Let the data flow – EHR2EDC in clinical trials

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Gold standard of clinical study data capturing is manual data input

Copying data from EHR into EDC systems manually

Copy paste mistakes, waste of time for site staff and the necessity to review the entries during source data verfication visits

Quality Review visits ensuring source data verification are time and cost intensive

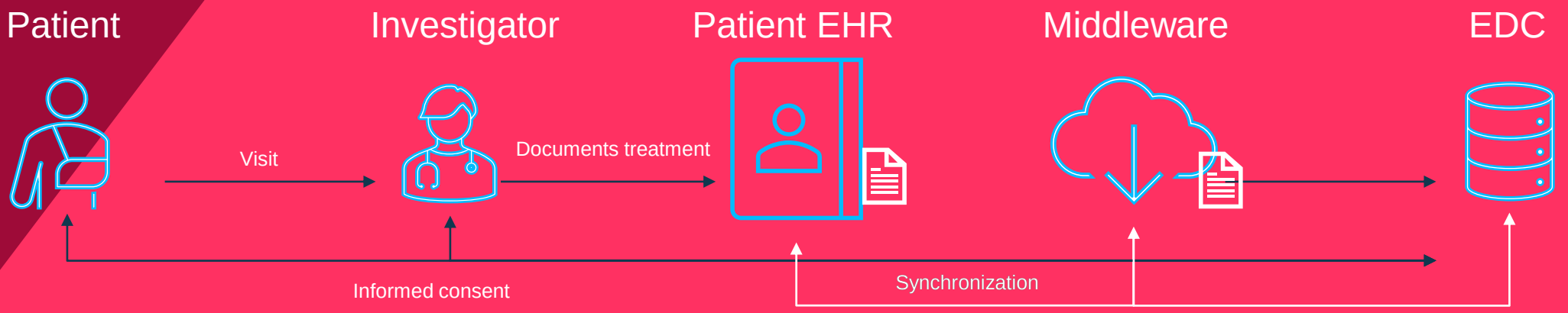
Investigators are paid for time spent of documentation

I have a dream,

that pseudonymized health data flow automatically from point of care to clinical research database to authorities

Let the data flow
Automatic Data Transfer in Clinical Studies (EHR2EDC)

FINE-Real Study a non-interventional study providing insights in a routine clinical setting



- // Lab values
- // Diagnoses
- // Medication (start, stop, dose, frequency)
- // Personal data (age, year of birth, weight, height, gender)

1) Mueller et al. 2023 Journal of Medical Internet Research - Automated Electronic Health Record to Electronic Data Capture Transfer in Clinical Studies in the German Health Care System: Feasibility Study and Gap Analysis

Beyond the idea of EHR2EDC there are multiple challenges for implementation

- **Prospective study design**
- **EHR not interoperable with EDC**
- **Variability of systems and lack of web connectivity**
- **Regulatory requirements (ICD, 21 CFR part 11, CDISC)**

Changing the status quo - benefits for investigators, sponsors and regulators

Addresses feasibility, connectivity, and compatibility

100%

compliance with the **GDPR** due to patient consent

Prospective primary data collection

1x1

high quality of the collected data

Reduce costs and improve study planning

15.000€

Savings per Patient due to 87,500 h in a 3.5 million-Data point study

Germany is moving forward in Digital Health – Political Framework

- GDNG enabling secondary use of health data
- Patients empowered to donate data to research data center (FDZ)
- ePA to EDC

Consequences for investigators, sponsors & EHR provider

- No double documentation is necessary
- Prospective Research would be implemented into everyday life
- Industry is aligning on standard data kit for research based on FHIR
- No interoperability without standards
- Involving authorities to align on standards, processes and data

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Health for all
Hunger for none

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