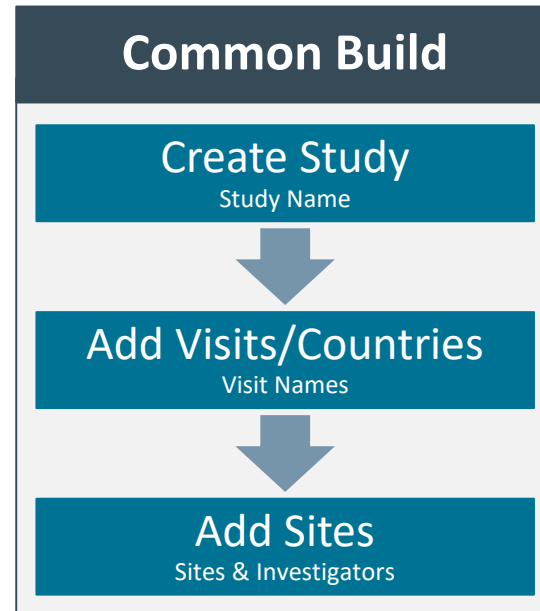


DISADVANTAGES

- Duplicative data entry
- Inconsistencies in the study
- Mapping required for analytics
- Not efficient

Future Outlook #2

Addressing complexity



Data Collection Build

Build CRF Forms
Forms & Edits

Trial Management Build

Build Monitoring Forms
Trip Report

RTSM Build

Build RTSM Forms
Forms & Edits

SSU Build

Build IP Release
Package
Documents and Activities



ADVANTAGES

- Streamlined master data
- Data entered once
- No integration
- Available via API for third party use
- Eliminates mapping for analytics

Future Outlook #2

Addressing complexity



*Build a study **ONCE**,*



*Enter data **ONCE**,*



*Do everything in **ONE** place.*

Conclusion

Thank you

claudio.garutti@oracle.com

Integrated Cloud

Applications & Platform Services

ORACLE®