

Where next for Clinical Trial EHR eSource data transfer – and is AI the answer?



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Agenda

→ eSource-to-Sponsor overview

→ Structured data today

→ What is the impact of structured data on clinical trials?

→ What data is unstructured and how much is there?

→ The endgame

→ Approaches to AI

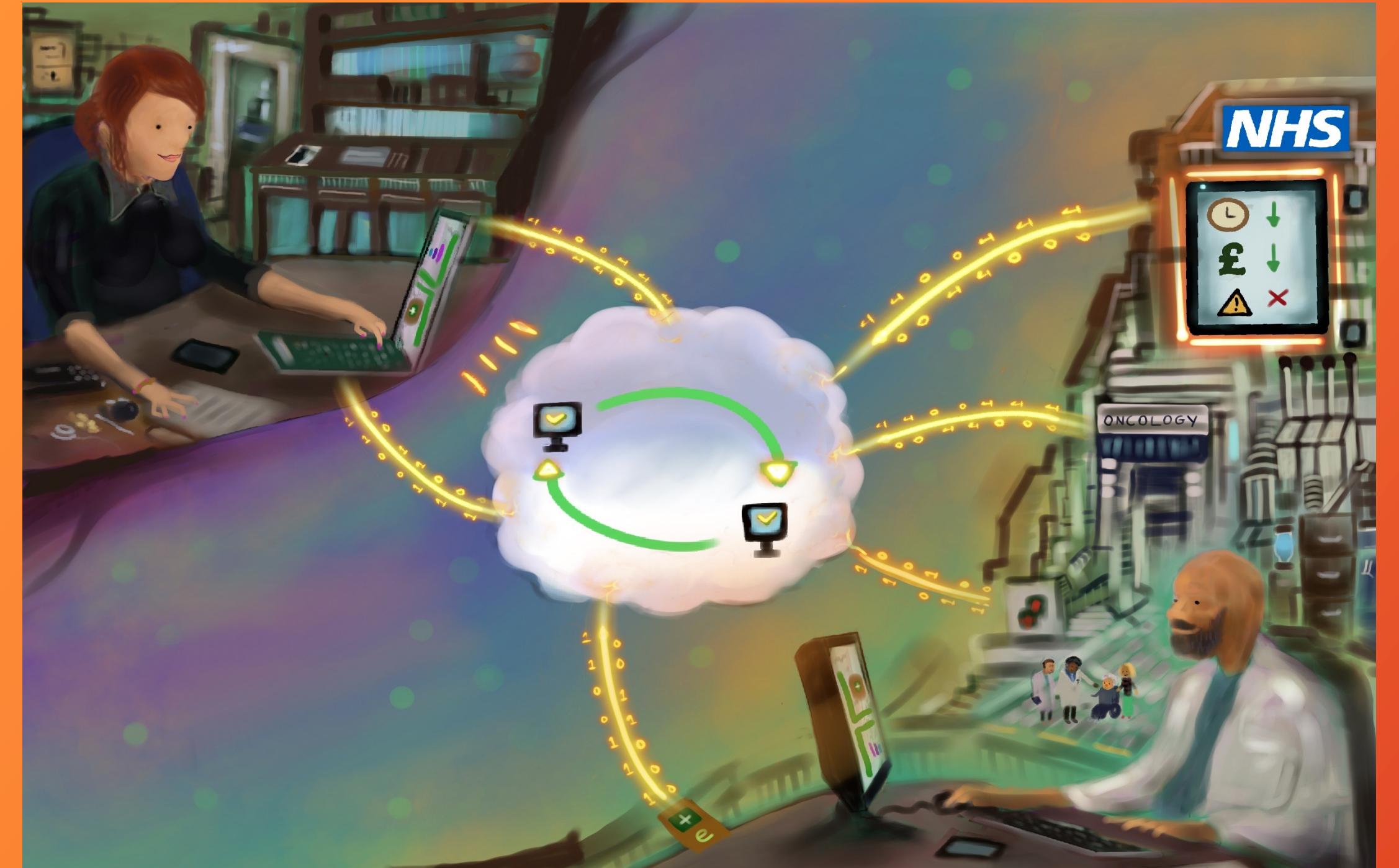
→ Is AI the answer to EHR eSource data transfer?

ACDM 2024
Copenhagen, 3-5 March 2024

BEFORE



AFTER



How technology enables EHR-to-EDC data transfer



Structured data domains with high EHR-to-EDC potential

1

Laboratory

The system is able to rapidly export lab data and this is often the largest burden in many study designs.

2

Concomitant Medications

Certain studies can have hundreds on conmeds per patient and this data can be transferred by the system.

3

Vital Signs

Often required in interventional studies and certain study designs (especially critical care) have a large burden here.

4

Demographics

A less valuable example as the volume of data required is often fairly low, but the system can still help if required.

What impact can EHR-to-EDC have on a study today?

ONCOLOGY STUDY – GASTRIC AND GASTROESOPHAGEAL JUNCTION CANCER

- 900 patients
- 20 visits per patient
- EHR-to-EDC used for 16 forms (15% of total forms)
- 6 vital signs forms
- 9 lab forms
- 1 conmeds form (avg. of 50 medications)

For this study example, from the 15% of mapped total forms, the system is transferring 50-70% of all data for the study.

Total number of data items per patient	1374
Average time taken due to manual data entry	3 minutes*
Average time taken per patient to enter data manually over 20 visits	4122 minutes = 68.7 hours

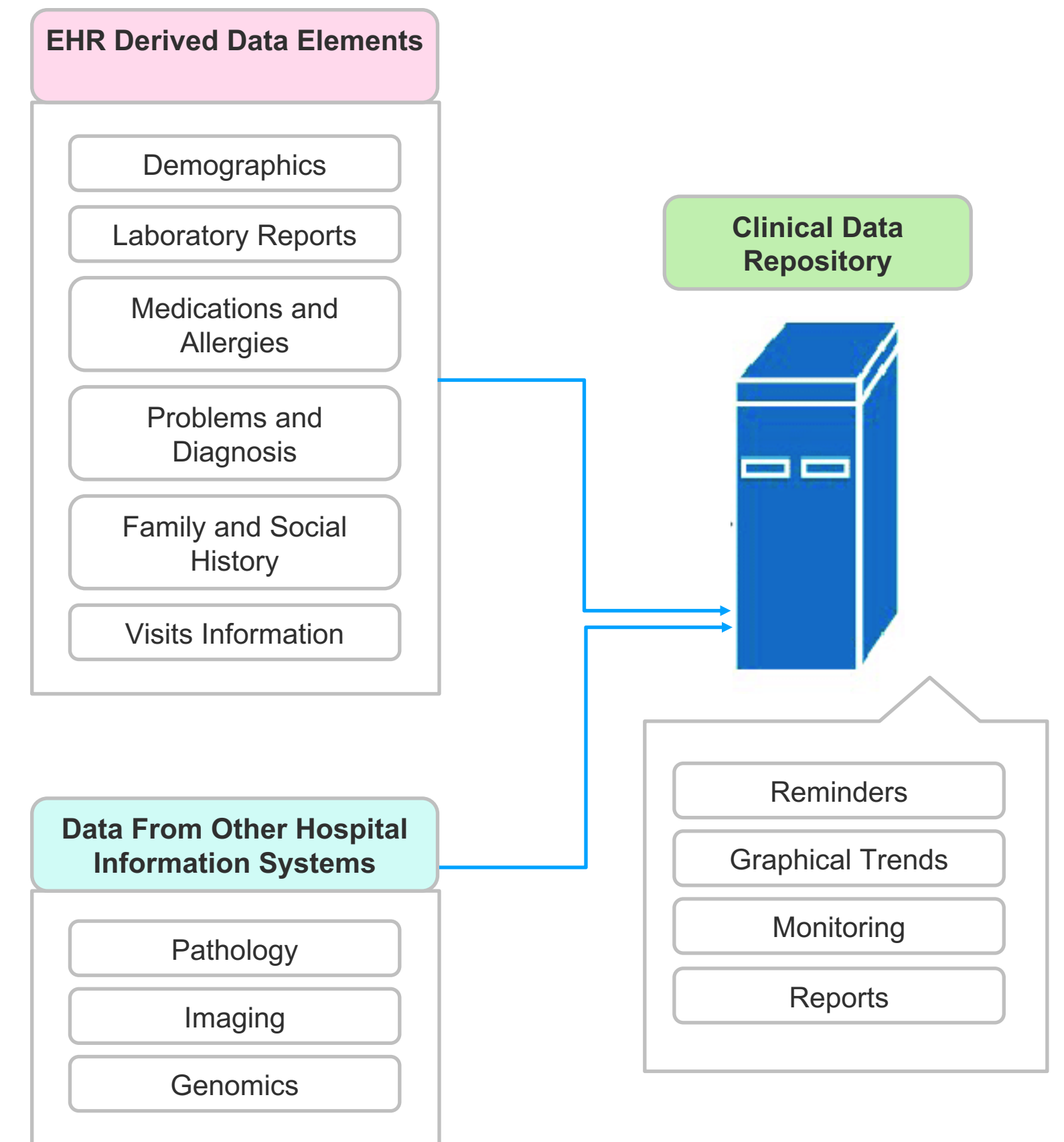
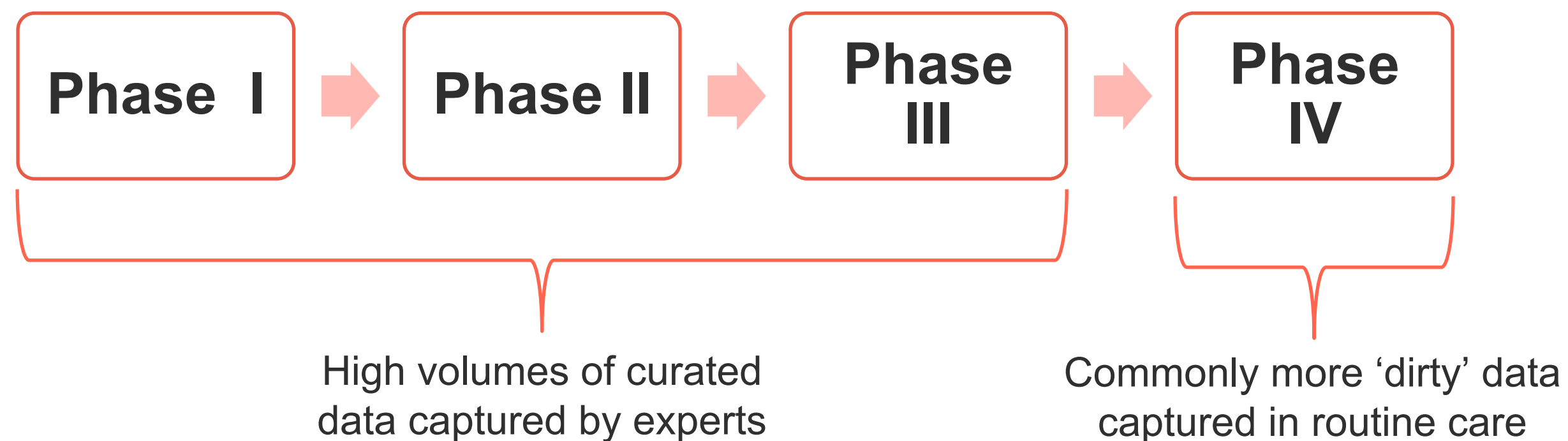


*Source: Sanofi, EHR2EDC consortium project

** Time per visit using automation benchmarked at 7 minutes per visit / 2.3 hours across 20 visits

Understanding unstructured data

- Typically, the 80/20 rule applies to unstructured data.
- If 50-70% of the data required for a clinical trial is structured data, how do we solve the other 30-50%?
- Research indicates that 80% of the unstructured data in healthcare is imaging – a highly specialised category.



Shah, Shahid & Khan, Rizwan. (2020). Secondary Use of Electronic Health Record: Opportunities and Challenges. IEEE Access. PP. 1-1. 10.1109/ACCESS.2020.3011099.

The endgame

- Providing unstructured data in a regulatory-compliant way requires a 'human in the loop'.
- When data is presented to site experts, they need to be able to look 'under the hood'.
- There are many challenges en route to this perfect endgame.

A Web Page

← → ↻ 🔍 https://

Tumour Evaluation

Patient Hospital Number: CV0056783 | EDC Subject ID: JA-OE-004

Please check the extracted data and select any relevant data.

Any Target Lesion Present	Recorded Date
<input checked="" type="checkbox"/> Yes View Context	21/07/2021
<input checked="" type="checkbox"/> 07/07/2021 View Context	21/07/2021
<input checked="" type="checkbox"/> 02/03/2021 View Context	15/04/2021



A Web Page

← → ↻ 🔍 https://

Document Analysis

Document Type: Discharge Summary
Document Date: 21 July 2021

Context

<input checked="" type="checkbox"/> Current	<input checked="" type="checkbox"/> Affirmed
<input type="checkbox"/> Past	<input type="checkbox"/> Negated
<input type="checkbox"/> Future	<input type="checkbox"/> Hypothetical
<input checked="" type="checkbox"/> Patient	<input checked="" type="checkbox"/> Confirmed
<input type="checkbox"/> Family	<input type="checkbox"/> Suspected
<input type="checkbox"/> Other	

Search Entities Identified:

- PARENT
- 52988006 (Lesion)
- CHILDREN
- 19316008 (Cytoid body - morphologic abnormality)
- 397325001 (Ferruginous body - morphologic abnormality)
- 68135008 (Fibrous obliteration - morphologic abnormality)
- 125379004 (Focal atrophy - morphologic abnormality)
- 16224971000119101 (Morton's neuroma - morphologic abnormality)

Source Document (Annotated):

Example Hospital
15 Example Road
Example City EX10 0EF

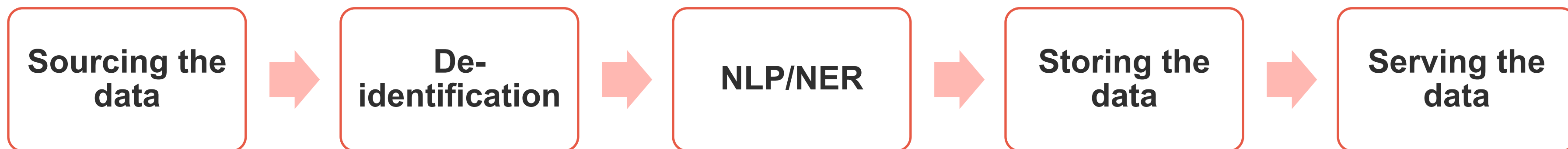
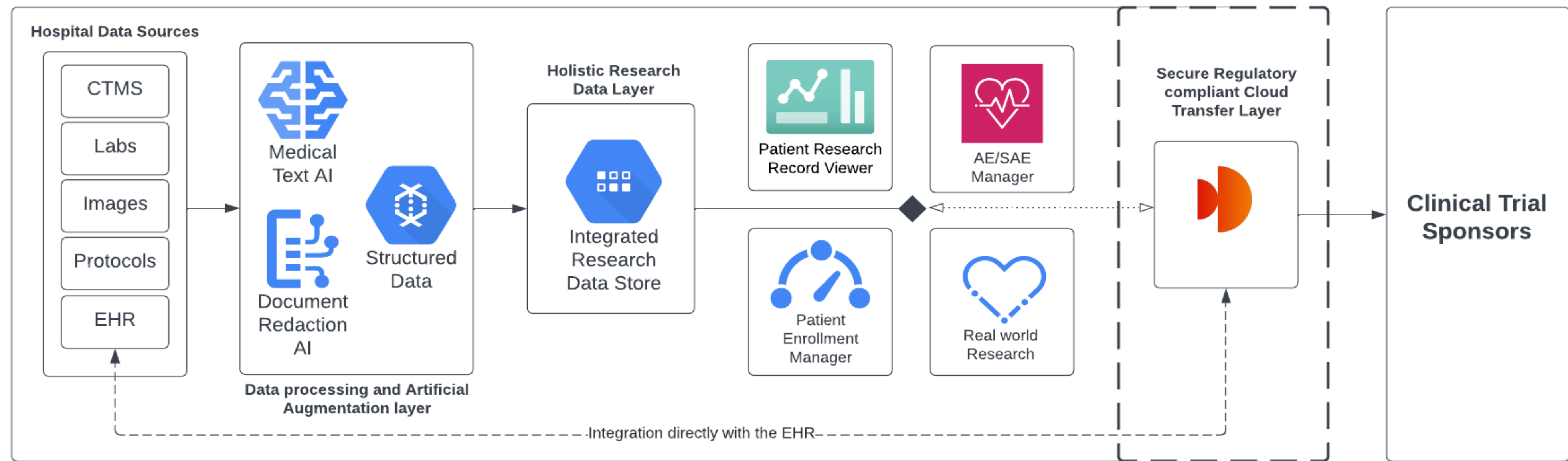
Patient: Smart, Owen
MRN: 00000695354
DOB/Age/Sex: 12/2/1952 69 Years Male

▲ Date of Report: 21 July 2021

Hard Palate Region Lesion Excision Sample Report

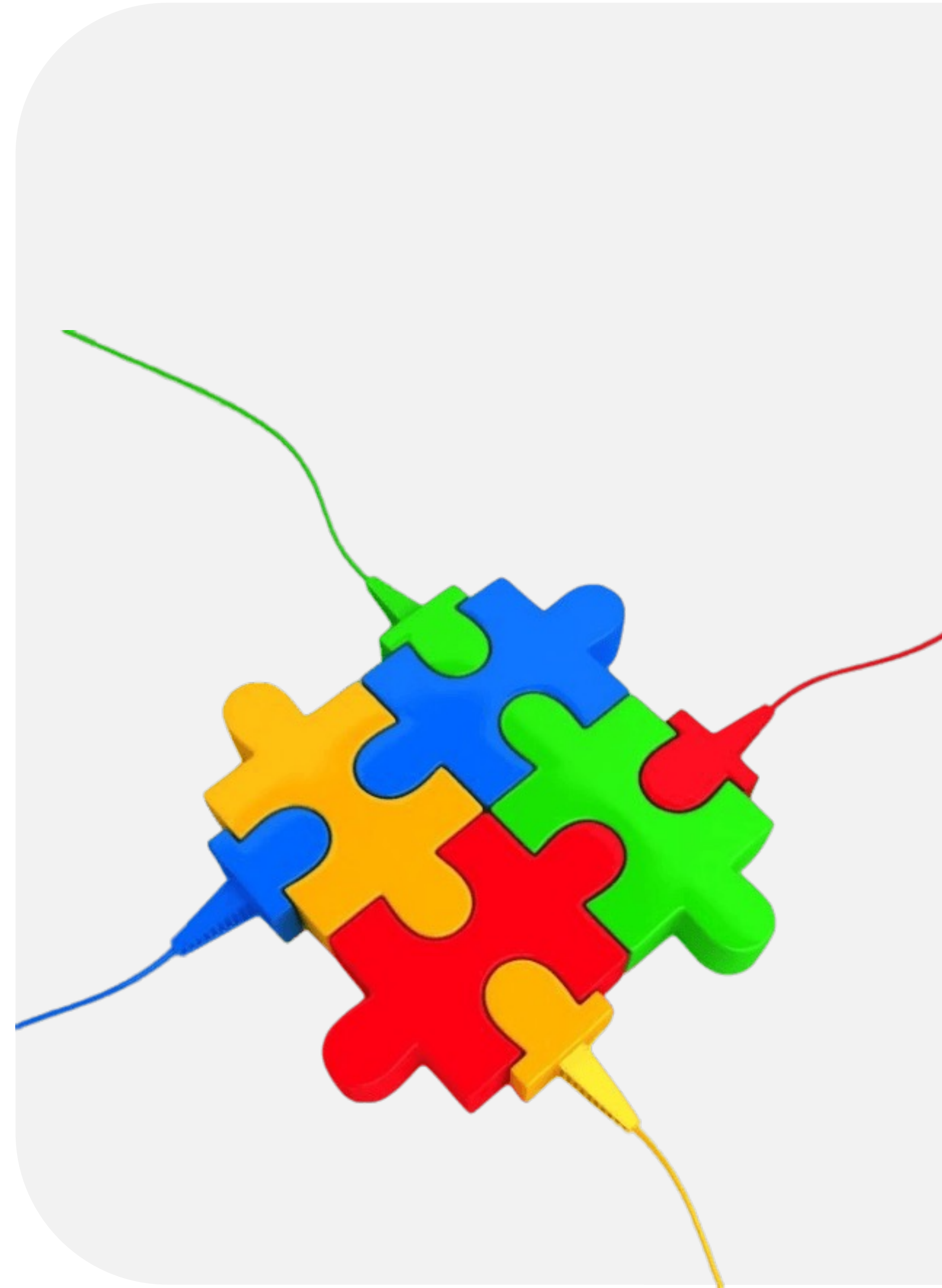
DATE OF OPERATION: MM/DD/YYYY
PREOPERATIVE DIAGNOSIS: Left hard palate lesion.
POSTOPERATIVE DIAGNOSIS: Left hard palate lesion.
OPERATION PERFORMED: Excision of left hard palate region.
SURGEON: John Doe, MD
ANESTHESIA: General endotracheal anesthesia.
OPERATIVE FINDINGS: Left lateral hard palate lesion excised with no exposed dental roots. The gross consistency lesion resembled trabecular bone and cartilage.
INDICATION FOR OPERATION: The patient is a (69)-year-old male with a history of a gradually enlarging left hard palate lesion. The lesion was asymptomatic, except for mass effect. It did result in difficulty with articulation and some mild dysphagia. He denied any pain. CT scan demonstrated a left hard palate lesion with ground-glass consistency. Options were discussed with the patient. We have recommended transoral conservative excision for removal of the lesion and biopsy. The risks, benefits, and alternatives were discussed with the patient with emphasis on the risk of general anesthesia, recurrent lesion, postoperative hemorrhage, loss of adjacent teeth and palatal defect. The patient verbalized understanding of these risks and consented to the procedure.
DESCRIPTION OF OPERATION: After obtaining informed consent, the patient was brought to the operating room and placed supine on the operating table. General anesthesia with endotracheal intubation was induced without difficulty. The eyes were protected with ointment and tape. The table was turned 90 degrees. The head drape was applied. A Crowe-Davis mouth gag was used to expose the oral cavity and the hard palate. The mucosa over the left hard palate mass was injected with 1% lidocaine with 1:100,000 epinephrine.

How do we reach the endgame?



So is AI the answer to EHR eSource data transfer?

- In part, but it is a more complex challenge.
- Not all unstructured data is created equally, and it comes from disparate sources.
- Different unstructured data requires specialist expertise.
- Many AI challenges are already being resolved, so how do we bring these together effectively for clinical research?



Thank you!

Questions?



acdm24 
Copenhagen
3rd-5th March



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Get in touch

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