



PhUSE Single Day Events

Uxbridge, UK

22nd May, 2017



Intelligent Data Flow: better access to data for better patient experiences and health outcomes

This SDE will be a day of discussions regarding innovative designs and solutions for expediting and improving patient dataflow from study design through to regulatory submissions. Discussions will be focused on:

- Improving the patient clinical trial experience
- Expanded use of metadata in support of patient clinical data flow
- Automated study build/setup, transformations, and programming
- Reducing manual intervention and mediation in non-value-added-data management activities
- Pivoting from data management to data science.



House Keeping Notes



Welcome to Amgen, Uxbridge

Below are a few housekeeping notes we would like to draw your attention to:-

- Should the **Fire Alarm** sound, please make your way to the Main Reception Area (through the double doors in front of Kew/Richmond) and exit the building via the main entrance. Our evacuation station is located at the far left of the car park *[Alarm Test at 2pm on Tuesday]*
- The **Restrooms** are located near Reception, on either side of the lifts, Ladies to the left and Gentlemen to the right.
- Should you require a **Taxi** after the conference, please complete one of the taxi request forms and pass to Gary Hearfield. These will be collected, taxis booked and confirmation given back to you during the afternoon break.

Please complete the form below to gain access to the network.

Visitor Registration

* Sponsor's Name:
Name of the Amgen staff member sponsoring this visit.

* Sponsor's Email:
Email of the Amgen staff member sponsoring this visit.

* Your Name:
Please enter your full name.

Company Name:
Please enter your company name.

* Email Address:
Please enter your email address.
This will become your username to log into the network.

* Confirm: ☐ I accept the [terms of use](#)

Register

* required field

Already have an account? [Sign In](#)



To Log onto the Wifi System:

1. Locate and select the "**AMGuest**" network
2. First-time guests click the "Need an Account" link to set up an account and specify Claire Boston (cboston@amgen.com) as the sponsor
3. You will receive login details which will remain valid for 24 hours



AGENDA

Time	Presentation	Presenter
8.30 - 9.00	Registration and Coffee	
9.00 - 9.30	Welcome and Introduction to SDE	Matthew Harrington, Accenture
9.30 - 10.00	PhUSE Updates PhUSE Edinburgh 2017 PhUSE Board Updates	Jules van der Zalm, OCS Consulting Anup Patel GSK
10.00 - 10.15	Morning Break	
10.15 - 11.15	Patient-Centric Clinical Data Capture	Douglas Bain, eClinicalHealth
11.15 - 12.15	How should we operationalize a “Metadatacentric” strategy, and what are the transformational impacts?	Jason Housley, GSK
12.15 - 13.15	Lunch	
13.15 - 14.15	It’s Time To Change: Leveraging Semantic Technology to Streamline Mapping Processes	Dave Iberson-Hurst Assero
14.15 - 15.00	Combining Graphing Technologies and Conceptual Ontologies for Better Data Analytics	Peter Tormay, Capish Intl
15.00 - 15.15	Afternoon Break	
15.15 - 16.00	Engaging the Patient: Integrated Patient Services	Jonathan Burr, Accenture
16.00 - 16.30	Conclusion and Panel Q&A	All Presenters



Welcome to Amgen, Uxbridge

- Requests of Meeting:
 - Will do our best to be prompt for breaks and re-starts
 - Be Engaged!
 - Stay present (laptops generally closed)
 - Ask questions, propose scenarios
 - Have fun



Sponsors

We would like to thank our sponsors for their support:



PhUSE Future Events

SDE	Date
Copenhagen, Denmark	June
Chilly-Mazarin, France	September
Beerse, Belgium & Bloemfontein, South Africa	November
Full details and event dates can be found on the PhUSE website: www.phuse.eu/single-day-events-2017	



The poster features a large, detailed photograph of Edinburgh Castle, a historic stone fortress perched on a rocky hillside under a clear blue sky. The PhUSE logo is in the top right corner. The text 'Annual Conference' is in the top left. The main title 'Edinburgh 2017' is prominently displayed in large white letters. Below it, the subtitle 'Digital Innovation in Healthcare' and the dates '8th-11th October' are listed. The venue 'Edinburgh International Conference Centre' is mentioned. At the bottom, the conference chair and co-chair are named, along with a QR code and the PhUSE website URL.

phuse

Annual Conference

Edinburgh 2017

Digital Innovation
in Healthcare
8th-11th October

Edinburgh International Conference Centre

Edinburgh Castle

Conference Chair Jules van der Zalm, OCS Consulting
Conference Co-Chair Katja Glaß, Bayer Pharma

For more information visit the PhUSE website – phuse.eu/annual-conference.aspx





The premier community for people working in the biometric area



@PhUSETwitta



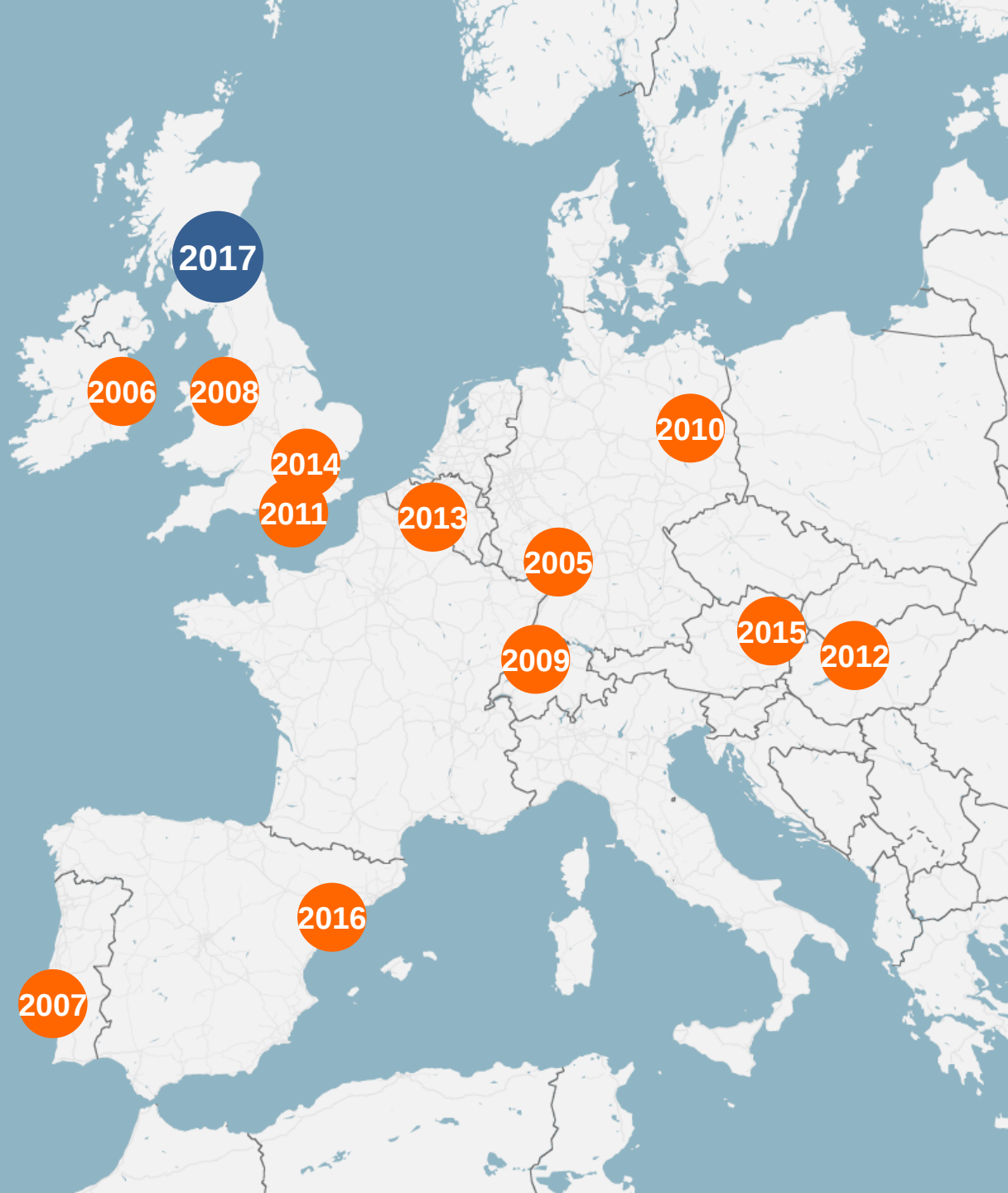
PhUSE



www.phusewiki.org

Digital Innovation in Healthcare







Old Town of Edinburgh



Edinburgh Castle



Haggis



Whisky





Edinburgh International Conference Center – EICC



Keynotes



Wayne Kubick, HL7

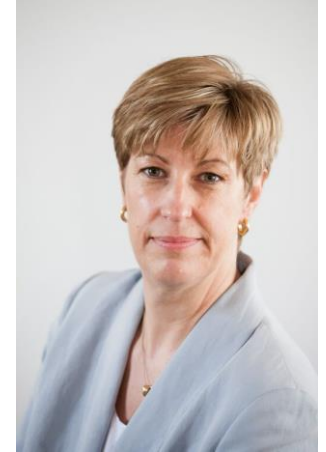
"The Shortest Distance Between Two Points"

An expert advisor and commenter, focusing on improving clinical research through technology and data standards.

Helen Morris-Brown

A business psychologist, TEDx speaker and performance coach.

Understand how to embrace change and optimise performance.



Gavin Hastings

Former Rugby Union player, who will share motivational anecdotes.



Key Dates

- Early Bird Registration Deadline – 30th June
- Hotel Booking Deadline – 30th June
- Hands on Workshop Registration opens – 1st September
- Conference Start Date – 8th October



Paper Submissions

**266 Paper Submissions
Across 14 Streams**

New Streams

- Analytics & Statistics
- Coding Tips & Tricks
- Data Standards & Governance
- Standards Implementation



Hands-on Workshops & Discussion Clubs

**R
Workshop**

**Introduction to
Linked Data &
Graph Databases**

**Propensity Score
Matching**

**CDISC – Moving
from 2D to 3D
Standards**

**CSS Discussion
Club**



Conference Highlights

Three Keynote Speakers

Sunday
Welcome Event & Poster
Session

125+
Presentations

**Interactive Hands-on Workshops &
Discussion Clubs**

**40 Exhibitors &
Sponsors**

Monday
Dinner & Social Event

We hope to see you there.....



Digital Innovation in Healthcare



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TENETS OF INTELLIGENT DATA FLOW

Simplified, real-time access to patient data and study information

Automated processes that reduce work and eliminate inefficiencies

Accelerated cycle times in study start-up and backend data management processes

Patient services designed into our clinical trials to foster a better patient experience

STRATEGIC IMPERATIVE FOR INTELLIGENT DATA FLOW

DATA SOURCES of Growing Complexity



Form-based Data Collected at clinical sites

Patient Diary Data



Connected Device Data

Lab Results Collected at Diagnostic Centers



DATA COLLATION, TRANSFORMATION and ANALYSIS

DATA USES of Growing Complexity

Structured Regulatory Submissions



Internal Decision Making

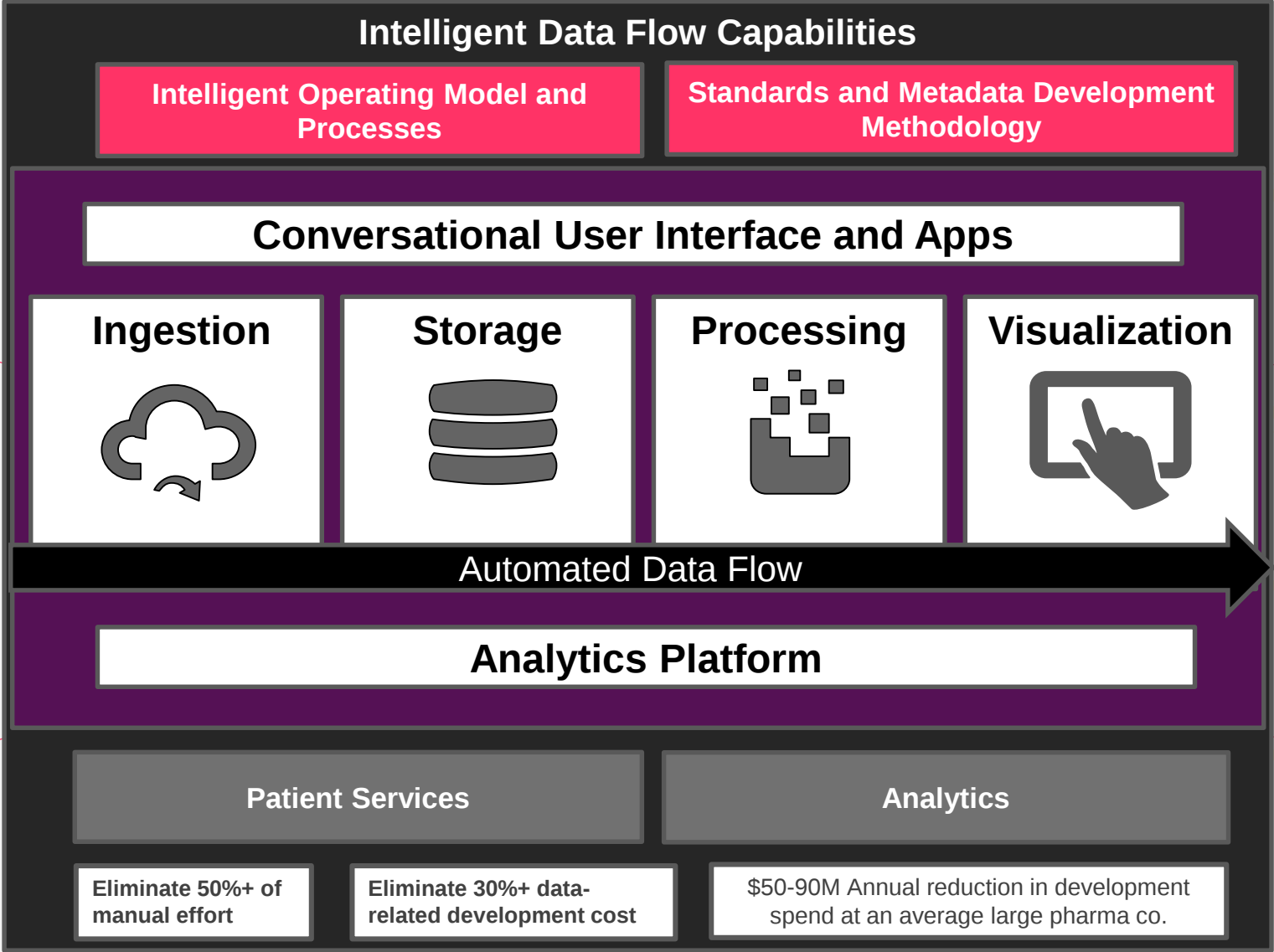
Iterative Program and Study Design & Analytics



Comparative Effectiveness Submissions to Payers

VISION FOR INTELLIGENT DATA FLOW

Data SOURCES



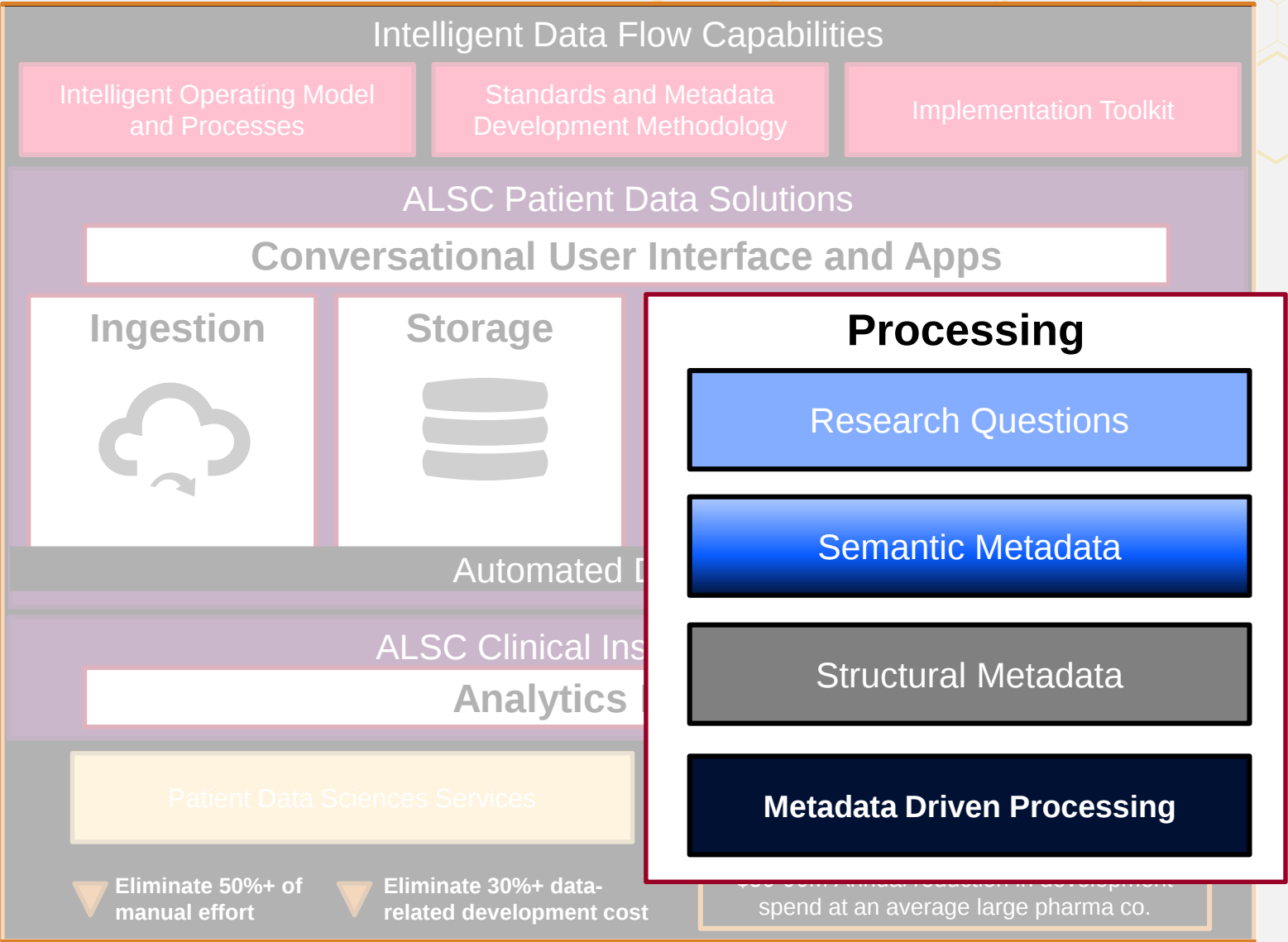
Data USES

COMPONENTS TO ENABLE INTELLIGENT DATA FLOW

We believe that clinical research is best characterized by the **questions** a particular study aims to address.

These questions and their associated concepts are the fundamental **units of thought that tie together an end-to-end** view of the data that will ultimately be **collected, aggregated, and analyzed**.

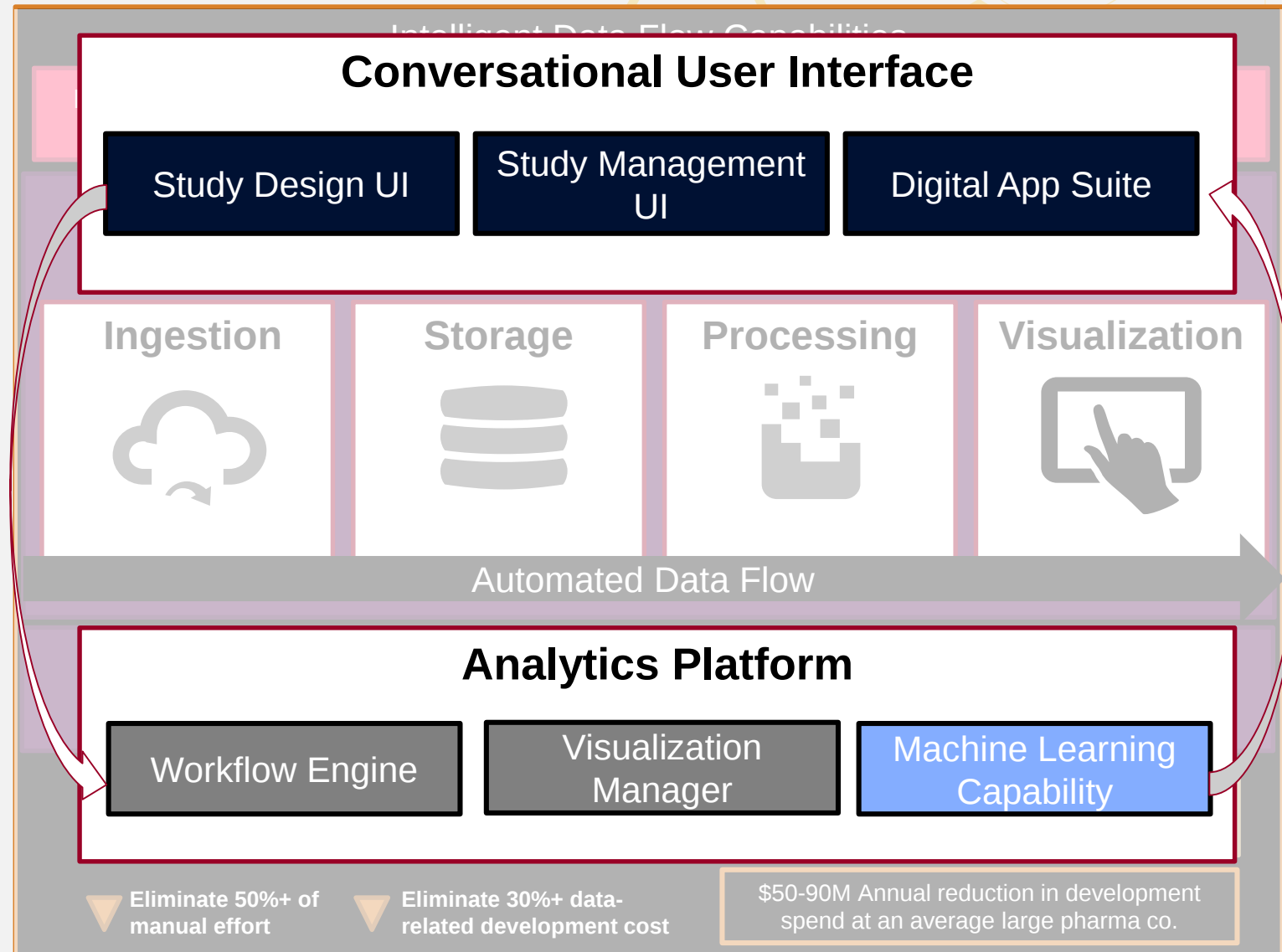
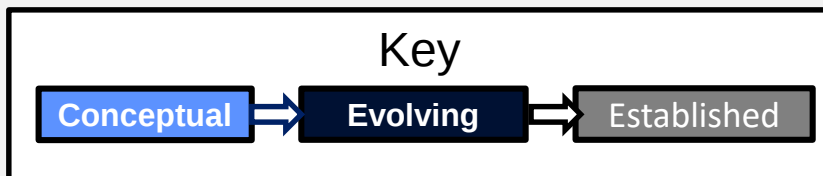
As such, to full apply **automation and metadata driven processing**, metadata must evolve **semantically** to facilitate user interactions and business decisions



COMPONENTS TO ENABLE INTELLIGENT DATA FLOW

We envision that users will engage with a suite of “**apps**” that support the **business outcomes** for which they are responsible, rather than with traditional, silo’d “systems.”

This design will incorporate **machine learning capabilities** throughout to enhance an business-user’s understanding of company and industry priorities via **research questions and work related activities**. Business decisions will result in the necessary tools and connections to support said priorities and objectives.



RE-VISITING TODAY'S AGENDA

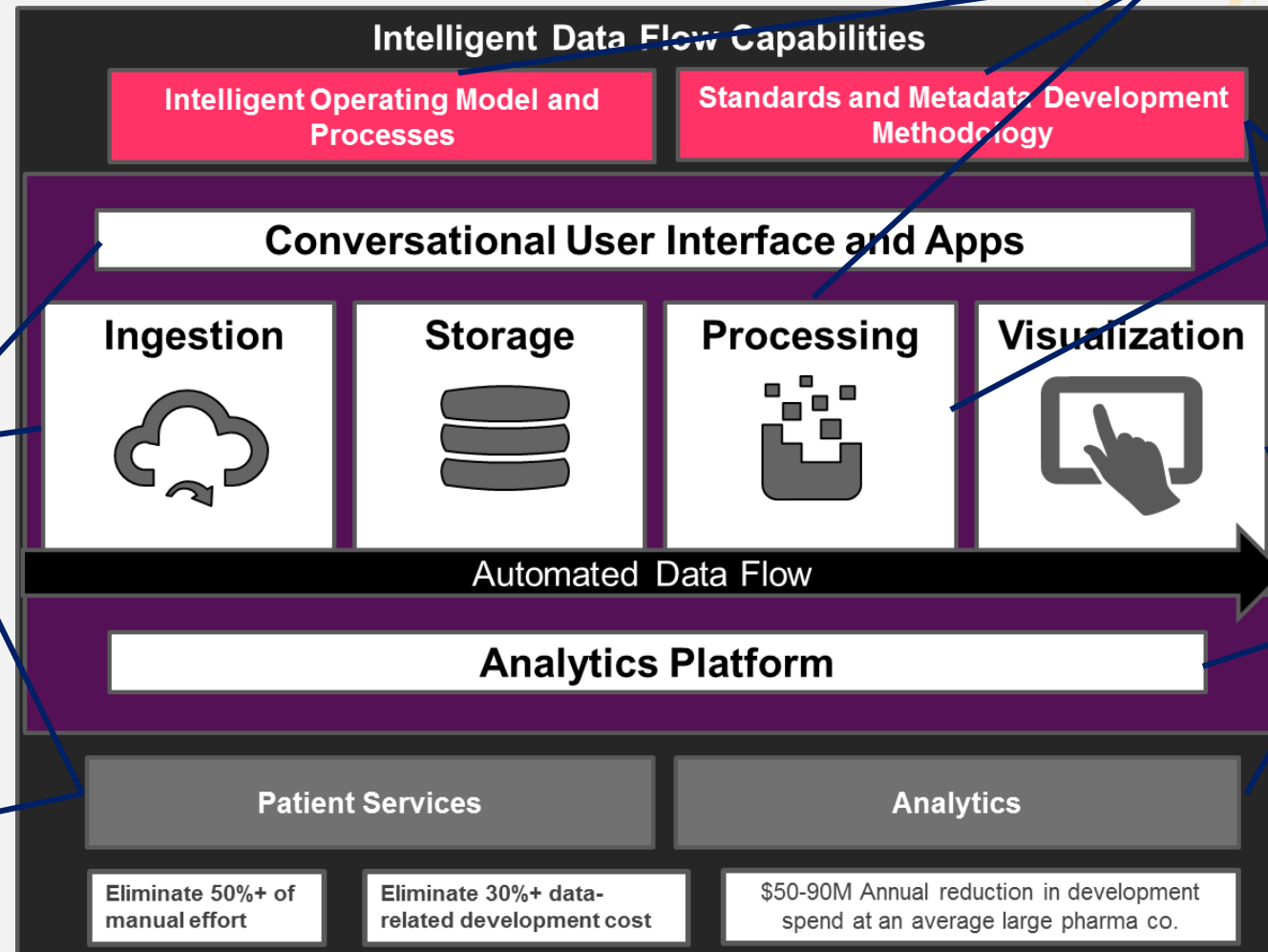
Operationalizing a
“Metadatacentric” Strategy
Jason Housley
GSK
11:15-12:15

It's Time To Change
Dave Ibersen-Hurst
Assero
13:15-14:15

Combining Graphing
Technologies and
Conceptual Ontologies
for Better Data Analytics
Peter Tormay,
Capish
14:15-15:00

Patient-Centric
Clinical Data Capture
Doug Bain,
eClinicalHealth
10:15-11:15

Integrated Patient
Services
Jonathan Burr
Accenture
15:15-16:00



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PATIENT DATA FLOW AND EXPECTED OUTCOMES

Intelligent Data Flow

Collection & Collation

Source Data Views

Data Management Views

- **Faster study start** – Database build in 2 days to under 2 weeks
- **Faster study close** – Less than 2 day cycle for database lock to clean file
- Elimination of avoidable protocol amendments for data and design changes
- Cleaning and monitoring via trends in the data (i.e. RBM-enabler)
- Enables adoption of digital collection methods and connected devices

Transformation

Tabulation Data

- **Faster data prep**
 - Compliant datasets produced in minutes
 - Pooled data (e.g. for ISS/ISE) within hours
- Elimination of effort preparing and transforming data
- Real-time access to tabulated data throughout study execution

Analysis & Reporting

Analysis Data

Submission Components

- **Faster data outputs**
 - Go/no-go decision packages within 24 hours
 - Top-line results within 48 hours
 - Final TLFs less than 2 weeks from DBL
- Elimination of effort producing standardized outputs
- Reduced effort producing custom outputs
- Real-time access to illustrative outputs throughout study execution

Integrated End-to-end Solution

- Automated, real-time, data-driven insights to influence program and study design
- **50%+ reduction in manual effort** related to data management and analysis across the development lifecycle
- **20-30% reduction in headcount** within data management and biostatistical programming functions
- **30%+ reduction in costs** for data-related development activities