



Acute Pancreatitis

Clinical Research



Timea Molnar

Centre for Translational Medicine, University of Pécs

The importance of data quality in the registries and clinical trials

12th November 2016
Budapest



Acute Pancreatitis

Clinical Research



Quality of clinical trials

- Depends on **data integrity** and **subject protection**
- Quality in clinical trials may be defined as the **absence of errors that matter**
- Trial quality ultimately rests on having a well-articulated investigational plan (e.g., protocol, analysis and management plans)
- Quality trial can be dramatically improved through **prospective attention to preventing important errors** that could undermine the ability to obtain meaningful information from the trial
- **Lack of data quality** standards and definitions introduces subjectivity **risk** in clinical trials
- Must haves: 1.) well-designed study protocol, 2.) Case Report Forms (CRFs), 3.) software/database used to record and store the data

Data Quality = Consistency + Integrity



- Improving data quality can not only generate better results, but also minimize the amount of subjects needed in a clinical trial (therefore costs) and reduce timeline slippage
- Steps to improve data quality
 1. Design leaner protocols that **minimize unnecessary data collection**
 2. Define the data quality strategy and data governance, develop an implementation plan
 3. Assign the **roles and responsibilities** for data governance



Acute Pancreatitis

Clinical Research



Data Quality = Consistency + Integrity

- Ensuring the reliability and integrity of healthcare data begins with the **accuracy and the completeness of the data** captured in the patient's health record (**source data**)
- Must have: established **policies, procedures** and **staff education**
- **Invest effort to ensure that research data is of high quality and validity!**



Acute Pancreatitis

Clinical Research



Quality Control

- **real-time review of data** to verify the accuracy and validity by study staff involved in the research
- should occur **on a regular basis** to ensure accuracy and completeness of study data
- ASAP clarify, validate and correct any unclear or out-of-range data

How we make it

APPLE-P



APPLE-R



Registry for Pancreatic Patients

AP



PC



CP



AIP



Amb



Control samples

Control



Search patient

Insurance number

e.g. 123456789

Search

Navigation

- > Felhasználók kezelése
- > Submitted forms
- > Rejected forms
- > Pending approvals
- > Adminisztráció
- > Patients
- > Kórházak szerkesztése

Edit inpatient

Edit inpatient

Forms submitted

12

Submit a new form for the current inpatient

EASY Form A

EASY Form B

Akut Pankreátitisz Form A

Akut Pankreátitisz Form B

Genetic testing result

Submitted forms

Form	Approval	Submitted on	Doctor	Actions
EASY Form A #475 Horváth Lászlóné	✓ ✓ ✓ ✓	2016, September 1 - 11:15	GS	edit, delete
EASY Form B #475/2 Horváth Lászlóné	✓ ✓ ✓ ✓	2016, September 1 - 11:42	GS	edit, delete
EASY Form B #475/3 Horváth Lászlóné	✓ ✓ ✓ ✓	2016, September 1 - 12:13	GS	edit, delete
EASY Form B #475/4 Horváth Lászlóné	✓ ✓ ✓ ✓	2016, September 1 - 12:22	GS	edit, delete
EASY Form B #475/5 Horváth Lászlóné	✓ ✓ ✓ ✓	2016, September 1 - 12:29	GS	edit, delete
EASY Form B #475/6 Horváth Lászlóné	✓ ✓ ✓ ✓	2016, September 1 - 12:31	GS	edit, delete
Akut Pankreátitisz Form A #AP1495 Horváth Lászlóné	✓ ✓ ✓ ✓	2016, September 1 - 12:39	GS	edit, delete
Akut Pankreátitisz Form B #AP1495/2 Horváth Lászlóné	✓ ✓ ✓ ✓	2016, September 1 - 13:04	GS	edit, delete
Akut Pankreátitisz Form B #AP1495/3 Horváth Lászlóné	✓ ✓ ✓ ✓	2016, September 1 - 13:06	GS	edit, delete
Akut Pankreátitisz Form B #AP1495/4 Horváth Lászlóné	✓ ✓ ✓ ✓	2016, September 1 - 13:07	GS	edit, delete
Akut Pankreátitisz Form B #AP1495/5 Horváth Lászlóné	✓ ✓ ✓ ✓	2016, September 1 - 13:09	GS	edit, delete
Akut Pankreátitisz Form B #AP1495/6 Horváth Lászlóné	✓ ✓ ✓ ✓	2016, September 1 - 13:11	GS	edit, delete



Acute Pancreatitis

Clinical Research



Thank you for your kind attention!