



Non-Interventional Studies

building and broadening the value story

Marika Chrápavá & Daniel Schwarz





Who we are?

...:Masaryk University spin-off



Who we are?

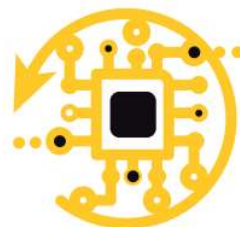
...:Masaryk University spin-off



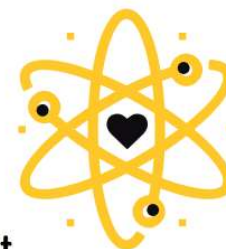
**data
management**



**data
analysis**



**information
technologies**



**project
management**





Why should you be bothered with NIS?



improve drug development
&
clarify the value of new therapies.





Outline

- NIS within the scheme of clinical research phases
 - Lifecycle of NIS
 - Tools & people behind NIS
 - EDC system and how it can facilitate a clinical research project
-
- NIS criteria and rules
 - Regulatory issues
 - System validation
 - System must-haves and nice-to-haves
-
- Recap: advantages of NIS against other types of studies
 - Q/A session



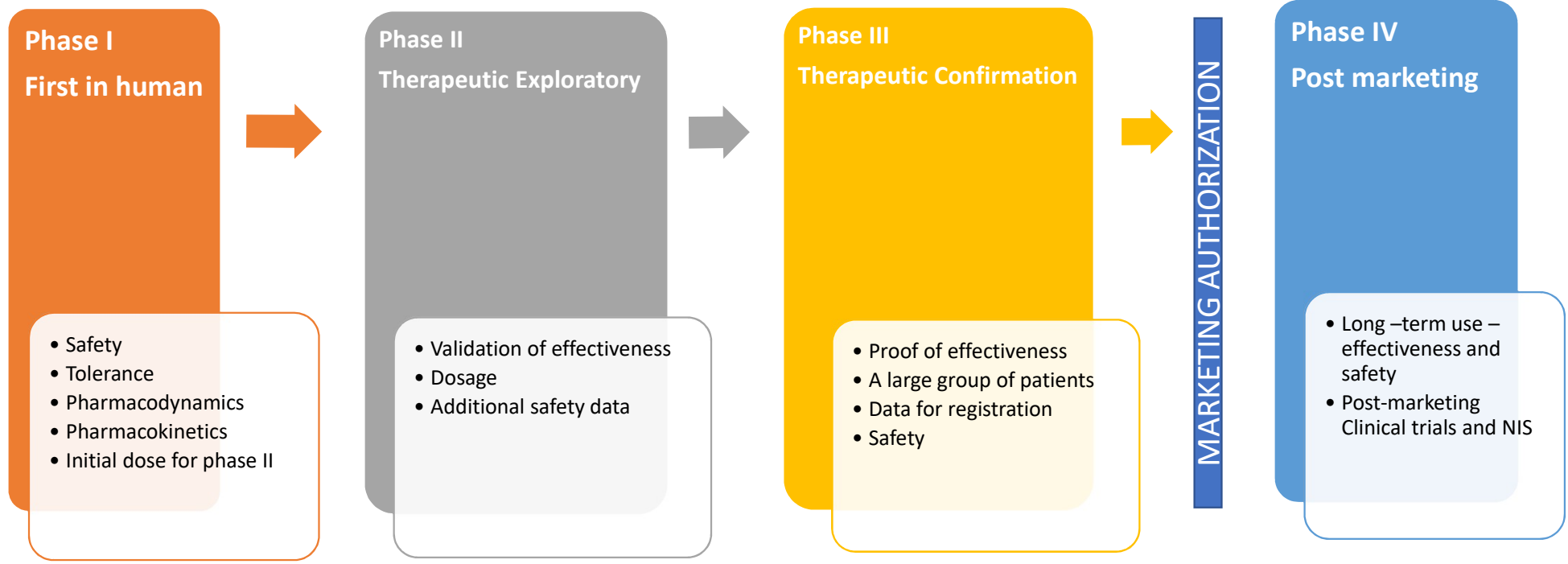
NIS

...and its position in the sequence
of clinical research phases





NIS within the scheme of clinical research phases





Lifecycle of NIS: purpose, design, criteria...

- Why should we perform a NIS or a secondary data analysis?
What is their **purpose**?
- What **design** should we choose for NIS or secondary data analysis?
- What are the **criteria** qualifying a research project as a NIS?
- Can be effectiveness and safety of a product derived from a NIS?



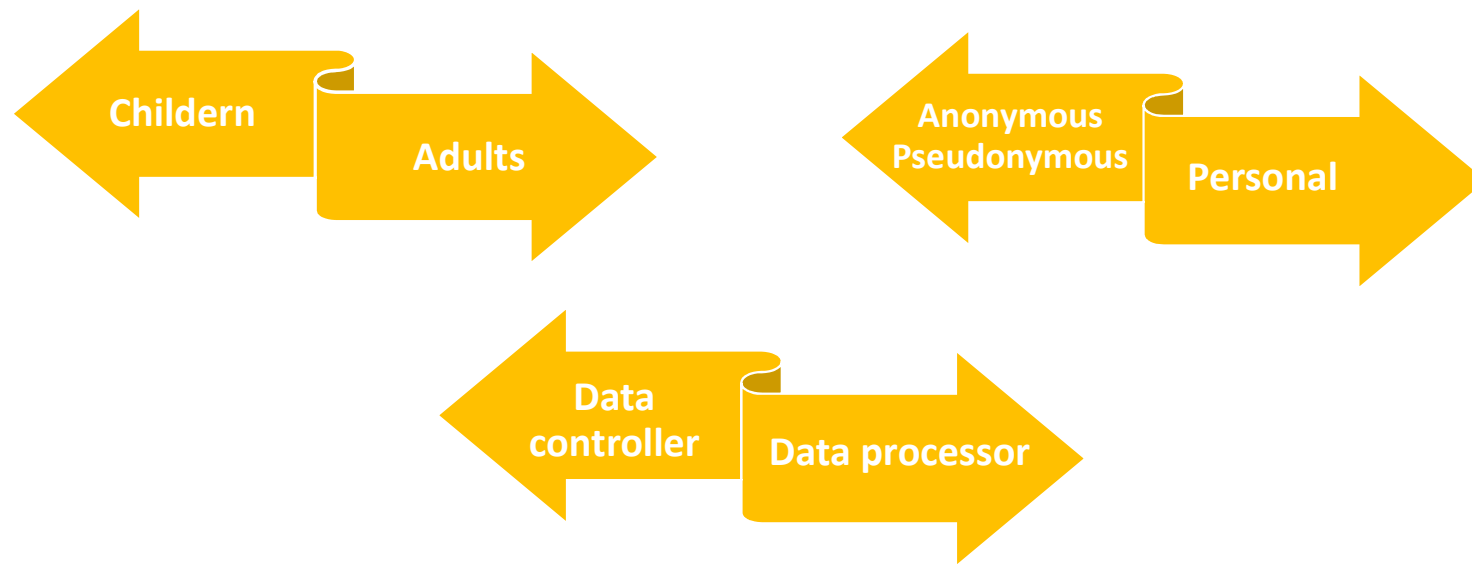
Lifecycle of NIS: Initiation – patients enrolment





ICF – Informed consent form

- ▶ Ethical rules, Declaration of Helsinki and GCP ICH E6
- ▶ Consent with data protection rules





Course of the study



- ✓ Application of GCP rules
- ✓ Good Documentation practice
- ✓ Data quality
- ✓ EDC system





Study termination and out comes

- ▶ Final study report
- ▶ Publication
- ▶ Results dissemination
- ▶ Change of SmPC, guidelines, market access, reimbursement,....



Tools vs. people

What is more important?





Tools vs. people ::: what is more important?

CLINICAL DATA MANAGEMENT
Institute of Biostatistics and Analyses
Science

[Listen on Apple Podcasts](#)

AUG 1, 2022
Jaroslav Koca - principal clinical data manager @ Cytel
The 7th episode focuses on the EDC systems and their impact on the quality of data. Jaroslav Koca - an experienced clinical data manager with a background in computer science who is now affiliated with Cytel as a principal clinical data manager. Let's listen to his insights.

▶ **PLAY** 29 min

JUL 1, 2022
Tomas Machulka - Premier Research
The sixth episode focuses on the very specific role of a data manager within interdisciplinary communication in clinical research projects. It features Mr. Tomas Machulka who is currently working at Premier Research as an associated manager for clinical data sciences. He serves as a bridge between different departments.

▶ **PLAY** 20 min

JUN 1, 2022
Richard Hulek - computer scientist @ RECETOX
The fifth episode focuses on data integrity and also on data integration in long-term studies. It features Richard Hulek - a computer scientist with a background in environmental science who is currently working at RECETOX in the integration of systems behind long cohort studies. Let's listen to his insights.

▶ **PLAY** 32 min

MAY 2, 2022
Antoine Pironet - medical data scientist @ AARDEX Group
The fourth episode focuses on data quality in clinical research, and how it relates to patient adherence. It features Antoine Pironet - a data scientist with a background in epidemiology who is currently working at AARDEX Group in analyzing data collected in national registries and data in electronic health records.

CLINICAL DATA MANAGEMENT
best practices

EPISODE #7: JAROSLAV KOČA

CLINICAL DATA MANAGEMENT
best practices

EPISODE #6: TOMÁŠ MACHULKA

CLINICAL DATA MANAGEMENT
best practices

EPISODE #5: RICHARD HŮLEK

CLINICAL DATA MANAGEMENT
best practices

EPISODE #4: ANTOINE PIRONET

CLINICAL DATA MANAGEMENT
best practices

EPISODE #3: ALEXANDER KRANNICH

CLINICAL DATA MANAGEMENT
best practices

EPISODE #2: ALEXANDER SCHACHT



PEOPLE behind data-driven clinical research



Business Intelligence

- data collection (eCRF development including validation, calculation & skip logic procedures)
- data analysis through reports and dashboards

Data Mining

- correlation, prediction
- ML/AI techniques
(classification, detection, text mining)

Data Management

- data collection settings
- transformation of structured data into scalable data warehouse

Data Science

- modeling (pattern recognition)
- causality (cause-and-effect)
- validation (goodness of fit)

Data Quality

Data Integrity

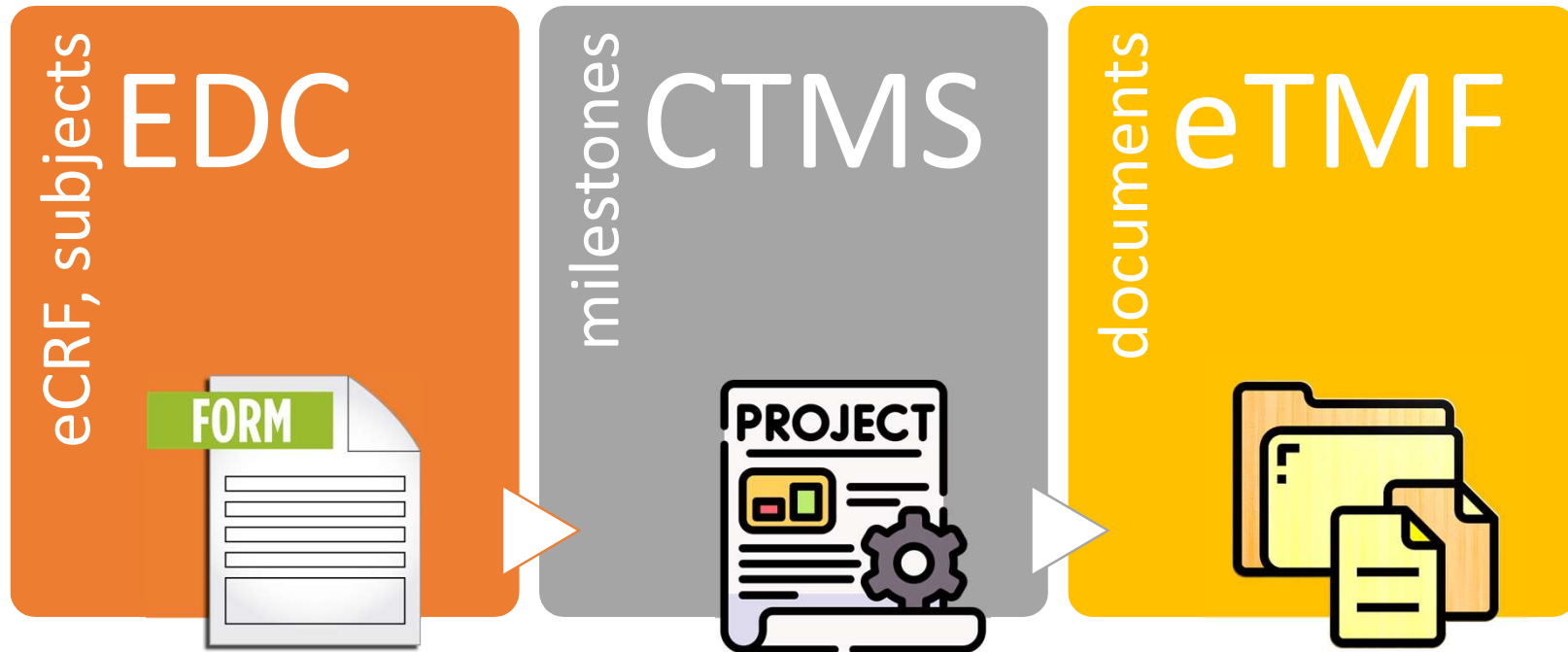
Data Insights

Data & SW Engineering

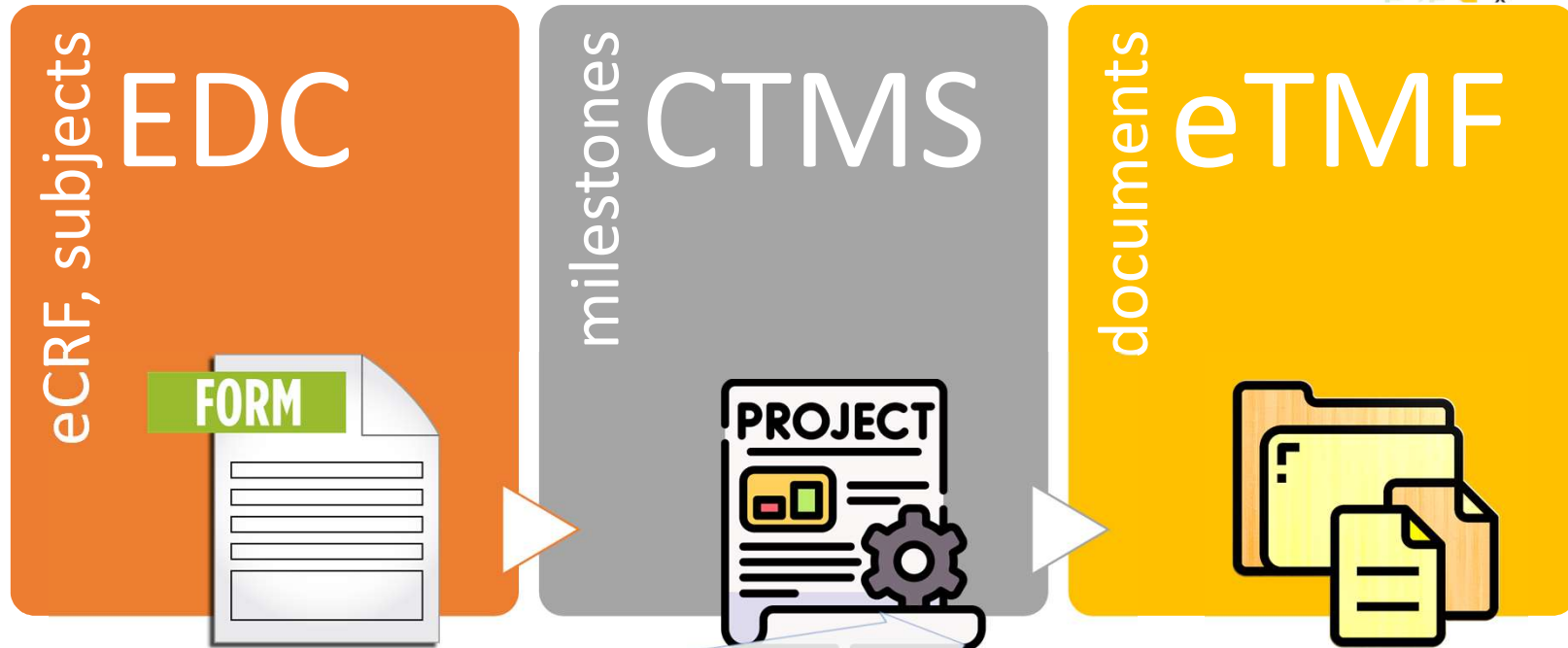
- EDC system
- Data warehouse



TOOLS for achieving good quality of data



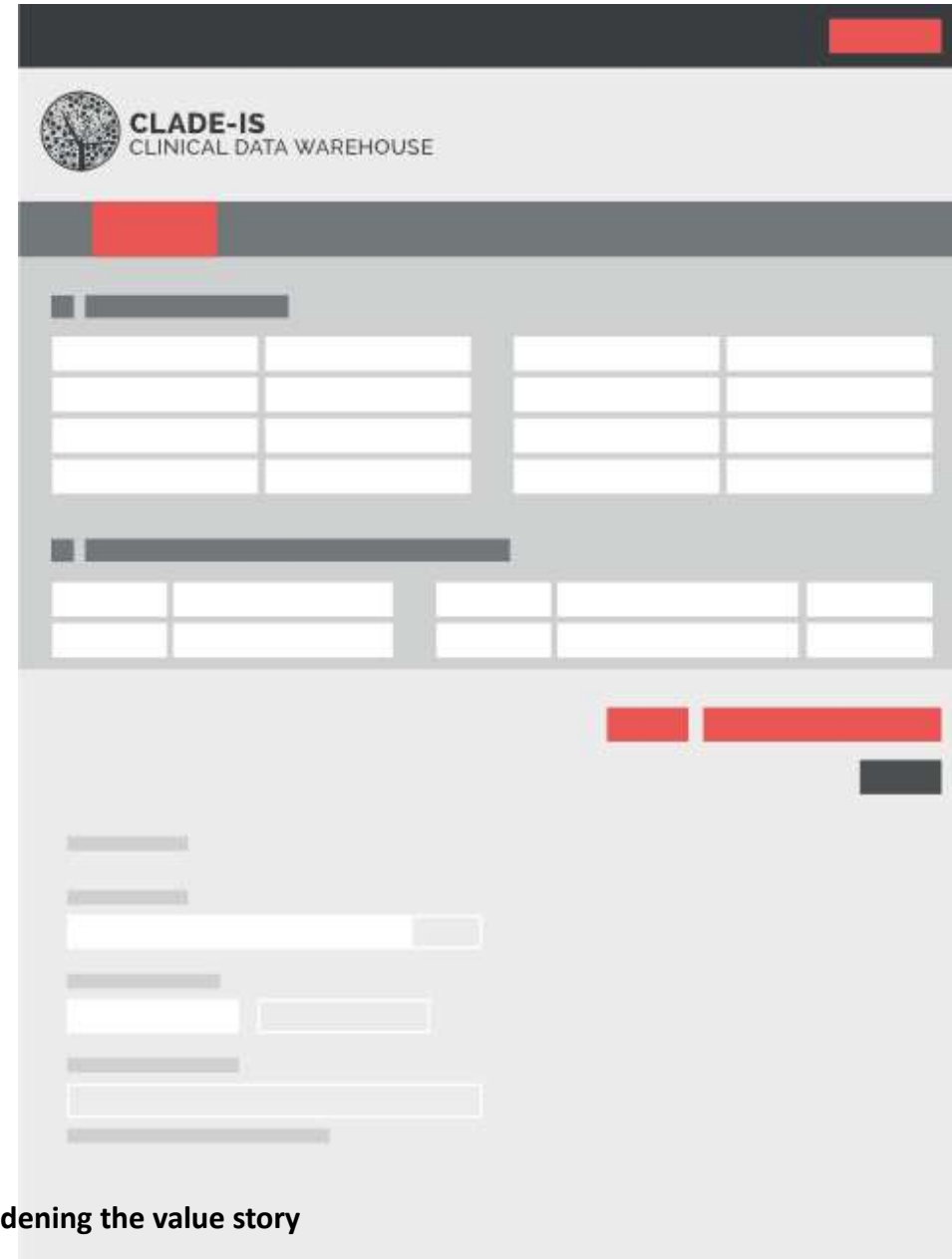
Additional TOOLS for achieving good quality of data





Electronic Data Capture

How can a good EDC system facilitate a clinical research project?



Healthy data

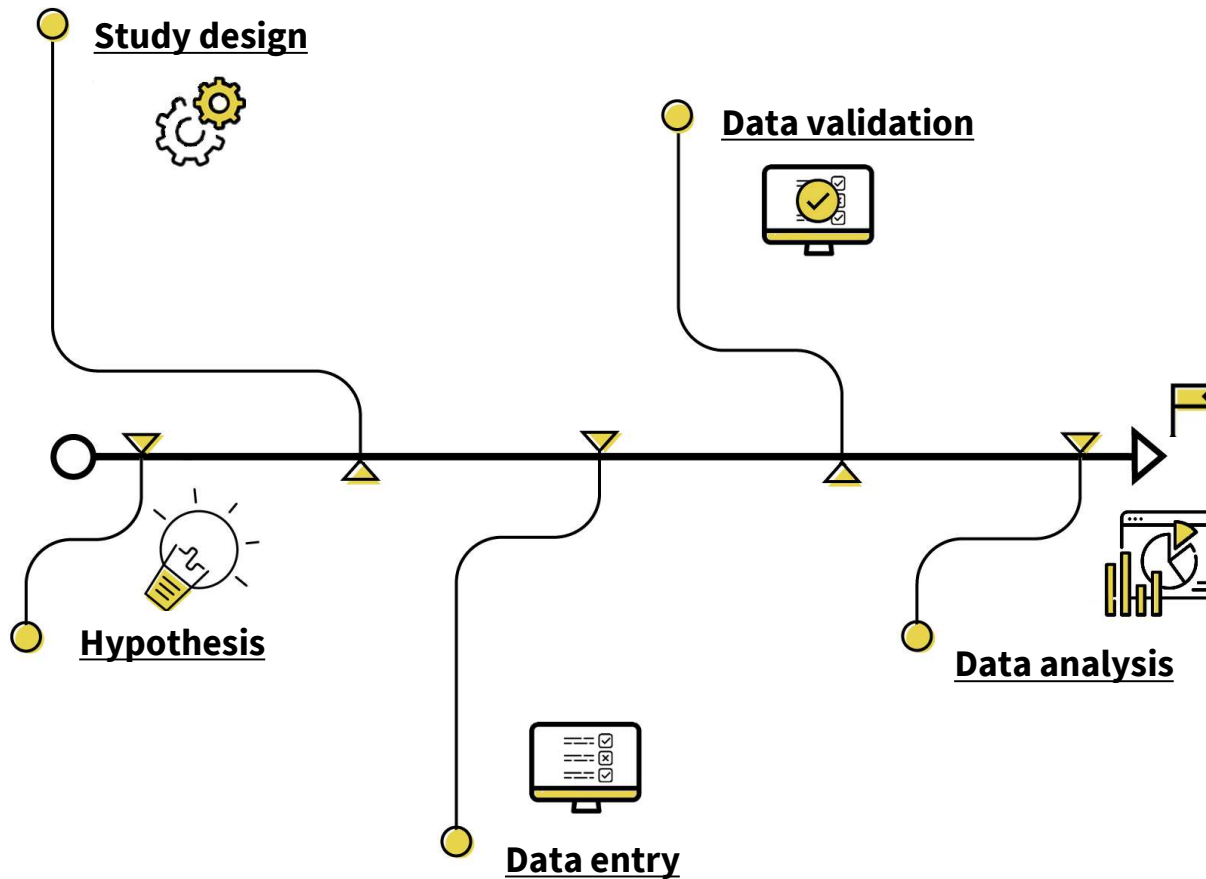
CLADE-IS represents an information system for clinical data warehousing. Researchers in health and life sciences industry use this EDC platform (Electronic Data Capture) for secure and intuitive data management.

Features

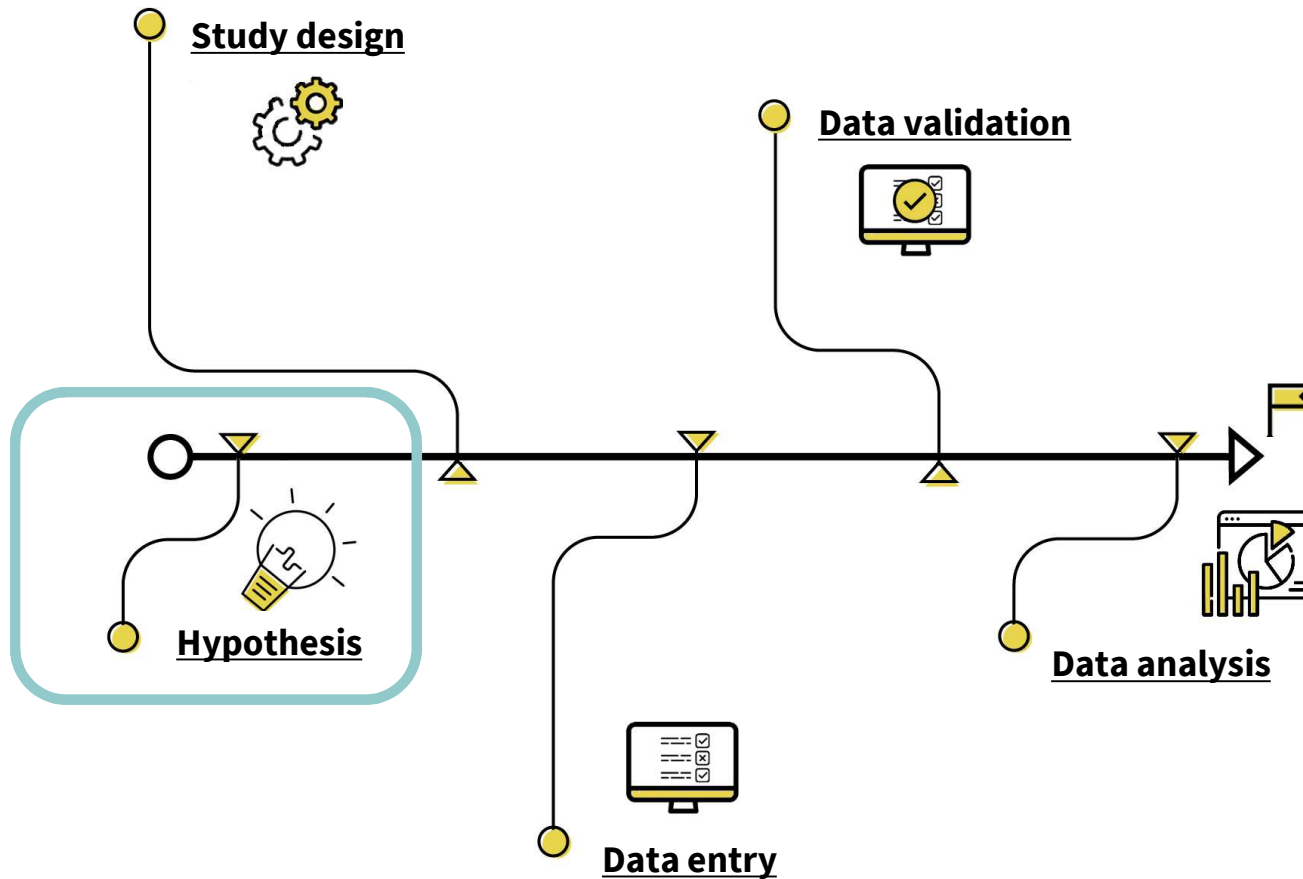
- **Robust eCRF (electronic Case Report Form) design**
- **Flexible data access management**
(configurable user roles and privileges, custom definitions of form statuses)
- **Easy & ergonomic user navigation**
- **Data insights through configurable dashboards and reports**



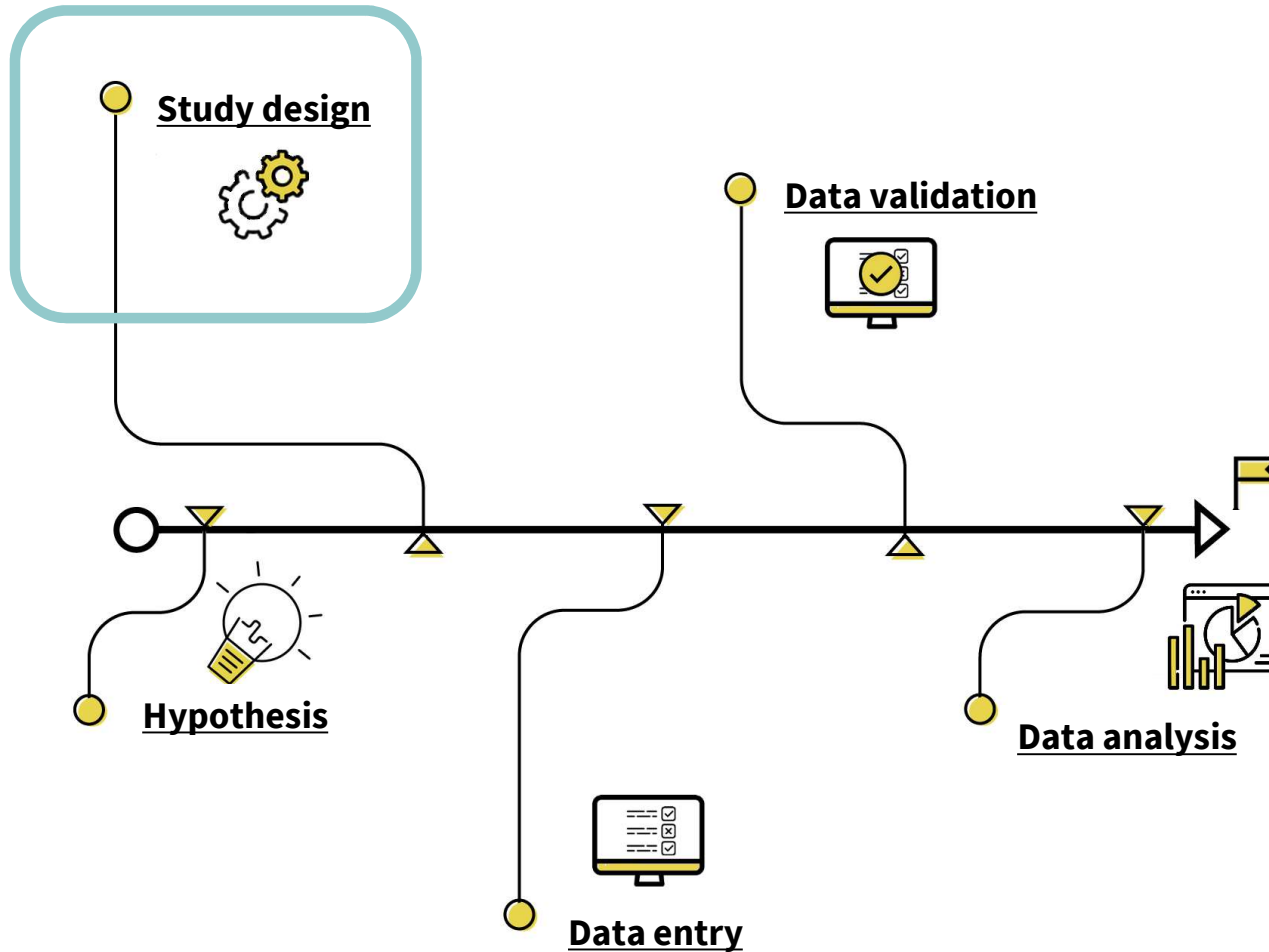
From a hypothesis to an outcome



From a hypothesis to an outcome



From a hypothesis to an outcome



Study design

Robust structure entities



Clade-IS Designer (22.12.0.0)

ATTRA - RA

ARMS AND PHASES

Overview

Arms

Phases

Arms and phases

Arm		Phases	
Arm - #	Arm - name	Phase - #	Phase - name
2	DefaultArmRA	8	EntryPhaseRA
2	DefaultArmRA	9	FollowUpPhaseRA
2	DefaultArmRA	10	AdverseEventsPhaseRA
2	DefaultArmRA	11	PreRAPhase
2	DefaultArmRA	12	EarlyRAPhase
2	DefaultArmRA	13	DiscontinuationPhaseRA
2	DefaultArmRA	14	ResearchPhaseRA
2	DefaultArmRA	15	ClinicalEvaluationPhaseRA

Who: Data manager

Where: Designer 

Study design



Study structure export



Study structure

Name: internal name
Identifier: key
Attributes: none

Extended settings ↓

Output format: show

SHOW STRUCTURE

Study structure

DEMO

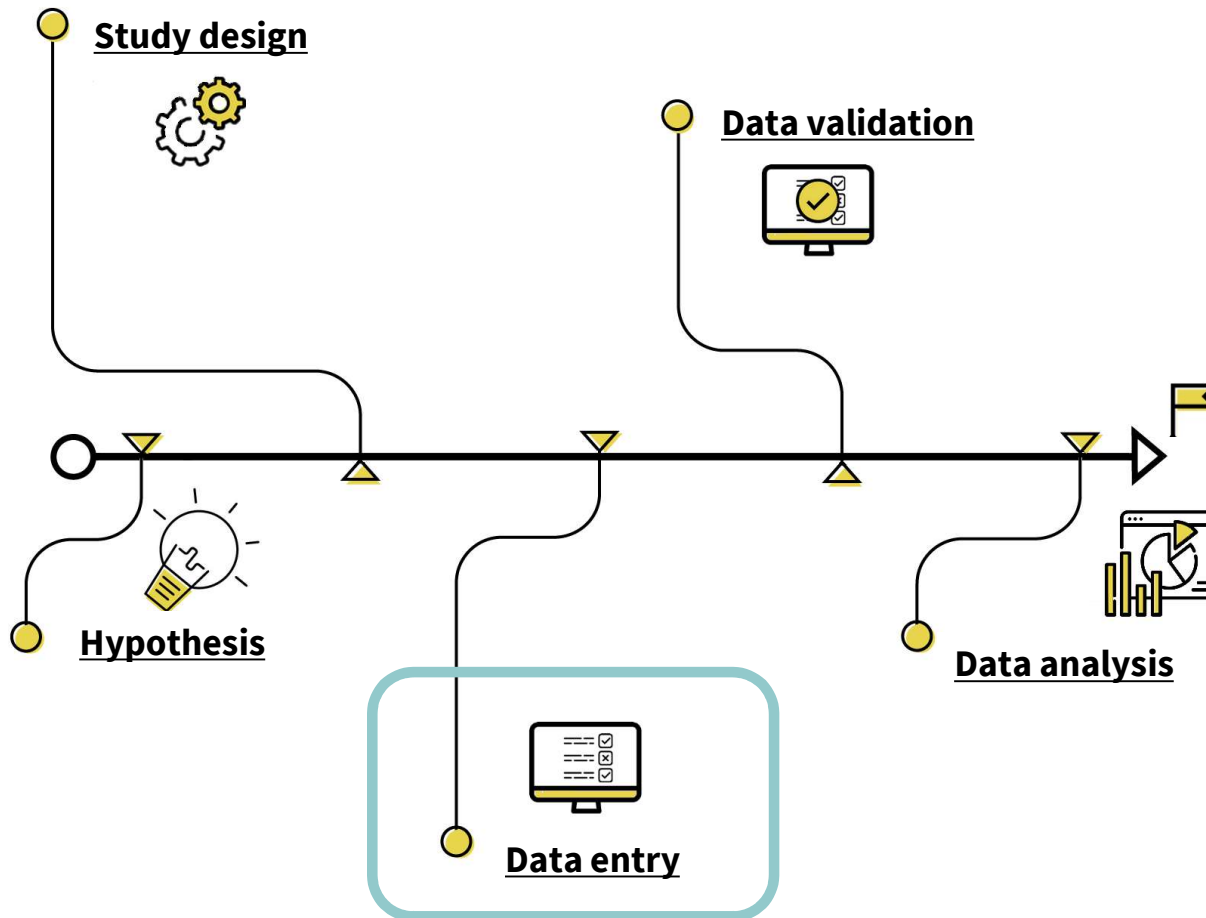
Study structure generated: 2022-09-06

Structure of patient form

- **PatientFormRA | [16]**
 - [max. instances count - 1]
 - o **PatientDetails | [116]**
 - **InformedConsentGDPR | [2687]**
Discrete value - select box [mandatory]
 - o Yes | [710]
 - o NoButWillBeObtained | [711]
 - o NoPatientDead | [712]
 - o NoPatientLostFromFollowUp | [713]
 - **DateOfInformedConsentGDPR | [2688]**
Date - calendar
 - **DateOfBirth | [799]**
Date - calendar [mandatory]
 - **Sex | [800]**
Discrete value - select box [mandatory]
 - o Male | [9]
 - o Female | [10]
 - **Initials | [801]**
Short text - long text [mandatory]
 - **ResponsiblePhysician | [1317]**



From a hypothesis to an outcome



Data entry

Create and edit forms



PATIENT'S PERSONAL DATA

* Informed consent under GDPR signed?
- Choose -

Date of ICF signing according to the GDPR
dd.mm.yyyy

* Date of birth
dd.mm.yyyy

* Sex
- Choose -

* Initials

* Attending physician ⓘ
start typing First Name or Last Name of the Physician

Patient's Memo ID ⓘ
automatically generated (not editable)

Who: Healthcare professional
Where: Study



Data entry



Data entry – UX features

Wide range of data types and question settings

- text - short text, long text
- date – date and time, date, time
- selectbox – enumerate, codebook
- number - integer, real
- yes / no
- file
- button
- heading text
- json
- ... other (custom)

1

SUBJECT QUESTIONS

* Date of birth

* Sex

Man Woman

* Initials

Autocomplete

ICF signed?

Yes No

2

Selection of tender joints

Specify (show figure) Hide figure No joint (0)

Selection of **tender** joints (n/28)

RIGHT SIDE LEFT SIDE

SHOULDER

ELBOW

RC WRIST

MCP PIP

KNEE

Who: Data manager

Where: Designer 

Study design





Data entry - UX features

Edit checks & instant validation

MEDICATION - BIOLOGICALS (PLEASE NOTE THE CURRENT STATUS, RESPECTIVELY ANY CHANGES SINCE THE LAST VISIT)

+ ADD

MEDICATION - RITUXIMAB

+ ADD

MEDICATION - TARGETED SYNTHETIC DMARDS (PLEASE NOTE THE CURRENT STATUS, RESPECTIVELY ANY CHANGES SINCE LAST VISIT)

+ ADD

MEDICATION (PLEASE RECORD THE CURRENT STATUS, RESPECTIVELY ANY CHANGES SINCE THE LAST VISIT)

Corticoids ⓘ DMARD synthetic ⓘ Non-selective NSAIDs ⓘ Cox-2 inhibitor ⓘ



Data entry

Responsivity

IBA-001-0022

Site	Investigator IBA	Enrolled by	Petra Jobánková	Date of patient creation	23 Jan 2019, 10:08
Initials	PJ	Date of birth	01/01/1982	Gender	Male
Informed consent by GDPR signed?	Yes				

Adverse Event | Adverse event

ID	163	Created	Petra Jobánková	19 Feb 2019, 15:01	Queries	0 / 0 / 0	Show
Status	Pending (AE)	Changed	Petra Jobánková	19 Feb 2019, 15:03			

Queries

Adverse Event Name

Adverse Event - specification

Therapy

Comments

ADVERSE EVENT NAME

* Preferred Term (PT)

Chest pain

PT code

10008479

System Organ Class (SOC)

General disorders and administration site conditions

ADVERSE EVENT - SPECIFICATION

* Start date

01/02/2019

Start time

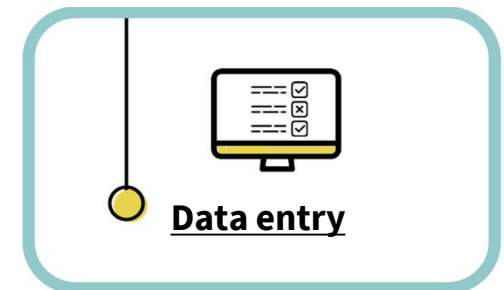
16:00

* Intensity

Moderate



Who: Healthcare professional
Where: Study



UX features

Skip logic

* Patient signed Informed Consent Form

Yes No

PATIENT SETTINGS

Training patient



Who: Healthcare professional
Where: Study

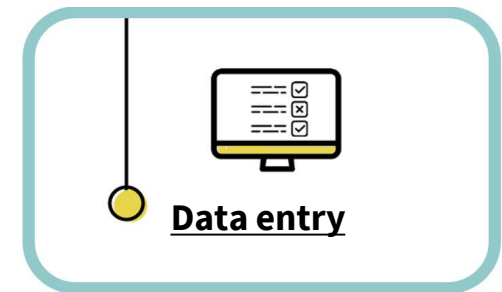


Data entry

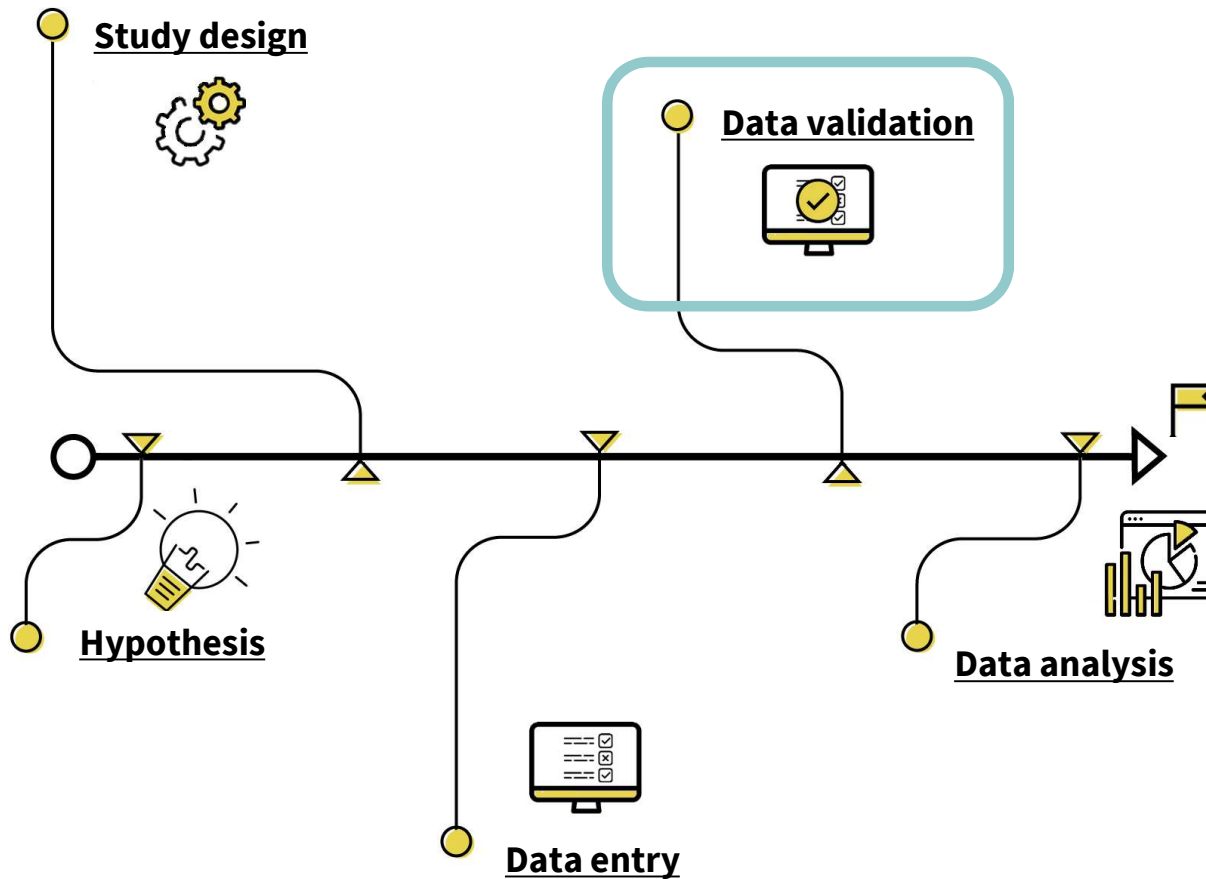
Single Form Mode – authentication through a hash code

A screenshot of the CLADE-IS login interface. The header shows the CLADE-IS logo and the text "CLADE-IS CLINICAL DATAWAREHOUSE". The login form has two tabs: "USER" and "KEY". Below the tabs are two input fields: "Username" and "Password", each with a lock icon on the left. A red "LOG IN" button is positioned below the password field. At the bottom of the page, there is a footer with the text "Version: dev-release/19.20" and "Template version: 2019-11-04T10:50:33" on the left, and the CLADE-IS logo on the right.

Who: Healthcare professional
Where: Study 



From a hypothesis to an outcome



Data Quality Checks



Queries

Query ID	Patient ID	Form name	Created the form	Message	Status	Action
4771	ATTRA-02790	Follow-up		Two Follow-up forms have the same Date.	new	Open
9310	RA_3321_RB	Adverse event		The Adverse Events form cannot be established with a date of origination of adverse event that follows the date on which the patient follow-up was terminated.	new	Open
575	RA_2773_V5	Follow-up		There is no Quality of life with SF36 filed for the entry visit or the visit after 1 year, 2 years, etc., or the date	new	Open
4770	ATTRA-02790	Quality of life		Two Quality of life forms are filed for the same patient.	new	Open
3180	RA_3007_LH	Termination of monitoring		The patient show indicate in the se	new	Open
4248	ATTRA-2090	Termination of monitoring		The patient show indicate in the se	new	Open
6300	ATTRA-02773	Follow-up		The first Follow-up form is not registered at all. Please register at all. Please add missing information if patient started the form (Evaluation	new	Open

Who: Monitor

Where: Study 

Chemotherapy dose reduction indicated, but no dose reduction in clinical database. Please correct data.

22 Jul 2021, 13:43 closed RESPONSES (5) / UNREAD (5)

23 Jul 2021, 08:13
 Total dose of each chemotherapy regimen was reduced, not available info here

23 Jul 2021, 08:16
 Carboplatin AUC5 total dose 400mg instead of 550mg Pemetrexed 500mg/m2 total dose 750mg instead of 980mg

19 Oct 2021, 14:40
 V0 values: Carboplatin AUC5 and Pemetrexed 500mg/m2 V2 values: Carboplatin AUC5 and Pemetrexed 500mg/m2 V3 values: Carboplatin AUC5 and Pemetrexed 500mg/m2 AND Chemotherapy dose reduction is answered YES. Dosage is reported the same on all visits, please explain the reduction or correct answer.

21 Oct 2021, 10:00
 Change was done for Pemetrexed, not such availability for Carboplatin units

2 Nov 2021, 11:40
 OK



Data lineage

Audit trail



QUESTIONS BY CONTENT | QUESTIONS BY TIME | FORM STATUS

Forms questions

INFORMED CONSENT

Informed consent

Change		Status		Value	
Date	Author	Original	New	Original	New
30/05/2018 09:26:18	Petra Jobankova	-	Empty		
30/05/2018 16:42:53	Petra Jobankova	Empty	Invalid		
30/05/2018 16:44:02	Petra Jobankova	Invalid	Done		Yes

Date of informed consent

Change		Status		Value	
Date	Author	Original	New	Original	New
30/05/2018 09:26:18	Petra Jobankova	-	Empty		
30/05/2018 09:26:35	Petra Jobankova	Empty	Skipped		
30/05/2018 16:44:02	Petra Jobankova	Skipped	Empty		

CML TREATMENT OVERVIEW

Who: QA manager
Where: Study

Data entry

	Treatment type (main)										
27	132120	30/05/2018 09:26:18	23628	INF-0001	INF-8201	Yes	Change to question	Q125	Data control	Data control	empty
28	132120	30/05/2018 09:26:18	23628	INF-0001	INF-8201	Yes	Change to question	Q126	Note	Data control	empty
29	132121	30/05/2018 09:26:18	23628	INF-0001	INF-8201	Yes	Change to question	Q673	Date of informed consent	empty	skipped
30	132121	30/05/2018 09:26:35	23628	INF-0001	INF-8201	Yes	Change to question	Q620	Date of informed consent	empty	skipped
31	132121	30/05/2018 09:26:35	23628	INF-0001	INF-8201	Yes	Change to question	Q627	Date of informed consent	empty	skipped
32	132121	30/05/2018 16:44:02	23628	INF-0001	INF-8201	Yes	Change to question	Q628	Phase of survival	empty	skipped



Data insights

Dashboard



<p>Number of patients</p> <hr/> <p>13 / 1 total / newly added <i>(new for last 30 days, testing and shared patients are not included)</i></p>	<p>Total number of forms</p> <hr/> <p>64 / 7 / 41 total / valid / pending <i>(testing and shared patients are not included)</i></p>
<p>Total number of queries</p> <hr/> <p>13 / 6 / 7 total / opened / closed <i>(testing and shared patients are not included)</i></p>	<p>Number of new queries</p> <hr/> <p>4 / 1 / 3 total / opened / closed <i>(last 30 days, testing and shared patients are not included)</i></p>

Who: Coordinator

Where: Study

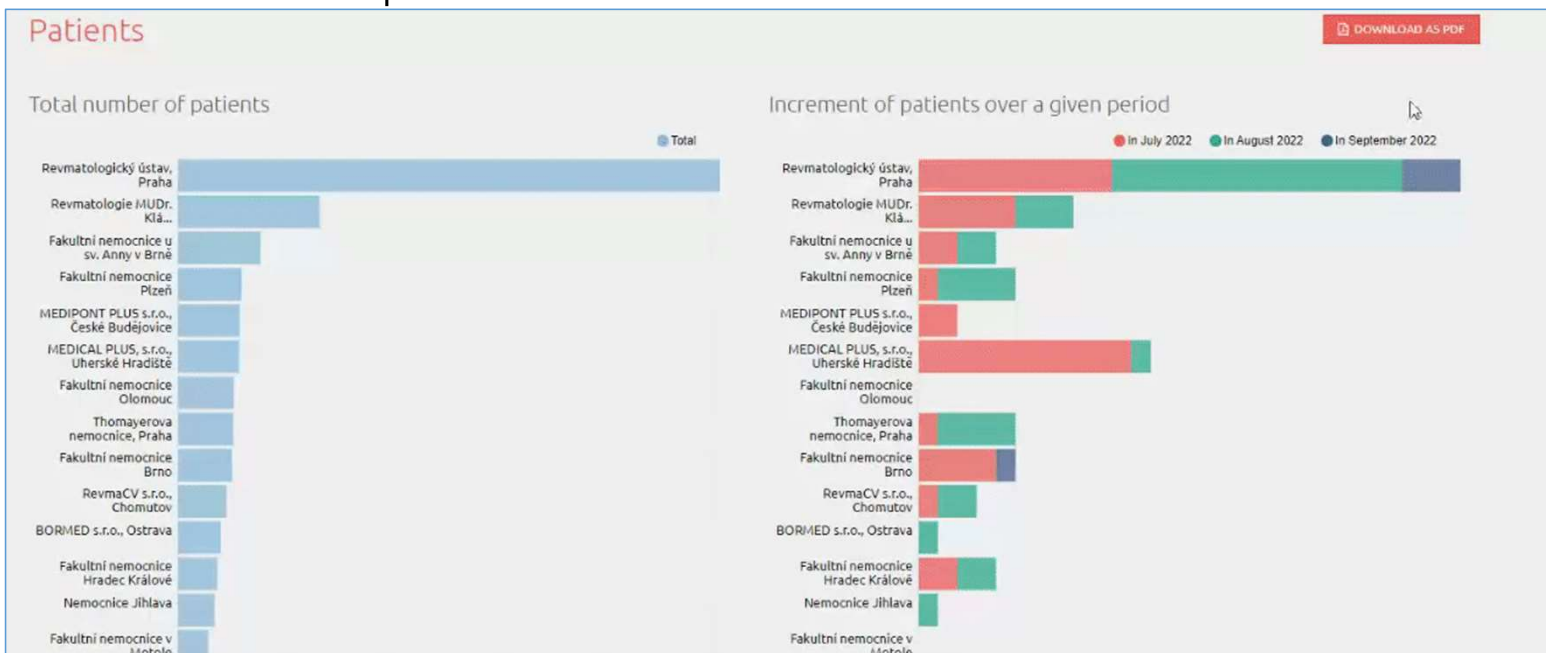


Data validation



Data insights

Interactive reports



Who: Coordinator

Where: Study



Data validation



Anomaly detection

Effic

ing

PubMed.gov Search PubMed User Guide

Advanced Save Email Send to Display options

> JMIR Med Inform. 2021 Apr 12. doi: 10.2196/27172. Online ahead of print.

Anomaly Detection Algorithm for Real-World Data and Evidence in Clinical Research

Vendula Churová^{1,2}, Roman Vyškovský^{1,2}, Kateřina Maršálová¹, David Kudláček², Daniel Schwarz^{1,2}

Affiliations + expand
PMID: 33851576 DOI: 10.2196/27172

Free article

Abstract

Background: Statistical analysis, which has become an integral part of evidence-based medicine, relies heavily on data quality that is of critical importance in modern clinical research. Input data are

FULL TEXT LINKS
JMIR Publications Preprint

ACTIONS
Cite Favorites

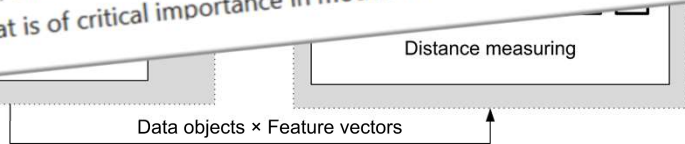
SHARE
Twitter Facebook Link

PAGE NAVIGATION

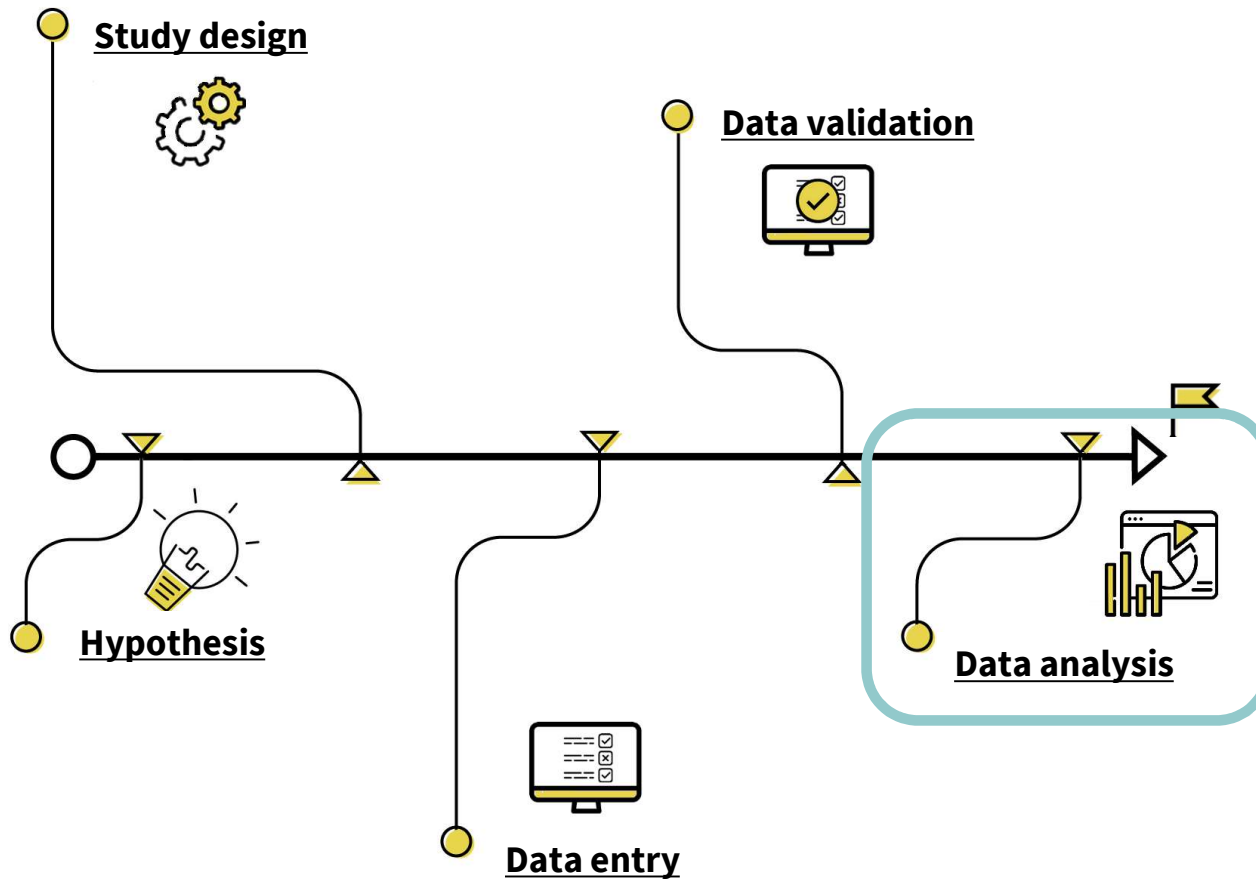
Coordinator

Study

Validation



From a hypothesis to an outcome



Toolkit for data analysis

Export

Logged in user: Radomír Stáňa (FN_Brno) LOG OUT

CLADE-IS REPORTER

Studie 9

Dashboard Reports overview **Study settings**

New complete export

[LOAD INPUT PARAMETERS FROM TEMPLATE](#)

Basic settings

* Centers
[Select all] [Deselect all]

* Form states
[Select all] [Deselect all]

Header format **?**
Alias_{n}

Export arrangement **?**
Multiple sheets - episodes on sheets separately

* Language mutation
en_GB

* Save the input parameters to a template
Do not save

Export name

Export name variable **?**

Template name

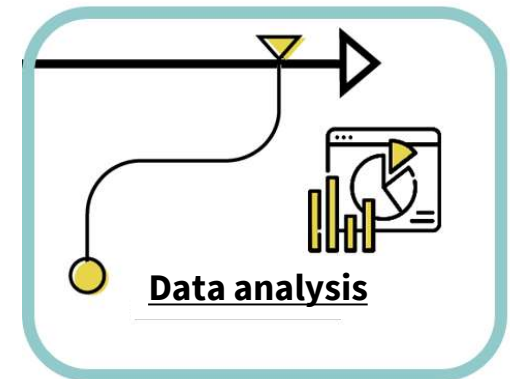
Template description

Extended settings

Notify by email after creating the export

Who: Analyst

Where: Reporter 



Toolkit for data analysis

Report



Institut biostatistiky a analýz, s.r.o.

Poštovská 68/3, 602 00 Brno

<http://www.biostatistika.cz> helpdesk@biostatistika.cz

Stav k datu: 04.11.2019 08:01

Registr HARM - Firma Abbvie

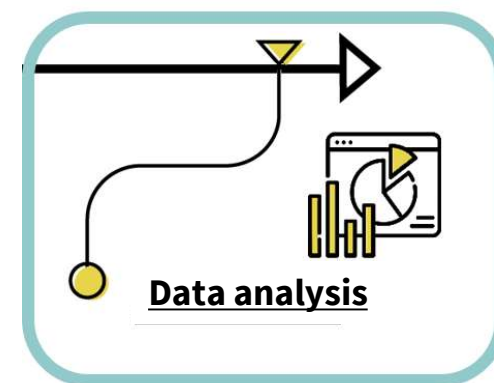
Aktuální přehled pacientů v registru

Centrum	Pacienti			Léčba (probíhající a ukončená)			Léčba (ukončená)					
	Celkem	Léčení	Neléčení	Terapeutický postup			Terapeutický postup			SVR		
				Dasabuvir + Ombitasvir + Paritaprevir / Ritonavir	Dasabuvir + Ombitasvir + Paritaprevir / Ritonavir + RBV	Glecaprevir + Pibrentasvir	Dasabuvir + Ombitasvir + Paritaprevir / Ritonavir	Dasabuvir + Ombitasvir + Paritaprevir / Ritonavir + RBV	Glecaprevir + Pibrentasvir	SVR	Relaps	Nelze hodnotit
Centrum zdravotní péče v obci Blatná	124	124	0	33	15	13	33	15	11	55	1	3
IBA Brno	328	328	0	64	27	80	64	27	44	121	1	13
IBA Brno - interní oddělení	46	46	0	4	2	5	4	2	5	11	0	0
IBA Brno - interní oddělení	100	88	12	13	3	13	12	3	7	19	1	2
IBA Brno - interní oddělení	101	101	0	24	1	26	22	0	26	41	0	7
IBA Brno - interní oddělení	73	73	0	4	5	19	4	5	13	21	0	1
IBA Brno - interní oddělení	211	211	0	30	2	25	30	2	8	38	1	1
IBA Brno - interní oddělení	264	264	0	37	18	32	37	18	32	83	3	1
IBA Brno - interní oddělení	24	24	0	6	0	0	6	0	0	5	0	1
IBA Brno - interní oddělení	52	52	0	29	2	0	28	2	0	30	0	0
IBA Brno - interní oddělení	299	268	31	49	12	68	48	10	52	104	1	5
IBA Brno - interní oddělení	0	0	0	0	0	0	0	0	0	0	0	0
IBA Brno - interní oddělení	167	156	11	6	0	35	6	0	18	23	1	0
IBA Brno - interní oddělení	19	19	0	2	0	9	1	0	6	4	0	3
IBA Brno - interní oddělení	0	0	0	0	0	0	0	0	0	0	0	0
IBA Brno - interní oddělení	132	132	0	22	1	8	22	1	8	31	0	0
IBA Brno - interní oddělení	9	9	0	0	0	3	0	0	3	3	0	0
IBA Brno - interní oddělení	74	74	0	7	2	12	7	1	8	13	2	1
IBA Brno - interní oddělení	63	63	0	1	19	0	1	17	0	15	0	3
IBA Brno - interní oddělení	50	50	0	6	5	11	5	4	10	19	0	0
IBA Brno - interní oddělení	60	60	0	29	11	1	4	1	0	5	0	0
Celkem	2196	2142	54	366	125	360	334	108	251	641	11	41



Who: Analytik

Where: Reporter 



Toolkit for data analysis

On-line vizualization

DEVELOPMENT OF THE DISEASE

TABLE GRAPH

Follow-up date	HAQ	DAS 28 - FW
12/05/2022	1.5	5.7325
24/11/2021	1.88	6.7709
24/08/2022	1.88	4.833
09/06/2022	2	6.0125
12/05/2022	1.5	5.7325
03/02/2022	1.88	7.1353
24/11/2021	1.88	6.7709

FORM STATUS

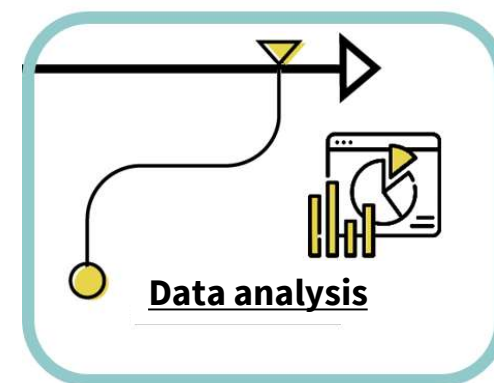
Form status

Valid

BACK

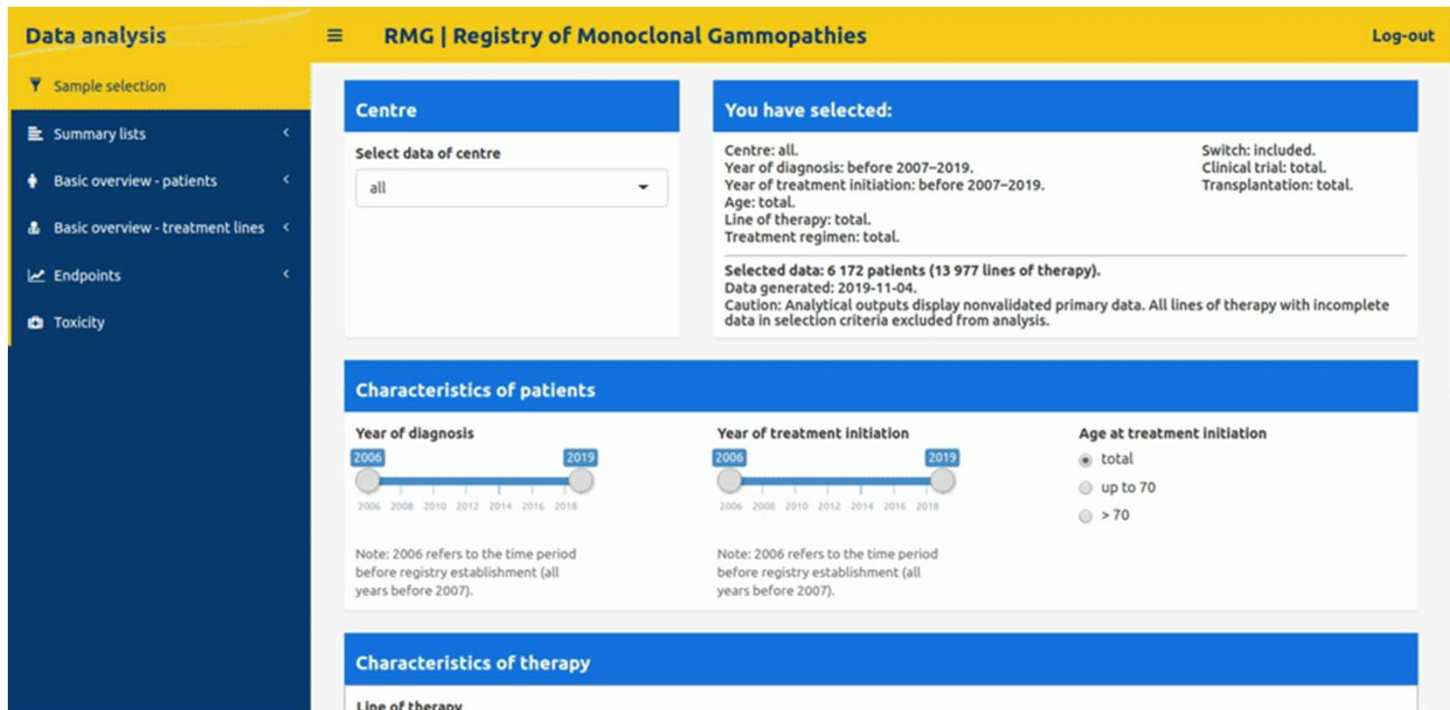
Who: Healthcare professional

Where: Study



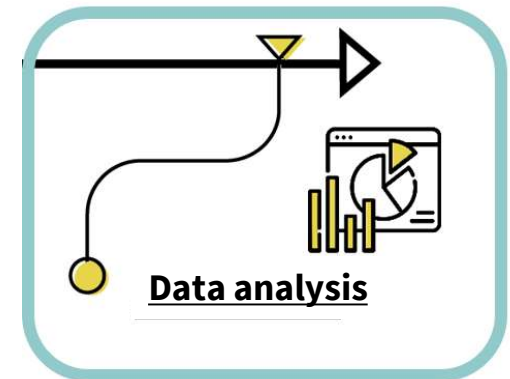
Toolkit for data analysis

Visual analytics on a project website

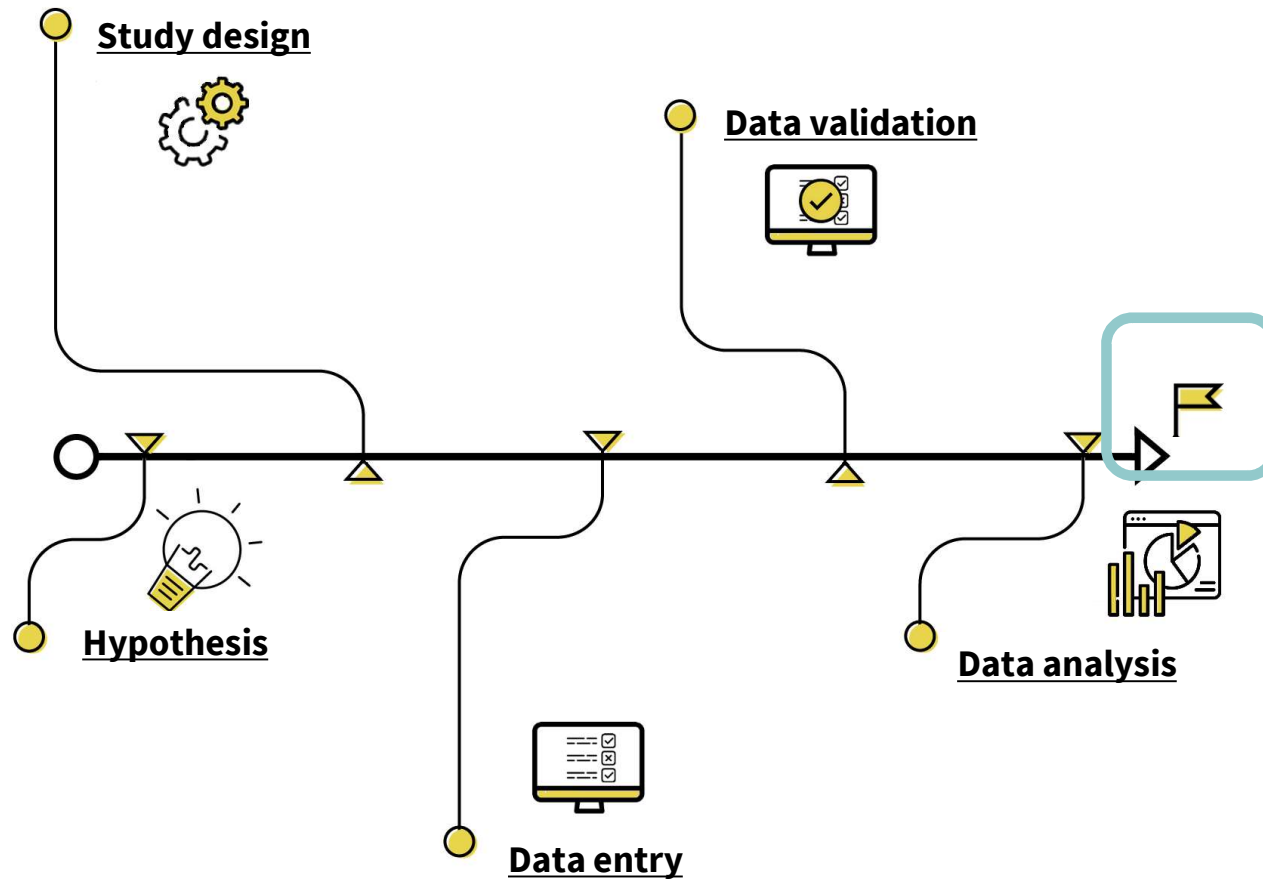


Who: Biostatistician

Where: Ext. website



From a hypothesis to an outcome



NIS

criteria and regulatory issues



NIS criteria and rules: medicinal product



Use of medicinal product with marketing authorization only

- is used in accordance with SmPC

- registered in the country when the data collection is planned

- available in the distribution network

- is prescribed and dispensed in the usual manner

- must not be provided for free: promotional samples cannot be used





NIS criteria and rules: other

Study must NOT be promoted

Marketing Authorization Holder may not provide financial compensation in excess of compensation for time and expenses

No additional diagnostic or monitoring procedures are applied

Patient selection must not be pre-influenced



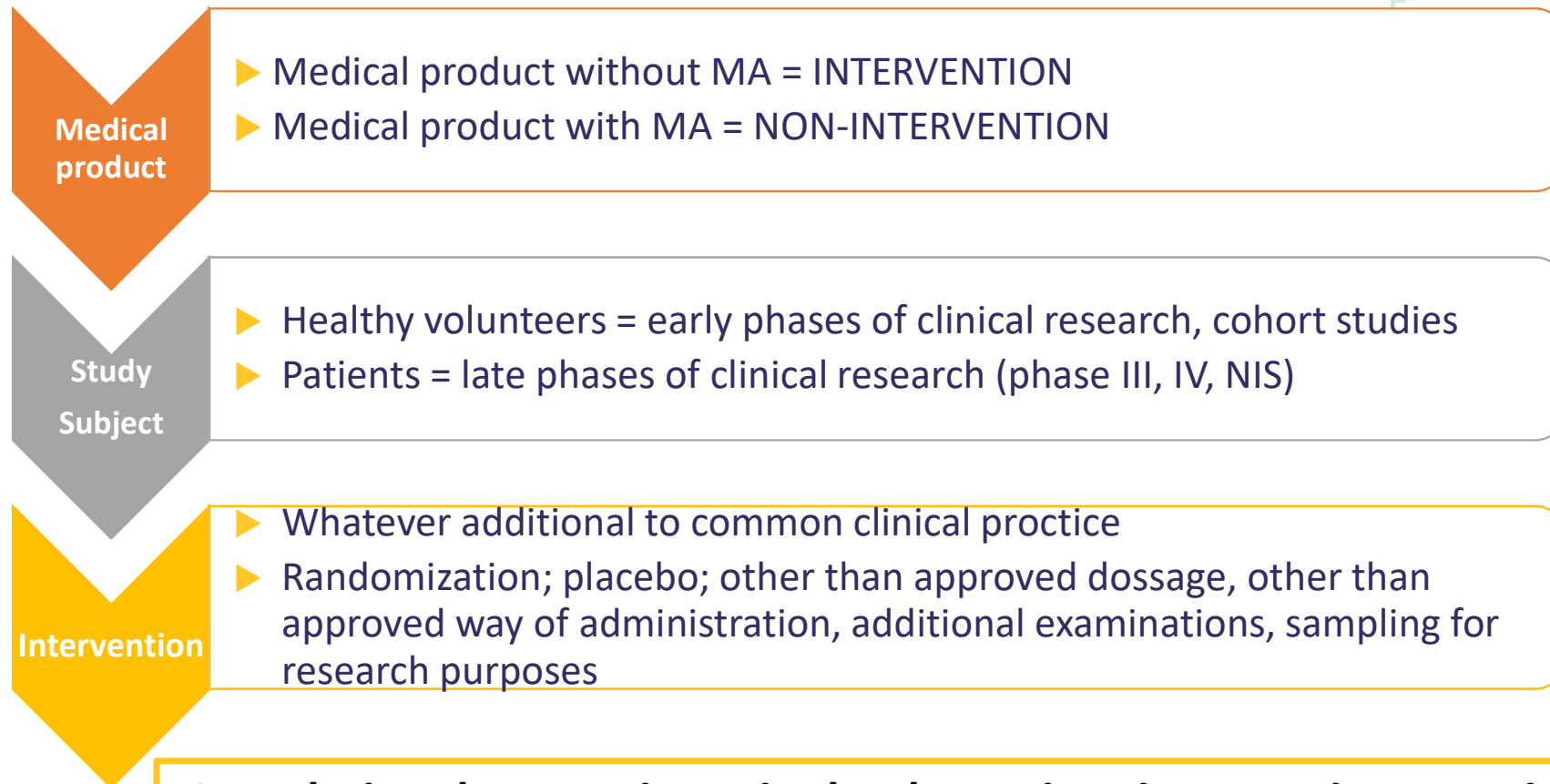
Regulatory: NIS from the legislation point of view



- ▶ 2001/20/ES: Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
- ▶ 536/2014/EU: REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC



Differences between intervention and non-intervention



Completing the questionnaire by the patient is not an intervention



System validation

self-assessment, certifications,
& penetration tests



Information Security Policy & ISMS certification



CERTIFICATE

Certification Body Management System No. 3053
TÜV SÜD Czech s.r.o.

certifies that

iba Institute of Biostatistics and Analyses

Institut biostatistiky a analýz, s.r.o.
Poštovská 68/3
CZ - 602 00 Brno
Ident. No.: 02784114

has established and applies an Information Security Management System for

- management of research projects in health and life sciences
- clinical data management, analysis and interpretation
- development and provision of CLADE-IS information system services for data registration, storage and processing

An audit was performed, Report No. 14.617.593
Proof has been furnished that the requirements according to

EN ISO/IEC 27001:2017
are fulfilled.

The certificate is valid from **22.07.2022** until **21.07.2025**
Certificate Registration No. **14.598.255**
Statement of applicability dated 08.06.2022.

TÜV SÜD Czech s.r.o. • Novodvorská ...
Prague, 24.06.2022

iba

ZERTIFIKAT ♦ **CERTIFICATE** ♦ **認 證 證 書** ♦ **СЕРТИФИКАТ** ♦ **CERTIFICADO** ♦ **CERTIFICAT**

F 1464114-IBEN/2021/CS5/ PRAGUE, 24/06/2022

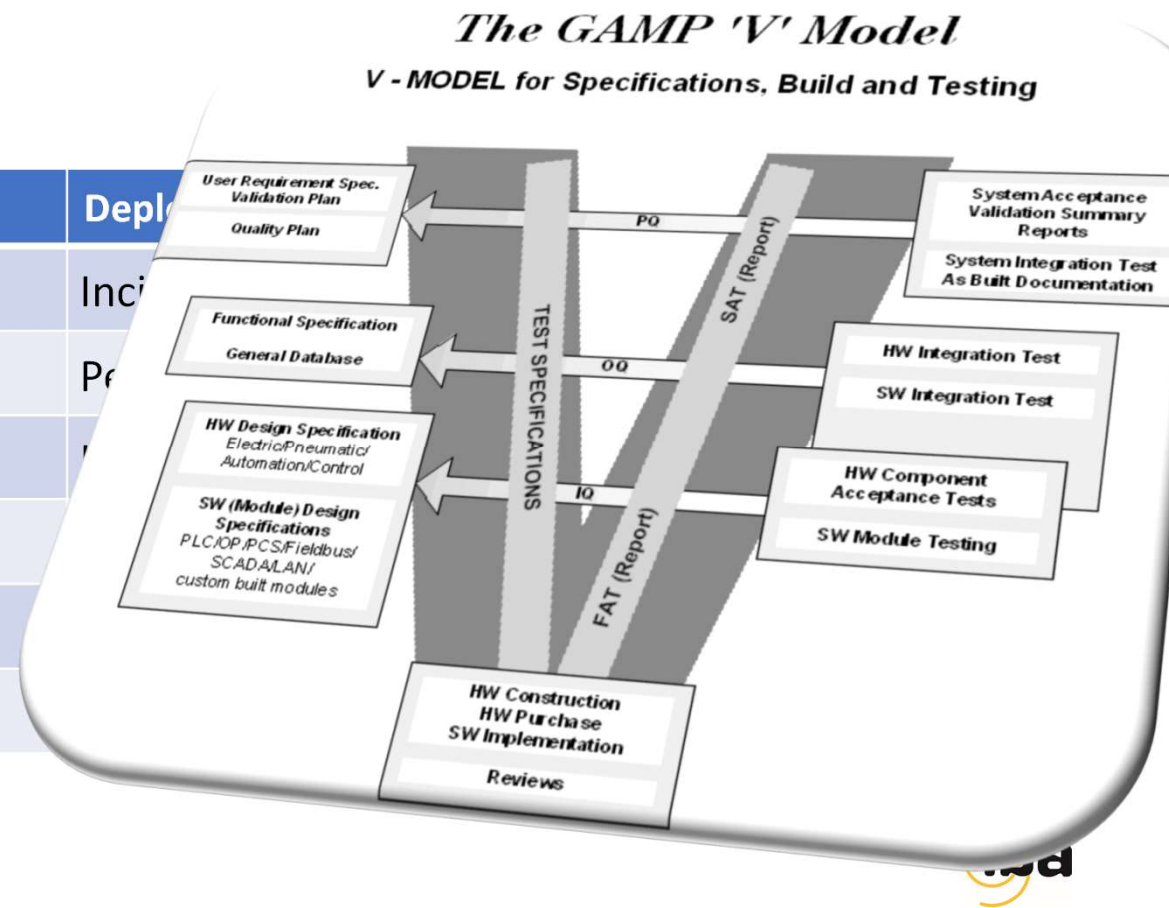


Relevant documentation

What should an organization that develops and/or operates an EDC system have documented?

- SOPs – Standard Operation Procedures,
- WIs – Working Instructions

Development & testing	Deployment
Release management	Incident
Software Development	Performance
Testing and verification	
Software documentation	
Management of changes in SW source code	
Safety of software development	





Security measures

- ✓ Logins,
- ✓ Storage space,
- ✓ Backups,
- ✓ Data reach,
- ✓ Failover,
- ✓ Data privacy,
- ✓ Permanent support & maintenance,
- ✓ GDPR compliance,
- ✓ and Security of facilities

Precautions...

= 3-D penetration tests:

- system/application
- IT infrastructure
- people

Compliance

- the EC Directive 2003/94/EC Annex 11
- USA (FDA) 21 CFR part 11

Stability...

= release management:

- separated Dev/Test/Prod environments
- Dev, Test1, Test2 cycles





How to prove or verify that a system is valid?



Self-assessment

- Documentation using SOPs and WIs
- Internal audits



Certification

- Documentation and the processes are compliant with a standard and/or recommendation(
- ISO 27k, GAMP, HIPAA,...

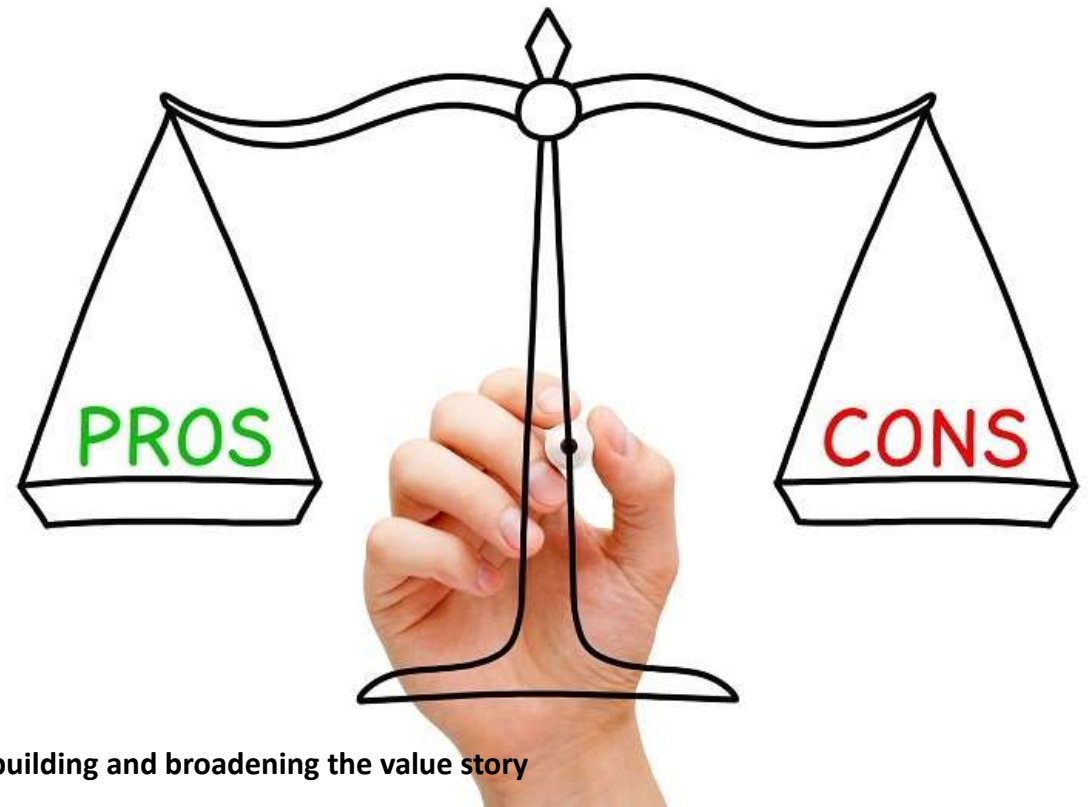


Additional tests

- Penetration tests
- IT infrastructure, System/Application, People (social engineering)






















NIS: Let's recap!

pros & cons





Advantages of NIS against other types of studies

Aspect	NIS & RWD/RWE projects	Clinical trials (RCTs)
 COSTS	 low costs	 very high costs
 SUCCESS	 high success rate	 low certainty
 ABILITY TO ANSWER RESEARCH QUESTION(S)	 can answer	 answers only the product-related questions, fails in answering more general research questions
 ROLE IN DRUG DEVELOPMENT	 significant	 significant
 REGULATORY ISSUES	 easy procedures	 complex and tedious procedures
 RECRUITMENT OF SUBJECTS	 easy and fast	 difficult, long-term, multiple challenges
 EVIDENCE OF CLINICAL VALUE	 very helpful	 limited





Conclusion(s)

NIS and RWE projects collect valuable data which have a potential:

- ▶ to inform clinical practice
- ▶ to develop and/or update new guidelines in health care
- ▶ to clarify the value of new therapies
- ▶ to improve drug development cycle

Pharma, biotech companies, and other R&D organizations including academics should value their data resources...

- ▶ ...and use them, among other things, in their future development(s).

Multiple data sources may create a space for errors, but you can avoid them...

- ▶ by employing well educated and experienced clinical data managers,
- ▶ and by using solid and validated tools and systems.





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