



# Algoritmy strojového učení jako klíč k vyšším standardům kvality zdravotnických dat

Contract Research --- Digital Health --- Real-World Data  
Clinical Data Management --- Electronic Data Capture  
Data Science --- Virtual Patients



## Kdo jsme?

...: CRO, spin-off Masarykovy univerzity



## Projekty za hranicemi klinických hodnocení

...: SW vývoj, vlastní R&D



SW house ?...



53 37.6

Query raw data → Server → Description of anomaly → Postproc

Data information → Preprocessing → Semi-flattened tables → Univariate testing → Evidence of anomaly → Detects

Dropping → Imputation → Recoding → Thresholding

Distance

Contents: Categorical, Censor, Event, Interval, Time

data management data analysis information technologies project management



## Making Waves

...: Our Voice in Clinical Research & Health Informatics Forums




**SPARK EUROPE WEBINAR SERIES 2022**  
Wednesdays at 4 pm CET

**Non-Interventional Studies: building and broadening the value story**



Daniel Schwarz & Marika Chrápavá  
7th September 2022 | 4 – 5 pm (CET) | Online Webinar




## Quality and regulation play a role !

...: Integrated quality management system



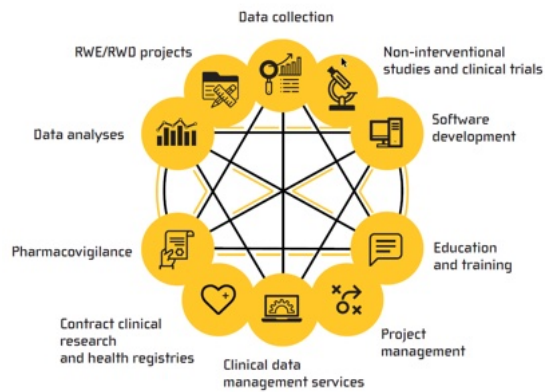






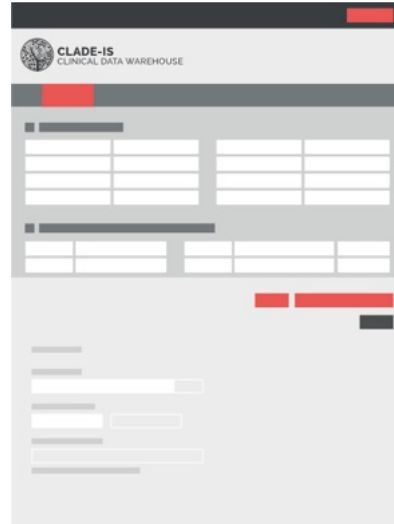
## Streamlined Services for Clinical Research

...: Discover the possibilities!




**Problémy k řešení:**  
„data is everything“  
manual data (re)-entry

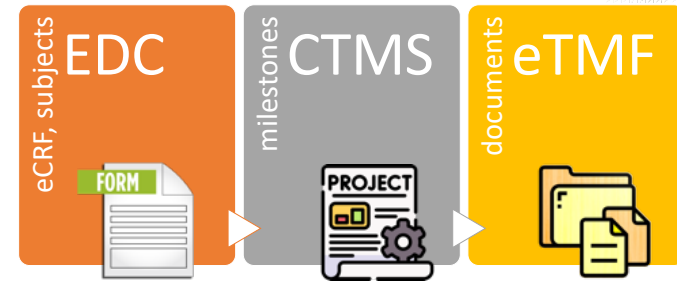




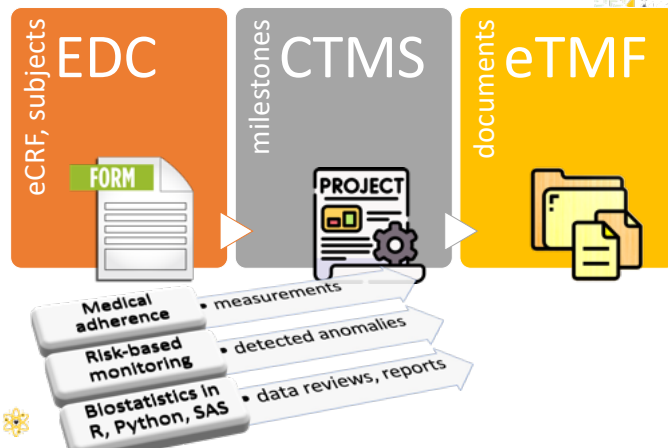
## Electronic Data Capture

Clinical Data Management platform

### TOOLS for achieving good quality of data



### TOOLS for achieving good quality of data



**CLADE-IS**  
CLINICAL DATA WAREHOUSE

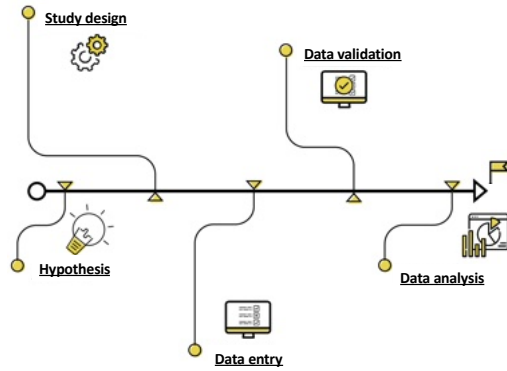
### Healthy data

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.

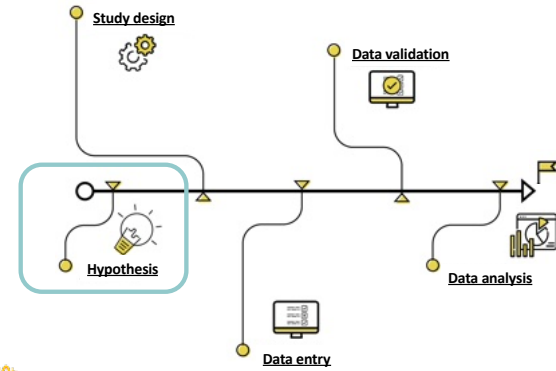
#### Features

- 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

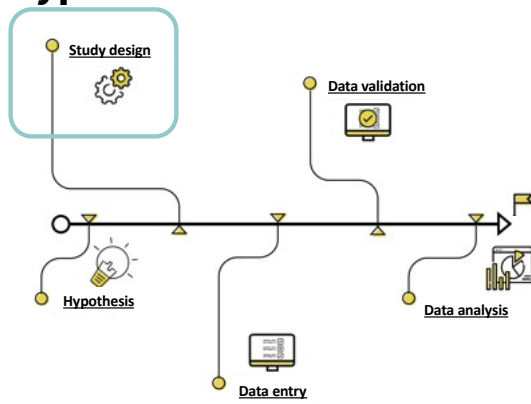
## From a hypothesis to an outcome



## From a hypothesis to an outcome



## From a hypothesis to an outcome



## Study design

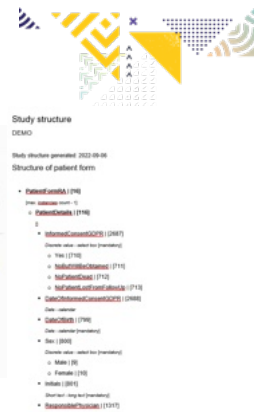
Robust structure entities

Arm #	Arm name	Phase #	Phase name
1	Observation	1	Observation
2	Observation	2	Observation
2	Observation	3	Observation
2	Observation	4	Observation
2	Observation	5	Observation
2	Observation	6	Observation
2	Observation	7	Observation
2	Observation	8	Observation
2	Observation	9	Observation
2	Observation	10	Observation
2	Observation	11	Observation
2	Observation	12	Observation
2	Observation	13	Observation
2	Observation	14	Observation
2	Observation	15	Observation
2	Observation	16	Observation
2	Observation	17	Observation
2	Observation	18	Observation
2	Observation	19	Observation
2	Observation	20	Observation
2	Observation	21	Observation
2	Observation	22	Observation
2	Observation	23	Observation
2	Observation	24	Observation
2	Observation	25	Observation
2	Observation	26	Observation
2	Observation	27	Observation
2	Observation	28	Observation
2	Observation	29	Observation
2	Observation	30	Observation
2	Observation	31	Observation
2	Observation	32	Observation
2	Observation	33	Observation
2	Observation	34	Observation
2	Observation	35	Observation
2	Observation	36	Observation
2	Observation	37	Observation
2	Observation	38	Observation
2	Observation	39	Observation
2	Observation	40	Observation
2	Observation	41	Observation
2	Observation	42	Observation
2	Observation	43	Observation
2	Observation	44	Observation
2	Observation	45	Observation
2	Observation	46	Observation
2	Observation	47	Observation
2	Observation	48	Observation
2	Observation	49	Observation
2	Observation	50	Observation
2	Observation	51	Observation
2	Observation	52	Observation
2	Observation	53	Observation
2	Observation	54	Observation
2	Observation	55	Observation
2	Observation	56	Observation
2	Observation	57	Observation
2	Observation	58	Observation
2	Observation	59	Observation
2	Observation	60	Observation
2	Observation	61	Observation
2	Observation	62	Observation
2	Observation	63	Observation
2	Observation	64	Observation
2	Observation	65	Observation
2	Observation	66	Observation
2	Observation	67	Observation
2	Observation	68	Observation
2	Observation	69	Observation
2	Observation	70	Observation
2	Observation	71	Observation
2	Observation	72	Observation
2	Observation	73	Observation
2	Observation	74	Observation
2	Observation	75	Observation
2	Observation	76	Observation
2	Observation	77	Observation
2	Observation	78	Observation
2	Observation	79	Observation
2	Observation	80	Observation
2	Observation	81	Observation
2	Observation	82	Observation
2	Observation	83	Observation
2	Observation	84	Observation
2	Observation	85	Observation
2	Observation	86	Observation
2	Observation	87	Observation
2	Observation	88	Observation
2	Observation	89	Observation
2	Observation	90	Observation
2	Observation	91	Observation
2	Observation	92	Observation
2	Observation	93	Observation
2	Observation	94	Observation
2	Observation	95	Observation
2	Observation	96	Observation
2	Observation	97	Observation
2	Observation	98	Observation
2	Observation	99	Observation
2	Observation	100	Observation

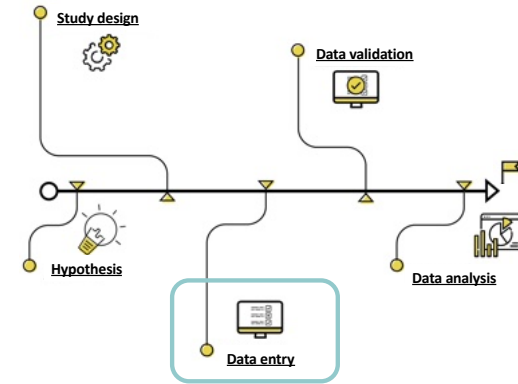
Who: Data manager  
Where: Designer



# Study structure export



# From a hypothesis to an outcome



# Data entry

Create and edit forms

**Who:** Healthcare professional  
**Where:** Study

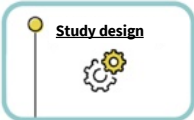


# Data entry – UX features

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)

**Who:** Data manager  
**Where:** Designer





## Data entry - UX features

Edit checks & instant validation

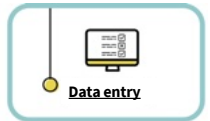


## Data entry

Responsivity



**Who:** Healthcare professional  
**Where:** Study

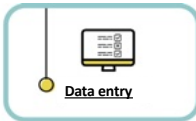


## Data entry

Single Form Mode – authentication through a hash code



**Who:** Healthcare professional  
**Where:** Study



## UX features

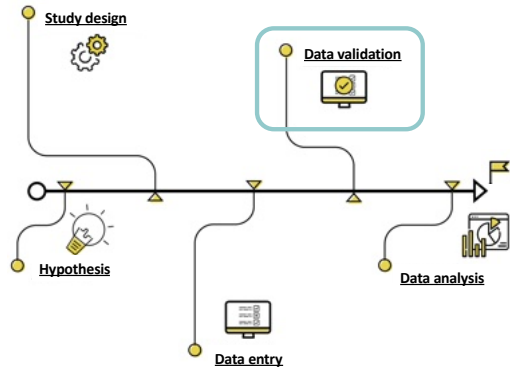
Skip logic



**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_98	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_95	Follow up		There is no Quality of life with SF36 filled 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 have the same Date.	new	Open
3180	RA_3007_14	Termination of monitoring		The patient should indicate in the up	new	Open
4248	ATTRA-2090	Termination of monitoring		The patient should indicate in the up	new	Open
6300	ATTRA-02773	Follow up		The First Follow-up register at all PE or add missing if patient started Form (Evaluation)	new	Open

**Who:** Monitor  
**Where:** Study



# Data lineage

## Audit trail

Change	Date	Author	Status	Original	New	Value	Original	New		
<b>INFORMED CONSENT</b>										
Informed consent										
Change	Date	Author	Status	Original	New	Value	Original	New		
	30/05/2018 09:26:18	Petra Jabankova	-	Empty	Empty			New		
	30/05/2018 10:42:53	Petra Jabankova	Invalid	Invalid	Invalid					
	30/05/2018 10:44:02	Petra Jabankova	Invalid	Done	Done			Yes		
Date of informed consent										
Change	Date	Author	Status	Original	New	Value	Original	New		
	30/05/2018 09:26:18	Petra Jabankova	-	Empty	Empty					
	30/05/2018 09:26:35	Petra Jabankova	Skipped	Skipped	Skipped					
	30/05/2018 10:44:02	Petra Jabankova	Skipped	Skipped	Skipped					
<b>ONLINE TREATMENT OVERVIEW</b>										
27	132120	30/05/2018 09:26:18	23628	INF-0001	INF-8201	Yes	Change to question	Q125	Data control	empty
28	132120	30/05/2018 09:26:18	23628	INF-0001	INF-8201	Yes	Change to question	Q126	Note	Data control
29	132121	30/05/2018 09:26:18	23628	INF-0001	INF-8201	Yes	Change to question	Q613	Date of informed consent	skipped
30	132121	30/05/2018 09:26:18	23628	INF-0001	INF-8201	Yes	Change to question	Q620	Date of last survival	skipped
31	132121	30/05/2018 09:26:18	23628	INF-0001	INF-8201	Yes	Change to question	Q627	Date of survival	skipped
32	132121	30/05/2018 09:26:18	23628	INF-0001	INF-8201	Yes	Change to question	Q638	Phase of survival	skipped

**Who:** QA manager  
**Where:** Study



# Data insights

## Dashboard

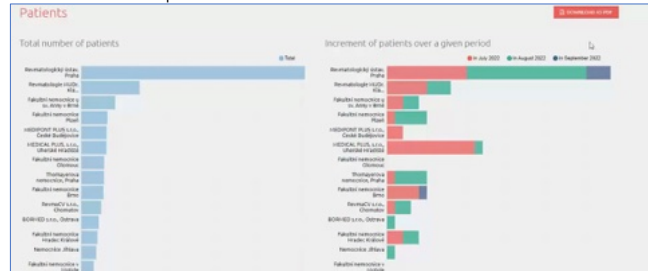
<p>Number of patients</p> <p><b>13 / 1</b></p> <p>total / newly added</p> <p><i>(new for last 30 days, testing and shared patients are not included)</i></p>	<p>Total number of forms</p> <p><b>64 / 7 / 41</b></p> <p>total / valid / pending</p> <p><i>(testing and shared patients are not included)</i></p>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

**Who:** Coordinator  
**Where:** Study

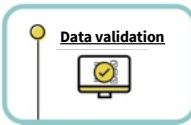


# Data insights

Interactive reports



**Who:** Coordinator  
**Where:** Study



# Anomaly detection

Efficient

**Anomaly Detection Algorithm for Real-World Data and Evidence in Clinical Research**  
Vendula Churová<sup>1, 2</sup>, Roman Vylčkovský<sup>1, 2</sup>, Kateřina Maršalová<sup>1</sup>, David Kudláček<sup>2</sup>, Daniel Schwarz<sup>1, 2</sup>  
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. Inout data are



**20190102-M-at-TEST-test | Český pacient**

<b>Jméno</b>	Milan Jarmo	<b>Centrum</b>	Investigator	<b>Ležák</b>	user_1
<b>Datum narození pacienta</b>	27. 8. 2023 23:12	<b>Datum narození</b>	02.01.2019	<b>Země a příjmení</b>	Albert (Phy00)
<b>Roční číslo</b>	birthNumber=001Phy00	<b>Podíl</b>	MUJ	<b>Stav</b>	all
<b>Datum - testování</b>	-	<b>DCFR</b>	Atc	<b>Místní formulář</b>	all

**Queries** | + přidat query

1. 9. 2023 16:34 u tohoto pacienta existuje podezření, že zadaná data obsahují anomálie

31. 8. 2023 8:25 Příklad změny pacientůvé query...

**Formuláře pacienta**

FÁZE: **Hlavní fáze (0)** | Následná fáze (1) | Předposlední fáze (0) | PE fáze (0) | AE fáze (0) | API fáze (0) | Designer fáze (0) | Vytvářet fáze (0) | Validaci fáze (0) | SQL fáze (0) | ICD fáze (1) | Vizualizační fáze (0) | PMS fáze (0)

Vytvořené query lze vidět na přehledu pacienta.

ihodnotu otázky upravit (a diskutovat o tom), ...

**20190102-M-at-TEST-test | Český pacient**

<b>Jméno</b>	Milan Jarmo	<b>Centrum</b>	Investigator	<b>Ležák</b>	user_1
<b>Datum narození pacienta</b>	27. 8. 2023 23:12	<b>Datum narození</b>	02.01.2019	<b>Země a příjmení</b>	Albert (Phy00)
<b>Roční číslo</b>	birthNumber=001Phy00	<b>Podíl</b>	MUJ	<b>Stav</b>	all
<b>Datum - testování</b>	-	<b>DCFR</b>	Atc	<b>Místní formulář</b>	all

**Queries** | + přidat query

1. 9. 2023 16:34 u tohoto pacienta existuje podezření, že zadaná data obsahují anomálie

1. 9. 2023 16:43 Otázka byla upravena.

31. 8. 2023 8:25 Příklad změny pacientůvé query...

**Formuláře pacienta**

FÁZE: **Hlavní fáze (0)** | Následná fáze (1) | Předposlední fáze (0) | PE fáze (0) | AE fáze (0) | API fáze (0) | Designer fáze (0) | Vytvářet fáze (0) | Validaci fáze (0) | SQL fáze (0) | ICD fáze (1) | Vizualizační fáze (0) | PMS fáze (0)



CLADE-IS CLINICAL DATA WAREHOUSE

20190102-M-at-TEST-test | Cvičný pacient

Rameno	Hlavní rameno	Centrum	Investigator	Lékař	user_1
Datum zápisu pacienta	27. 8. 2023 23:12	Datum narození	02.01.2019	Jméno a příjmení	Albert (Phy00)
Radio číslo	BR01Number-49 (Phy00)	Podíl	MUJ	Stavba	st
Datum - testovací	-	DCFR	Acti	Místní formuláře	Acti

Queries | **Hide query**

Roman Vykavský, 1. 9. 2023 16:24 | U tohoto pacienta existuje podotčení, že zadaná data obsahují anomálie. **Zavřít** | Odpověď (0) | Znovu otevřít

system, 1. 9. 2023 11:18 | Chyba ve validaci: all subject | Odpověď (0) | Zavřít

Roman Vykavský, 31. 8. 2023 8:25 | Přiklad první pacientův query... | Odpověď (0) | Smazat | Zavřít

**A query zavřít.**

Formuláře pacienta

FÁZE: **Hlavní fáze (0)** | Následná fáze (1) | Předpovědní fáze (0) | FE fáze (0) | AE fáze (0) | API fáze (0) | Designer (0) | Vizualizační fáze (0)

PH03.k01e (0)

Formulář se všemi stávkami (1) | Více formulářů není možné zapsat

Hesypovný formulář (0) | Zavřít nový formulář

Formulář datům (0) | Zavřít nový formulář

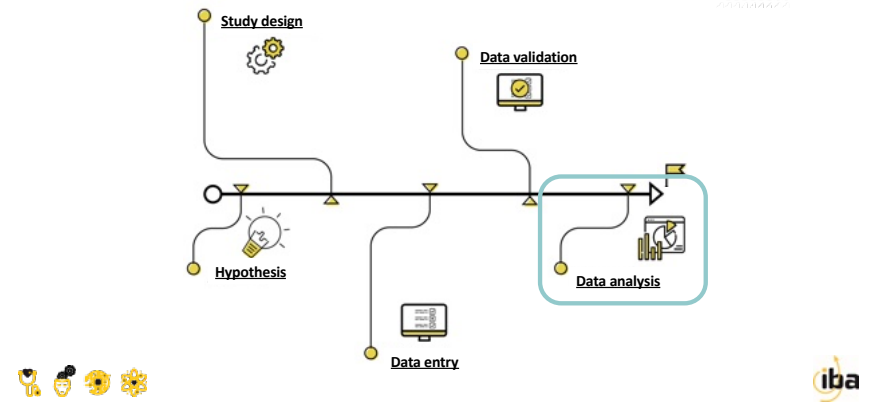
Form eventy (0) | Zavřít nový formulář

Randomizační formulář (0) | Zavřít nový formulář

Formulář se zadanými číselníky (0) | Zavřít nový formulář

Formulář k výpočtům (0) | Zavřít nový formulář

# From a hypothesis to an outcome



# Toolkit for data analysis

Export

CLADE-IS REPORTER

Study 9

New complete export

Basic settings

Options

Export name

Export date

Export format

Export description

Export parameters to a template

Export name variables

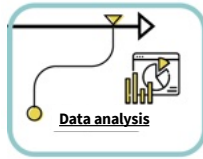
Template name

Template description

Exported settings

Apply by email after creating the export

Who: Analyst  
Where: Reporter



# Toolkit for data analysis

Report

Instytut biostatystyki i analizy, s.r.o.

Průběžná 602/3, 602 00 Brno  
http://www.biostatistika.cz/helpdesk@biostatistika.cz

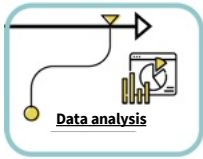
Stav k datu: 04.11.2023 09:05

Registr HARM - Brno

Aktuální přehled pacientů v registru

Kategorie	Kategorie	Podkategorie	Měsíční podrobný výhled										Celkový souhrn			
			01	02	03	04	05	06	07	08	09	10	11	12	Spolu	Podíl
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Who: Analytik  
Where: Reporter

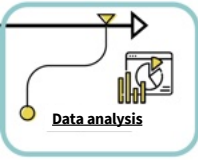


# Toolkit for data analysis

On-line visualization

Follow-up date	HAQ	SDS 31-PW
12/04/2022	1.5	5.7323
24/11/2021	1.88	6.7706
24/06/2022	1.88	6.833
09/06/2022	2	6.8125
12/05/2022	1.5	5.7323
08/02/2022	1.88	5.7323
24/11/2021	1.88	6.7706

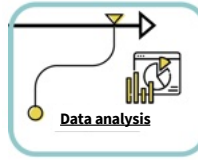
**Who:** Healthcare professional  
**Where:** Study



# Toolkit for data analysis

Visual analytics on a project website

**Who:** Biostatistician  
**Where:** Ext. website

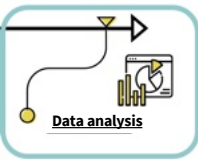


# Toolkit for data analysis

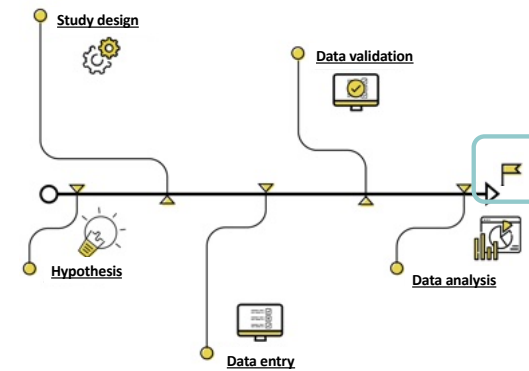
Visual analytics on a project website



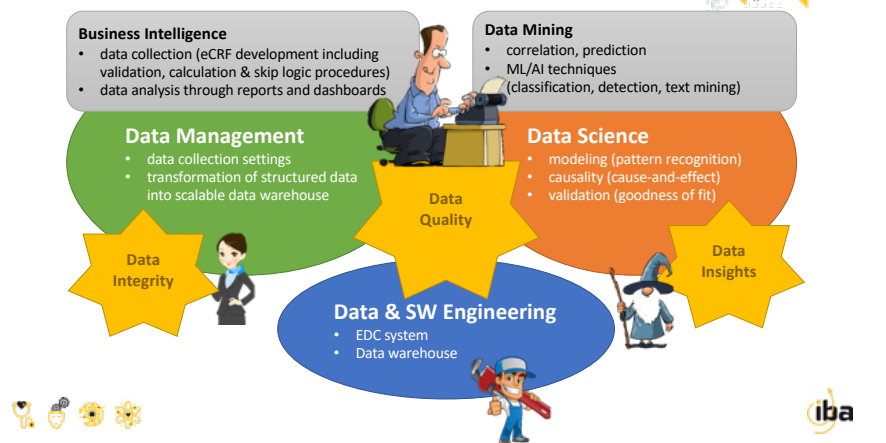
**Who:** Biostatistician  
**Where:** Ext. website



# From a hypothesis to an outcome



## PEOPLE behind data-driven clinical research



## Integrace systémů

...: API

### CLADE-IS na straně příjemce

- ✓ Existující CLADE-IS API
- ✓ Individuální řešení

### CLADE-IS na straně odesílatele

- o API druhé strany

### Naše zkušenosti: přenos laboratorních dat

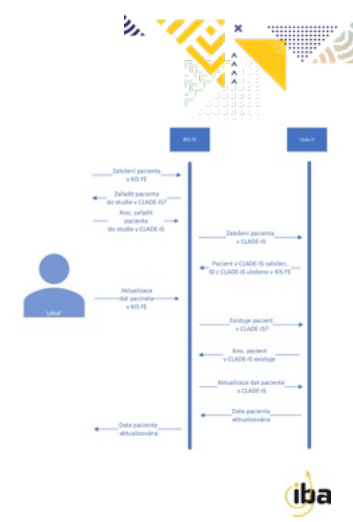
- Ideální startovní bod integrace.
- Velké množství čísel/hodnoty, ve kterých lze snadno udělat chyby při ručním přepisu.
- Jednoduché mapování (jednotky).



## Integrace systémů

...: API = bezpečnost

- Zabezpečení datové cesty.
- Testování a validace přenosu.
- Průběžná kontrola přenášených dat (testovací datasets).



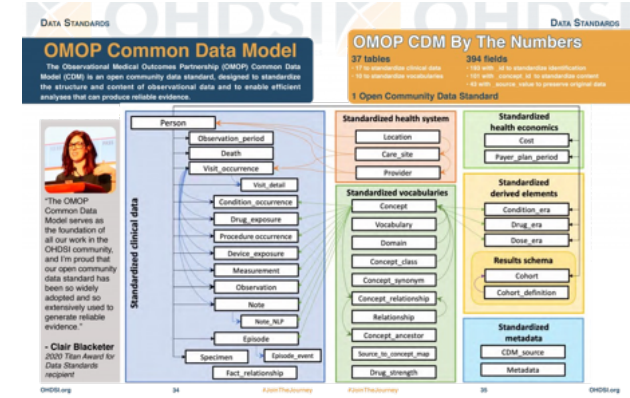
# Integrace systémů

...: datové standardy



# Integrace systémů

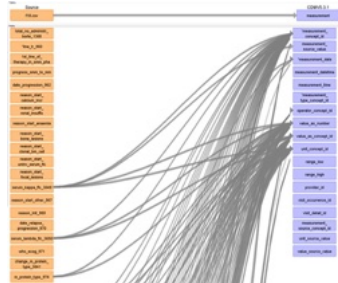
...: datové standardy



# Integrace systémů

...: EHDEN a OMOP

- Evropský ekosystém pro zpracování a využití zdravotnických dat
- IBA je certifikovaný SME partner v síti EHDEN



# Integrace systémů

...: Automatizace pomocí AI/robotů



# Pozvánka



EPISODE #1: IVO PROKEŠ

## CLINICAL DATA MANAGEMENT best practices



EPISODE #2: ALEXANDER SCHACHT



EPISODE #4: ANTOINE PIGNATELLI



EPISODE #6: TOMÁŠ MACHULEK



EPISODE #7: JAROSLAV KOČA



EPISODE #3: ALEXANDER KRANICH



EPISODE #5: RICHARD HÜLER



EPISODE #8: ADAM CHEX



- [www.biostatistika.cz](http://www.biostatistika.cz) | [www.clade-is.com](http://www.clade-is.com)
- [schwarz@biostatistika.cz](mailto:schwarz@biostatistika.cz)
- <https://www.linkedin.com/in/daniel-schwarz-197705/>
- <https://ibanodcast.podbean.com/>



healthy data