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The importance of data quality in the registries and clinical trials

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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





Acute Pancreatitis

Clinical Research



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







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 haves: established policies, procedures and staff education
- Invest effort to ensure that research data is of high quality and validity!



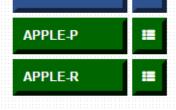




Quality Control

- 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



Registry for Pancreatic Patients



Control samples



Search patient

Insurance number

e.g. 123456789 Search

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Submit a new form for the current inpatient



Submitted forms

Form	Approval	Submitted on	Doctor	Actions
EASY Form A #475 Horváth Lászlóné	0000	2016, September 1 - 11:15	GS	edit, delete
EASY Form B #475/2 Horváth Lászlóné	0000	2016, September 1 - 11:42	GS	edit, delete
EASY Form B #475/3 Horváth Lászlóné	0000	2016, September 1 - 12:13	GS	edit, delete
EASY Form B #475/4 Horváth Lászlóné	0000	2016, September 1 - 12:22	GS	edit, delete
EASY Form B #475/5 Horváth Lászlóné	0000	2016, September 1 - 12:29	GS	edit, delete
EASY Form B #475/6 Horváth Lászlóné	0000	2016, September 1 - 12:31	GS	edit, delete
Akut Pankreátitisz Form A #AP1495 Horváth Lászlóné	0000	2016, September 1 - 12:39	GS	edit, delete
Akut Pankreátitisz Form B #AP1495/2 Horváth Lászlóné	0000	2016, September 1 - 13:04	GS	edit, delete
Akut Pankreátitisz Form B #AP1495/3 Horváth Lászlóné	0000	2016, September 1 - 13:06	GS	edit, delete
Akut Pankreátitisz Form B #AP1495/4 Horváth Lászlóné	0000	2016, September 1 - 13:07	GS	edit, delete
Akut Pankreátitisz Form B #AP1495/5 Horváth Lászlóné	0000	2016, September 1 - 13:09	GS	edit, delete
Akut Pankreátitisz Form B #AP1495/6 Horváth Lászlóné	0000	2016, September 1 - 13:11	GS	edit, delete





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Thank you for your kind attention!