Clinical Data Gathering and Management

ATLAS Project - NTA1

Introduction

- Clinical data gathering and management, from the PoV of an engineer developing devices and/or algorithms together with MDs

- Goals
  - Collect and deliver an error-free, valid database for the purpose of the study
  - Comply with ethical rules

Clinical data ?

- Information collected during the course of patient care, or as part of a formal clinical trial program

- Such data are typically acquired through:
  - Electronic health record
  - Patient/disease registries
  - Clinical trial data

Before gathering data

What are you looking for ?

- Setting and understanding the overall goal !
- Do we need to generate new data ?
  - Available datasets
  - Retrospective studies
- Ok, I need to …
  - Observational/Interventional?

https://www.nature.com/sdata/policies/repositorie

Which kind/quantity of data ?

- Number of patients needed ?
- One/multiple surgeons ?
- Monocenter / multicenter ?

What type of data is needed ?

- Often, not only the main data !

- Circumstantial data
  - patient-related necessary information
  - Equipment used, parameters

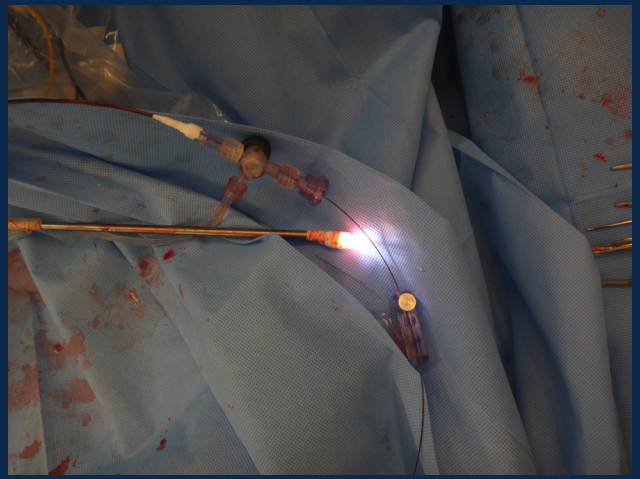
Interventional data gathering – Technical aspects

“MD Proofing”

- MDs focus on surgery. They will NOT use your device as YOU intend to !

Redundancy

- Systems can break/malfunction, especially during first preclinical cases

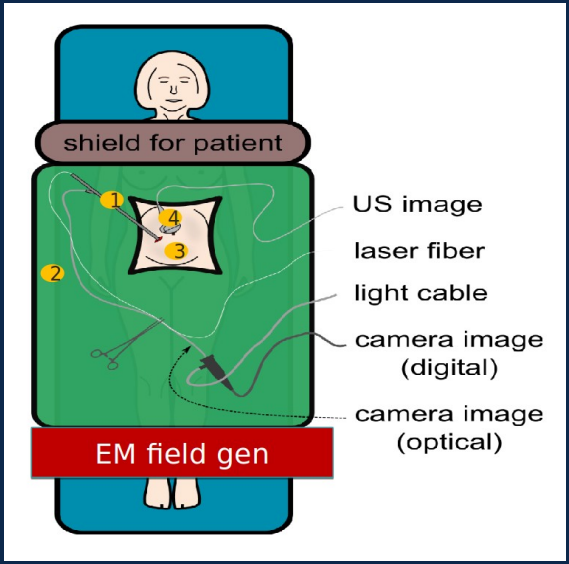


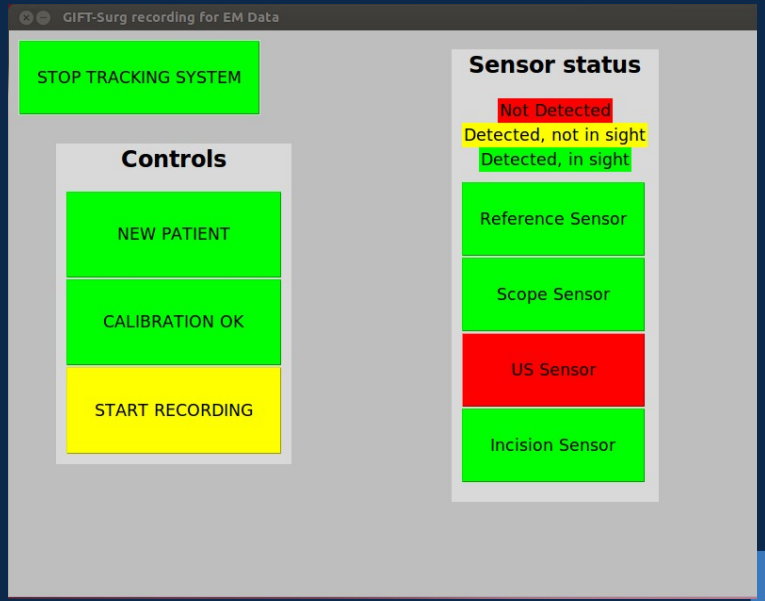
Main device

Backup device

Interfaces / GUI

- Make graphical interfaces simple and failproof
- Data visualisation can be a tool, but also a distraction !





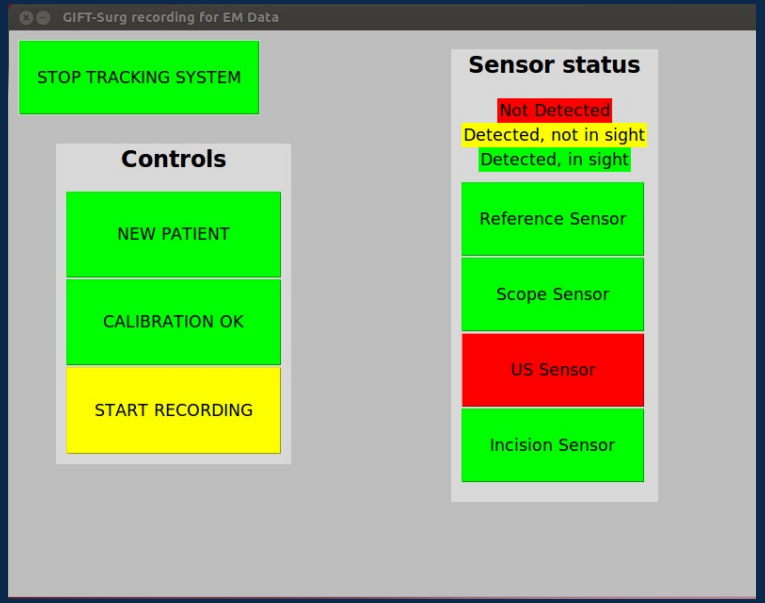
Checklists

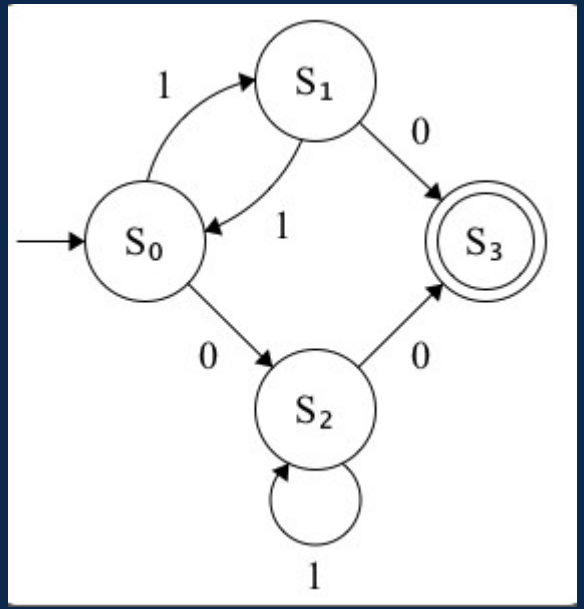
- Step-by-step instructions !
- Steps may start the day before the operation
- Required instrumentation + backup
- Timekeeping !

Date:
Procedure type:
Protocol number:

Clinical Staff	Engineers	Additional note	Time
Step 0 : initial preparation			
	Prepare USB Stick	Ideally the day before	
Prepare patient			
Start Ultrasound machine	US Machine model: ..... US Probe model: ..... US Machine settings:		
Step 1 : recording images			
Find the valve on echo			
Record a video of the valve	Views taken: ..... Video recorded? Y/N		
Record a Doppler flow video	Views taken: ..... Video recorded? Y/N		
	Verify recording		
Finish operation			
Step 2 : saving images			
	Save data on USB stick		
General notes and observations			

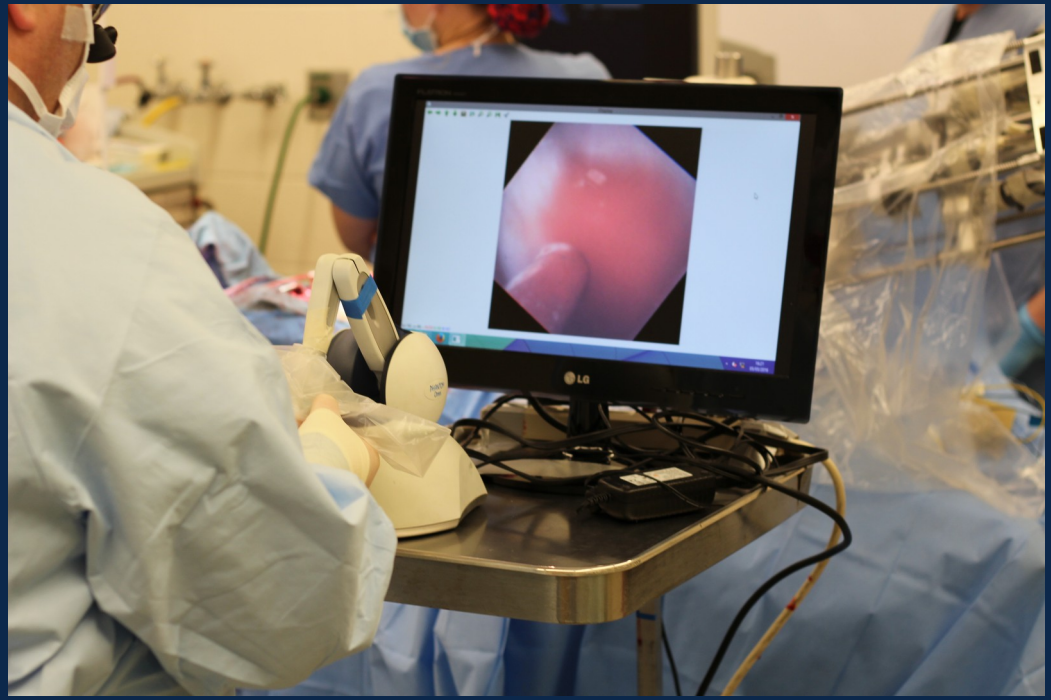
Testing, testing, testing !





When to stop testing ?

- Software version freeze
- No late testing !

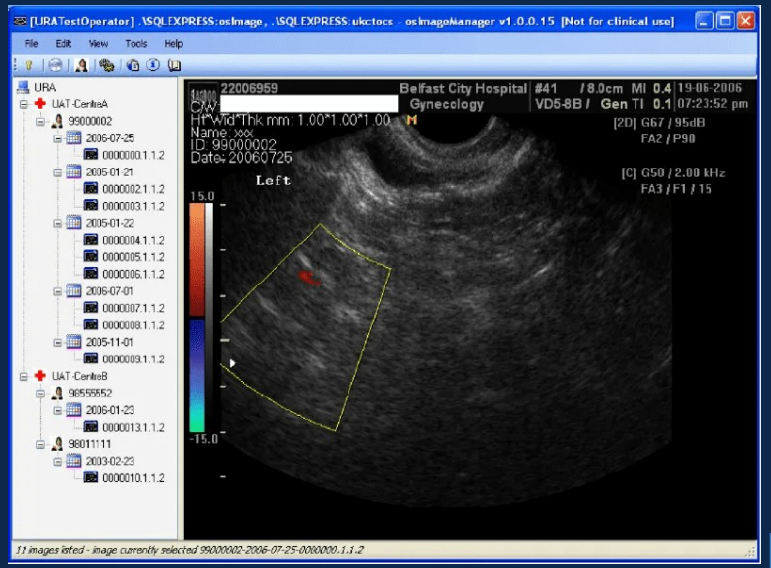


Data Management – Ethical aspects

Anonymization and privacy

- Metadata
- Medical images
- Anonymization not only for the patient

Flouty et al, 2018, *FaceOff: Anonymizing Videos in the Operating Rooms*



Sensitive data can hide anywhere !

- Date and/or sequential IDs may allow to trace back the patient
- Random IDs

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 December 2018
EMA/796532/2018

Data anonymisation - a key enabler for clinical data sharing

Workshop report

30 November – 1 December 2017, European Medicines Agency, London

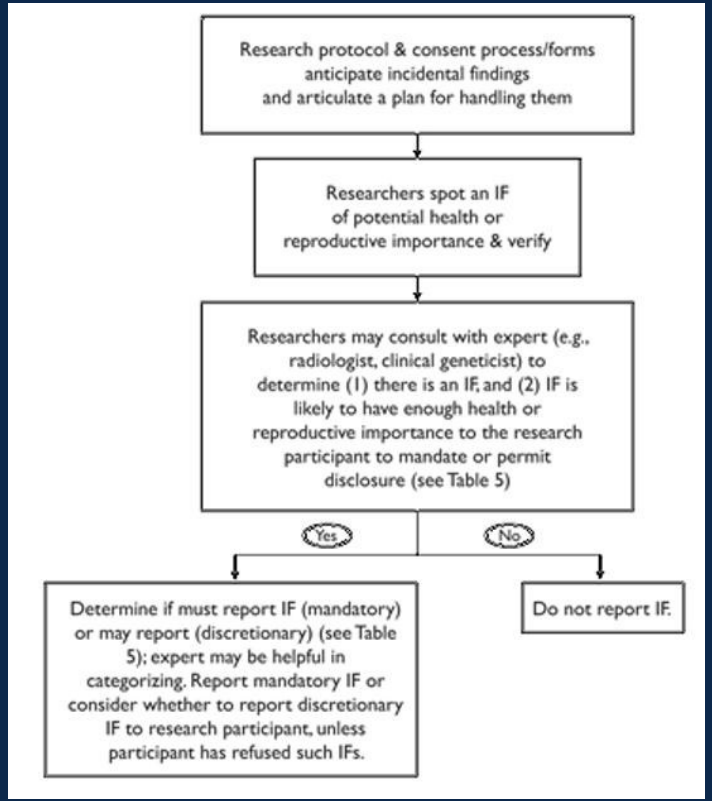
Anonymization should NOT be one-way

- Incidental findings: necessity to find again the patient if a serious condition is found when analyzing the data

- Example: MRI study
  - brain cancer
  - Unknown pregnancy

Recommended Classification of Incidental Findings

Category	Relevant IFs	Recommended Action
Strong Net Benefit	• information revealing a **condition likely to be life-threatening** • information revealing a **condition likely to be grave that can be avoided or ameliorated** • genetic information revealing significant risk of a condition likely to be life-threatening • genetic information that can be used to avoid or ameliorate a condition likely to be grave • genetic information that can be used in reproductive decision-making: (1) to avoid significant risk for offspring of a condition likely to be life-threatening or grave or (2) to ameliorate a condition likely to be life-threatening or grave	• **Disclose** to research participant as an incidental finding, unless s/he elected not to know.
Possible Net Benefit	• information revealing a nonfatal condition that is likely to be grave or serious but that cannot be avoided or ameliorated, when a research participant is likely to deem that information important • genetic information revealing significant risk of a condition likely to be grave or serious, when that risk cannot be modified but a research participant is likely to deem that information important • genetic information that is likely to be deemed important by a research participant and can be used in reproductive decision-making: (1) to avoid significant risk for offspring of a condition likely to be serious or (2) to ameliorate a condition likely to be serious	• **May disclose** to research participant as an incidental findings, unless s/he elected not to know.
Unlikely Net Benefit	• information revealing a condition that is not likely to be of serious health or reproductive importance • information whose likely health or reproductive importance cannot be ascertained	• **Do not disclose** to research participant as an incidental finding.



More information – references

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doi: 10.4103/0253-7613.93842 PMID: 22529469

Data management in clinical research: An overview

Binny Krishnankutty, Shantala Bellary, Naveen B.R. Kumar, and Latha S. Moodahadu

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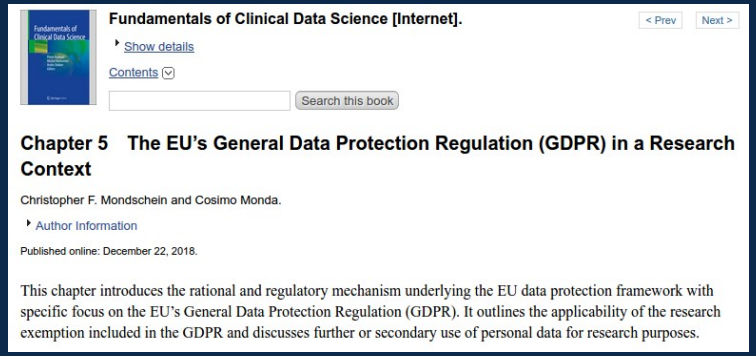

Fundamentals of Clinical Data Science [Internet].

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Chapter 5 The EU's General Data Protection Regulation (GDPR) in a Research Context

Christopher F. Mondschein and Cosimo Monda.

Author Information

Published online: December 22, 2018.

This chapter introduces the rational and regulatory mechanism underlying the EU data protection framework with specific focus on the EU's General Data Protection Regulation (GDPR). It outlines the applicability of the research exemption included in the GDPR and discusses further or secondary use of personal data for research purposes.

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J Law Med Ethics. 2008; 36(2): 219–211. PMID: 18547191
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Managing Incidental Findings in Human Subjects Research
Analysis and Recommendations

Susan M. Wolf, Frances P. Lawrenz, Charles A. Nelson, Jeffrey P. Kahn, Mildred K. Cho, Ellen Wright Clayton, Joel G. Fletcher, Michael K. Georgieff, Dale Hammerschmidt, Kathy Hudson, Judy Illes, Vivek Kapur, Moira A. Keane, Barbara A. Koenig, Bonnie S. LeRoy, Elizabeth G. McFarland, Jordan Paradise, Lisa S. Parker, Sharon F. Terry, Brian Van Ness, and Benjamin S. Wilfond

The Duty to Look for Incidental Findings in Imaging Research

Julian J. Koplin, Martin R. Turner, and Julian Savulescu

ABSTRACT Imaging research regularly yields incidental findings that may have personal medical or reproductive decision-making significance to study participants. It is widely assumed that researchers have a moral obligation to disclose at least some kinds of incidental findings to research participants. However, it is also a widely held view that researchers do not have a moral obligation to actively look for abnormalities irrelevant to the aims of their study. This paper challenges that assumption.

KEYWORDS incidental findings, imaging research, return of research results, human subjects research

Koplin, J. J., M. R. Turner, and J. Savulescu, "The Duty to Look for Incidental Findings in Imaging Research," *Ethics & Human Research* 42, no. 2 (2020): 2-12. DOI: 10.1002/ehr.500043