Algoritmy AI/ML
jako klíč k vyšším standardům zdravotnických dat

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

iba Institute of Biostatistics and Analyses

Daniel Schwarz

..:: propojování akademického světa s prostředím businessu

iba Institute of Biostatistics and Analyses

MUNI | SIMU MED

Česká společnost pro umělou inteligenci
a digitální inovativní technologie v medicíně
Česká lékařská společnost J. Evangelisty Purkyně

CSAIM

Kdo jsme?

..:: CRO, spin-off Masarykovy univerzity

Projekty za hranicemi klinických hodnocení

..:: SW vývoj, vlastní R&D

EHDEN
EUROPEAN HEALTH DATA & EVIDENCE NETWORK

ecrin

...well-recognized CRO!

Kvalita a regulace hrají důležitou roli!

..:: Integrovaný systém managementu kvality

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Czech

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
a Quality 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. 13.035.985
Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled.

The certificate is valid from 09.06.2020 until 08.06.2023
Certificate Registration No. 13.032.609

Prague, 09.06.2020

IAF S 3053

TÜV SÜD Czech s.r.o. • Novodvorská 994 • 142 21 Prague 4 • Czech Republic • certification@tuv-sud.cz

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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An audit was performed, Report No. 13.035.985
Proof has been furnished that the requirements according to

EN ISO/IEC 27001:2017

are fulfilled.

The certificate is valid from 09.06.2020 until 21.07.2022
Certificate Registration No. 12.164.656, revision No. 1
This certificate is a revision of the certificate No. 12.164.656, issued 22.07.2019.
Statement of applicability dated 06.3.2020.

Prague, 09.06.2020

S 3053

TÜV SÜD Czech s.r.o. • Novodvorská 994 • 142 21 Prague 4 • Czech Republic • certification@tuv-sud.cz

EU-MDR 2017/745

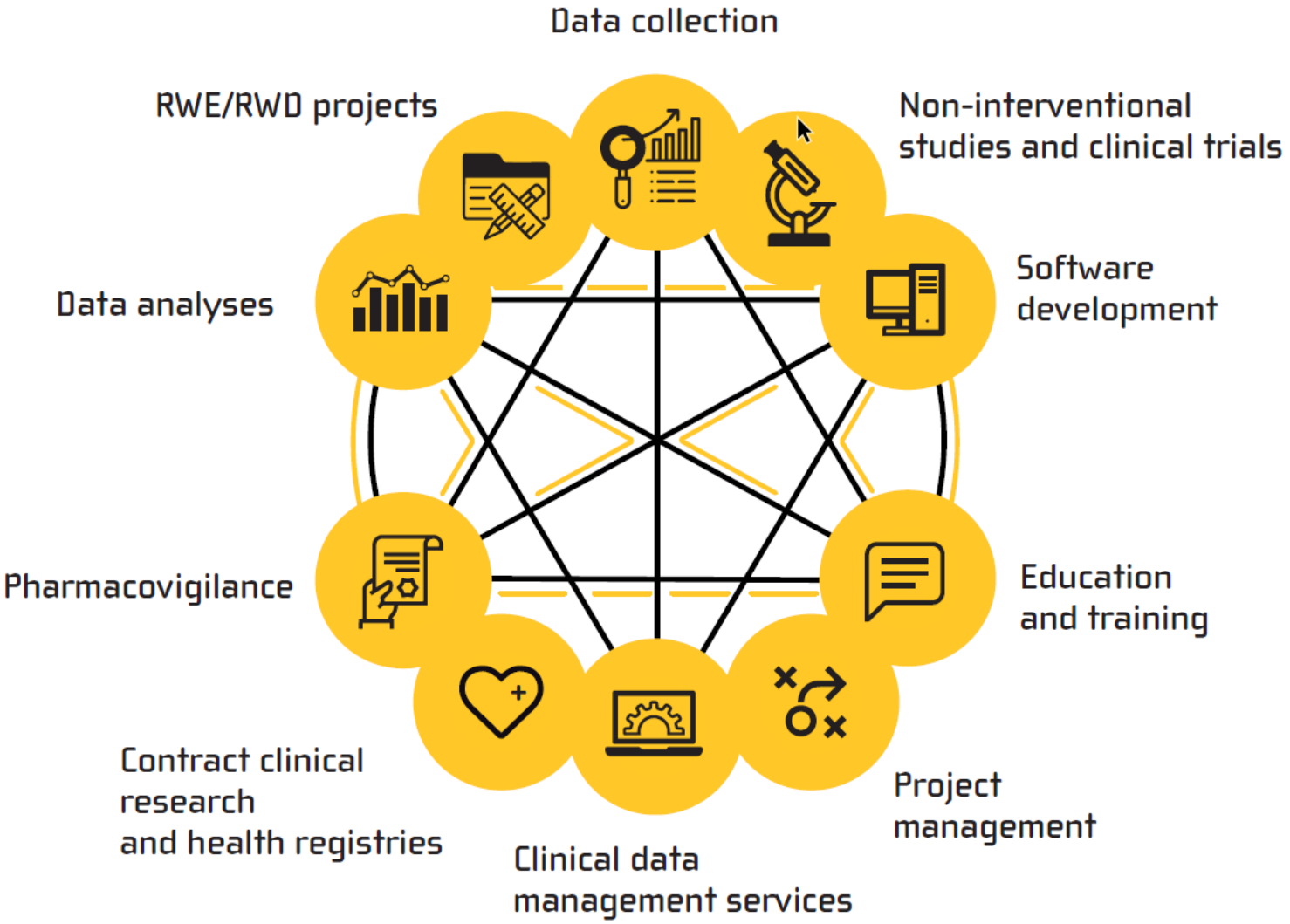
ISO 14155 ISO

GOOD CLINICAL PRACTICE compliant

GDPR iba ready

Streamlined Services for Clinical Research

..:: Discover the possibilities!



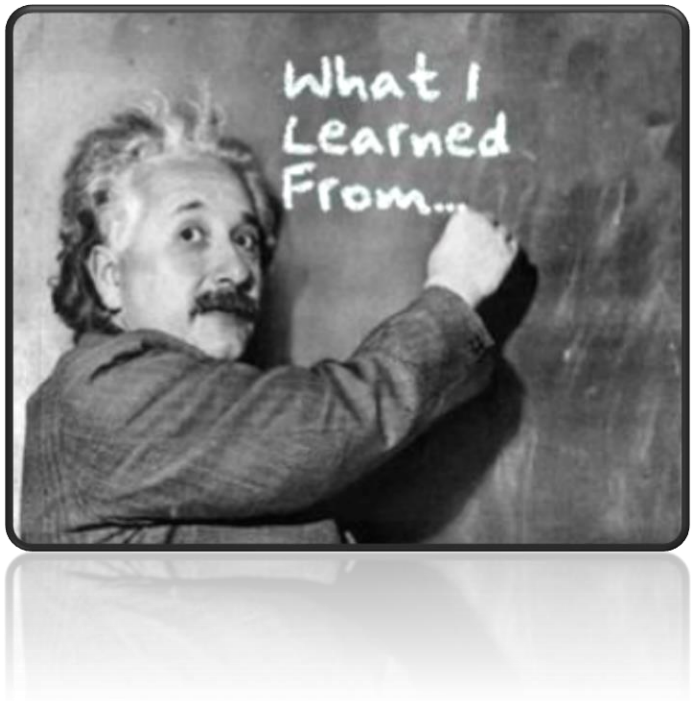
Proč zdravotnické případové studie

..:: Regulace jako hnací síla inovací?

1. **Standardy bezpečnosti a účinnosti:**
   MDR, IVDR – spolehlivost, bezpečnost, důvěra
2. **Jasné směrnice pro vývoj a inovace:**
   ČAUI – návody k dosažení shody s regulatorními požadavky
3. **Přístup na trh:**
   CE, FDA – regulační schválení jako „brána“ k investicím
4. **Podpora etického využití AI:**
   Vysvětlitelnost modelů & zabránění zaujatosti – spravedlivé, transparentní AI
5. **Financování a pobídky pro dosažení shody:**
   Finanční podpora pro společnosti splňující regulatorní požadavky

Proč zdravotnické případové studie

..:: Regulace jako hnací síla inovací?



Regulace zaměřené na bezpečnost, účinnost a transparentnost podporují důvěru, která je základem pro inovace i úspěšné podnikání.

Evoluce AI

..:: Strojové učení – od historie k inovacím

Turing, A. M. (1950). Computing machinery and intelligence. *Mind, 59*(236), 433–460.

Shannon, C. E. (1948). "A Mathematical Theory of Communication." *The Bell System Technical Journal*, 27, 379-423, 623-656.

Shannon, C. E. (1952). "Theseus, a Learning Machine." *Life Magazine*.

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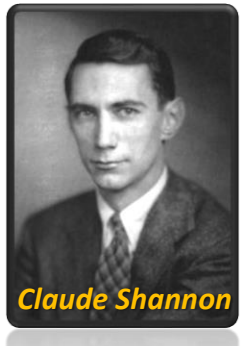

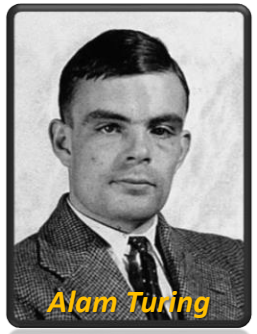

Evoluce AI

..:: Strojové uče

Turing, A. M. (1950

Shannon, C. E. (194 ical Journal, 27, 379-423, 623-65

Shannon, C. E. (195

Shannon, C. E. (195 n Theory, 1(1), 66-75.

VOL. LIX. NO. 236.] [October, 1950

MIND

A QUARTERLY REVIEW

OF

PSYCHOLOGY AND PHILOSOPHY

I.—COMPUTING MACHINERY AND INTELLIGENCE

BY A. M. TURING

1. *The Imitation Game.*

I PROPOSE to consider the question, 'Can machines think?' This should begin with definitions of the meaning of the terms 'machine' and 'think'. The definitions might be framed so as to reflect so far as possible the normal use of the words, but this attitude is dangerous. If

Evoluce AI

..:: Strojové učení – od historie k inovacím

Turing, A. M. (1950). Computing machinery and intelligence. *Mind, 59*(236), 433–460.

Shannon, C. E. (1948). "A Mathematical Theory of Communication." *The Bell System Technical Journal*, 27, 379-423, 623-656.

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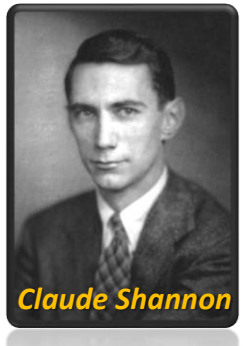
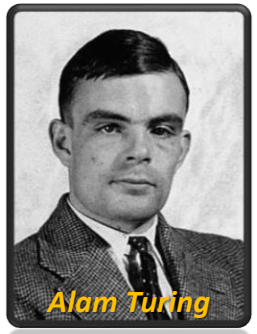




Evoluc

..:: Strojov

Turing, A. M.

Shannon, C. urnal,
27, 379-423,

Shannon, C.

Shannon, C. ry, 1(1), 66-75.

The Bell System Technical Journal

Vol. XXVII *July, 1948* *No. 3*

A Mathematical Theory of Communication

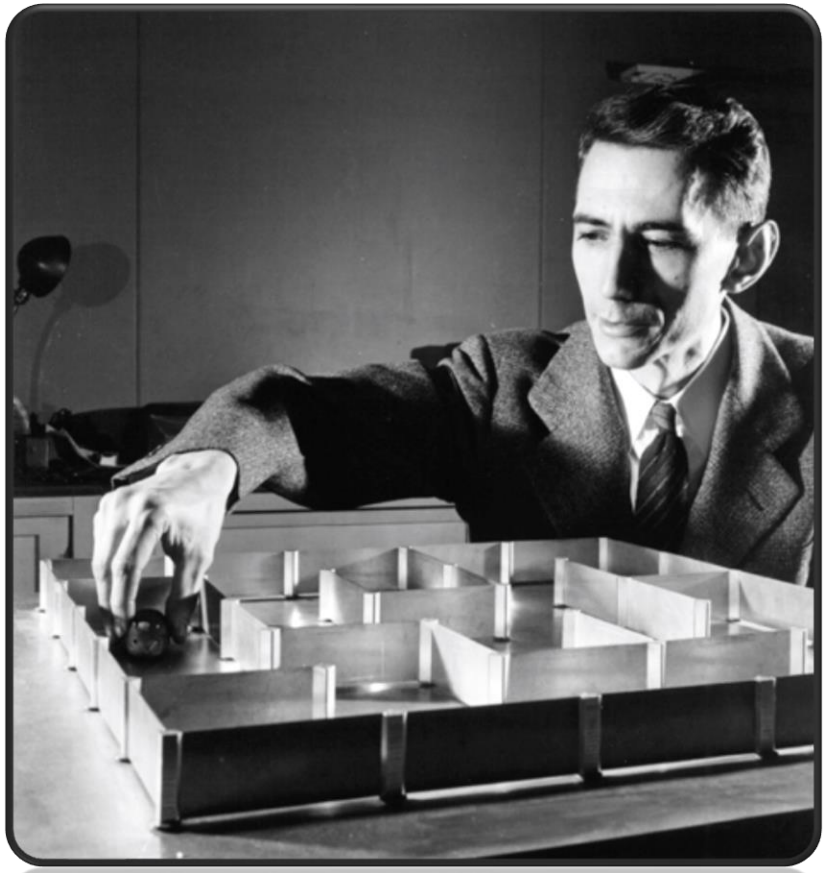
By C. E. SHANNON

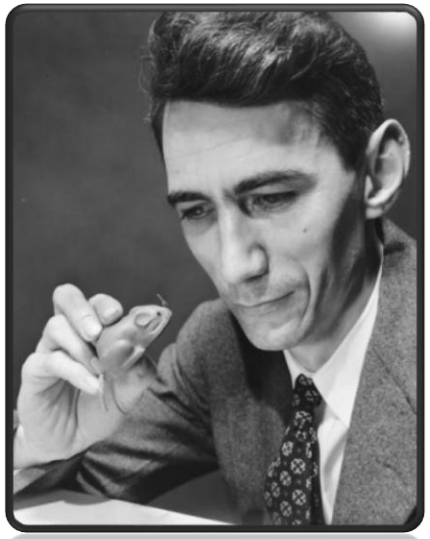
Introduction

THE recent development of various methods of modulation such as PCM and PPM which exchange bandwidth for signal-to-noise ratio has intensified the interest in a general theory of communication. A basis for such a theory is contained in the important papers of Nyquist[1] and Hartley[2] on this subject. In the present paper we will extend the theory to include a number of new factors, in particular the effect of noise in the channel, and the savings possible due to the statistical structure of the original message and due to the nature of the final destination of the information.

Claude Shannon & Theseus

..:: 1952: první sestrojený učící se stroj





- *Bell labs, http://www.bell-labs.com*

Přílišná očekávání

..:: Podceněné výzvy umělé inteligence & odvážné predikce

1960 **Emile Delavenay** v knize o strojovém překládání přirozeného jazyka:

“While a great deal remains to be done, it can be stated without hesitation that the essential has already been accomplished.”

1965 **Irving John Good** ve svých statích o AI:

“It is more probable than not that, within the twentieth century, an ultraintelligent machine will be built and that it will be the last invention that man need make.”

1968 **Marvin Minsky**, technický poradce u filmu 2001: Vesmírná odysea

“*The HAL 9000 is a conservative estimate of the level of artificial intelligence in 2001.*”

Rozmach hlubokého učení

..:: Realistické výzvy a očekávání ohledně budoucího vývoje AI.

2015 **John Sowa** ve svých statích o neúspěchu AI:

“No computer system today can learn and use language as fast, as accurately, and as flexibly as a three-year-old child.”

Rozmach hlubokého učení

..:: Neuplatněný potenciál IBM Watson

Zdravotnické AI kazuistiky

..:: Různorodost a společné rysy

Zdravotnické AI kazuistiky

..:: Různorodost a společné rysy

Diagnostika

Aireen

carebot
AI DRIVEN HEALTHCARE

Terapie

CYBERDYNE

da Vinci S HD
SURGICAL SYSTEM

Zdravotnické AI kazuistiky

..:: Různorodost a společné rysy

Diagnostika

- Analýza mnohorozměrných dat,
- a detekce abnormalit

…bez přímé fyzické interakce.

Terapie

- Robotika a exoskeletony,
- zpřesnění / řízení pohybu

…vstupní kontrolní signály od člověka.

Minimalizace lidských chyb spojených s kognitivním bottleneckem

Zdravotnické AI kazuistiky

..:: Různorodost a společné rysy

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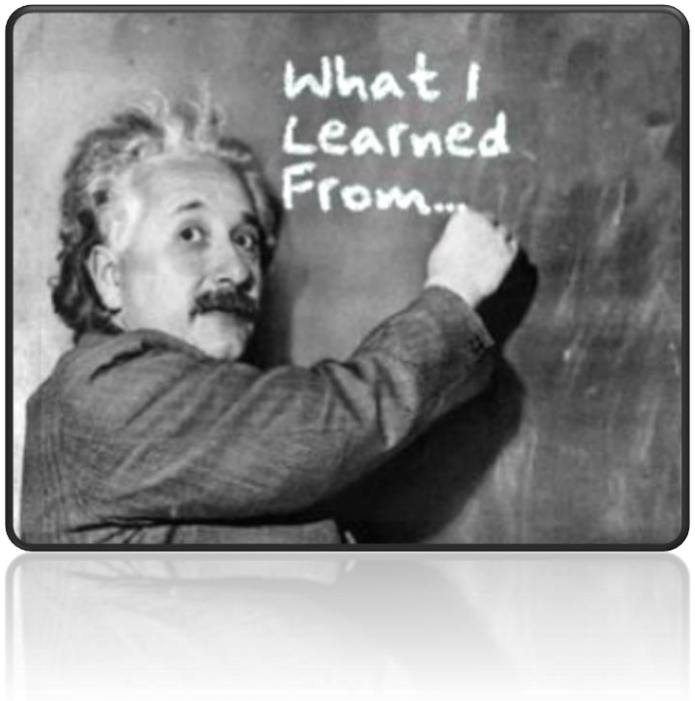
Minimalizace lidských chyb spojených s kognitivním bottleneckem

Administrativní systémy:
zpracování přirozeného jazyka - analýza textových dat - provádění rutinních úkonů - zvyšování efektivity.

Společné a rozdílné rysy AI aplikací

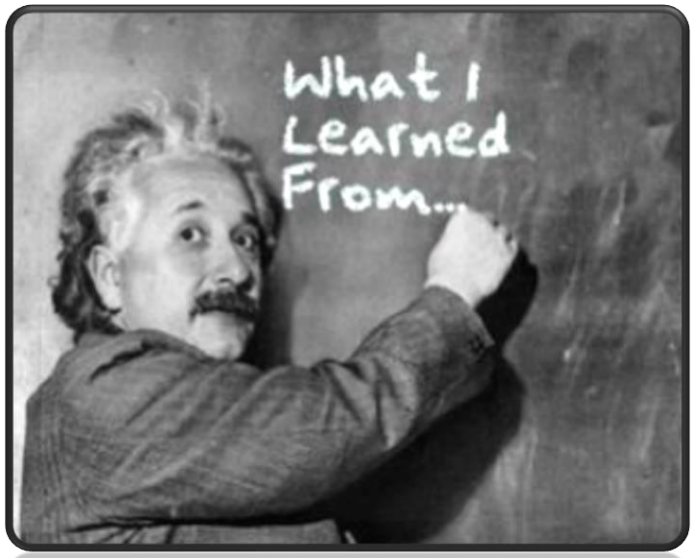
..:: Cognitive bottleneck



Společným jmenovatelem je schopnost AI/ML aplikací řešit lidské limity, jako je kognitivní úzké hrdlo. AI přichází jako neúnavný pomocník, který pomáhá zvládnout komplexní data, minimalizovat chyby a zefektivnit procesy.

Společné a rozdílné rysy AI aplikací

..:: Cognitive bottleneck



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Jak dobrá je AI?

..:: Kvalitní data jsou klíčem k úspěchu AI

Zdroje „nekvality“ dat:

1. **Šum a anomálie:**
   chyby měření, překlepy, fraud
2. **Zkreslení v datech**
   bias, předsudky
3. **Chybějící nebo neúplná data**
   nevyplněné hodnoty

Nesprávné závěry a predikce.

Ztráta důvěry ve výsledky.
Náklady na opravy.
Etické důsledky.

„Data is the new electricity“
--- Andrew Ng (Coursera, Google Brain)

Jak dobrá je AI?

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Institute of Biostatistics and Analyses

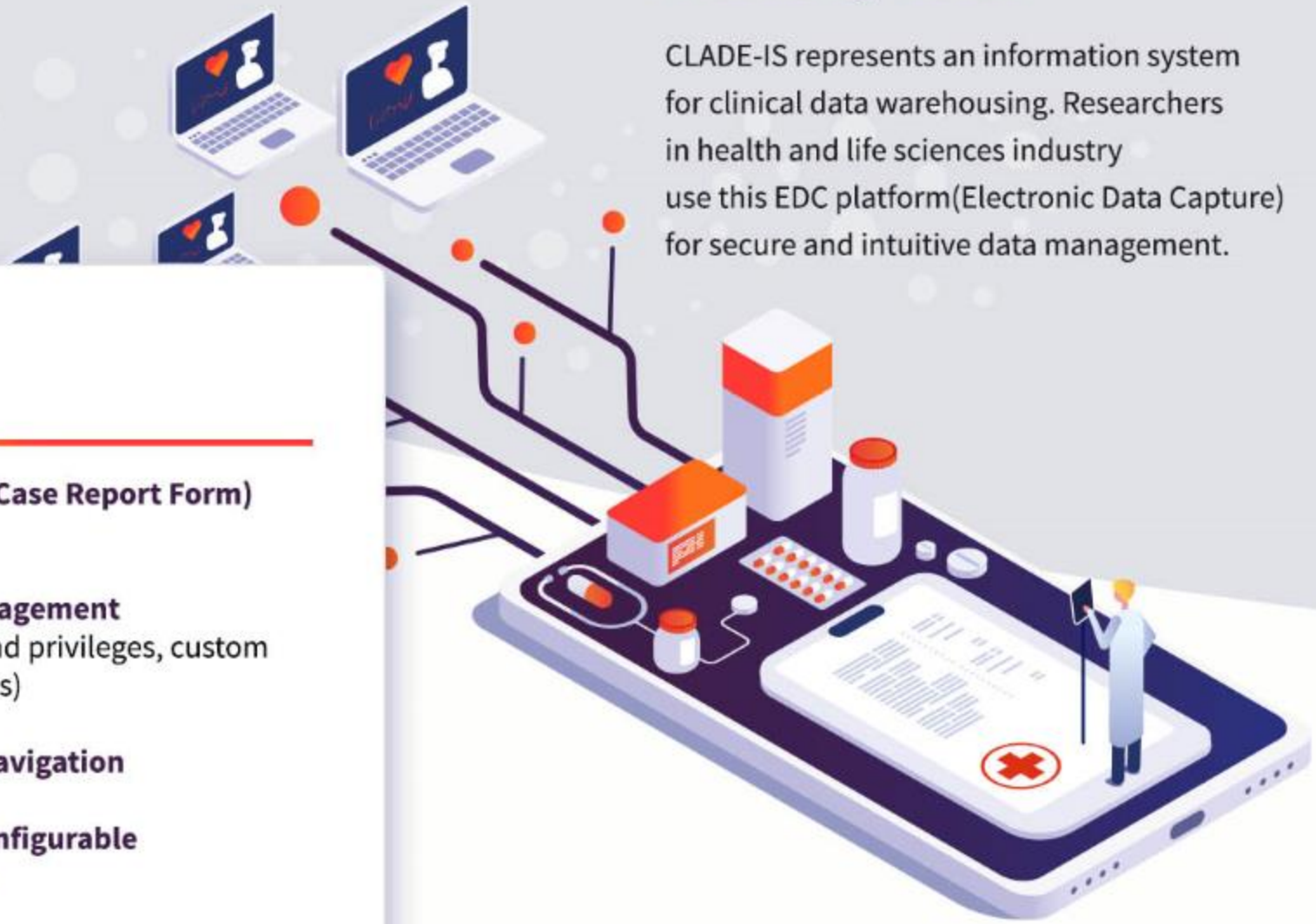
Electronic Data Capture

Clinical Data Management platform

CLADE-IS
CLINICAL DATAWAREHOUSE

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.

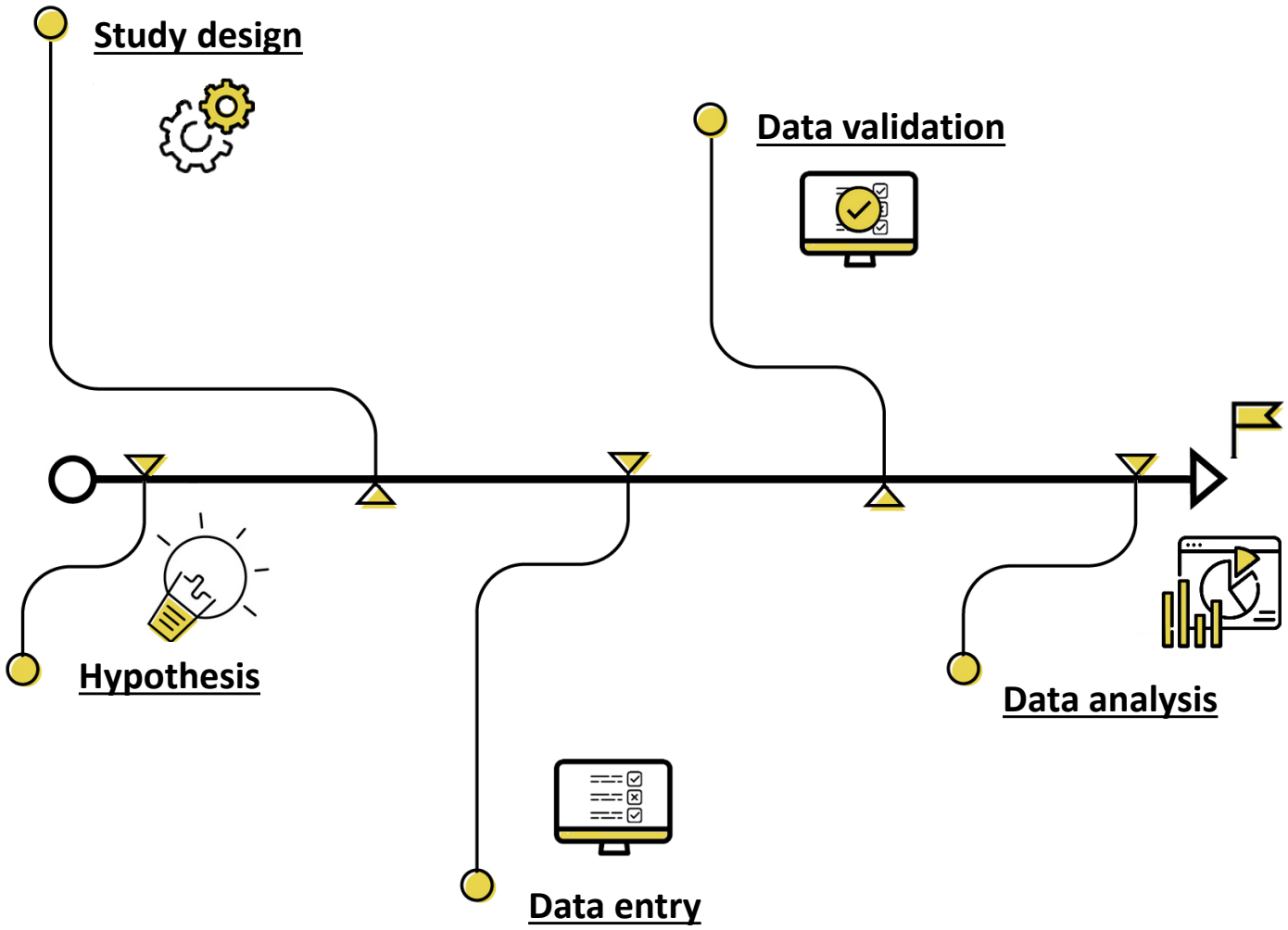


Features

- **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**

iba

From a hypothesis to an outcome



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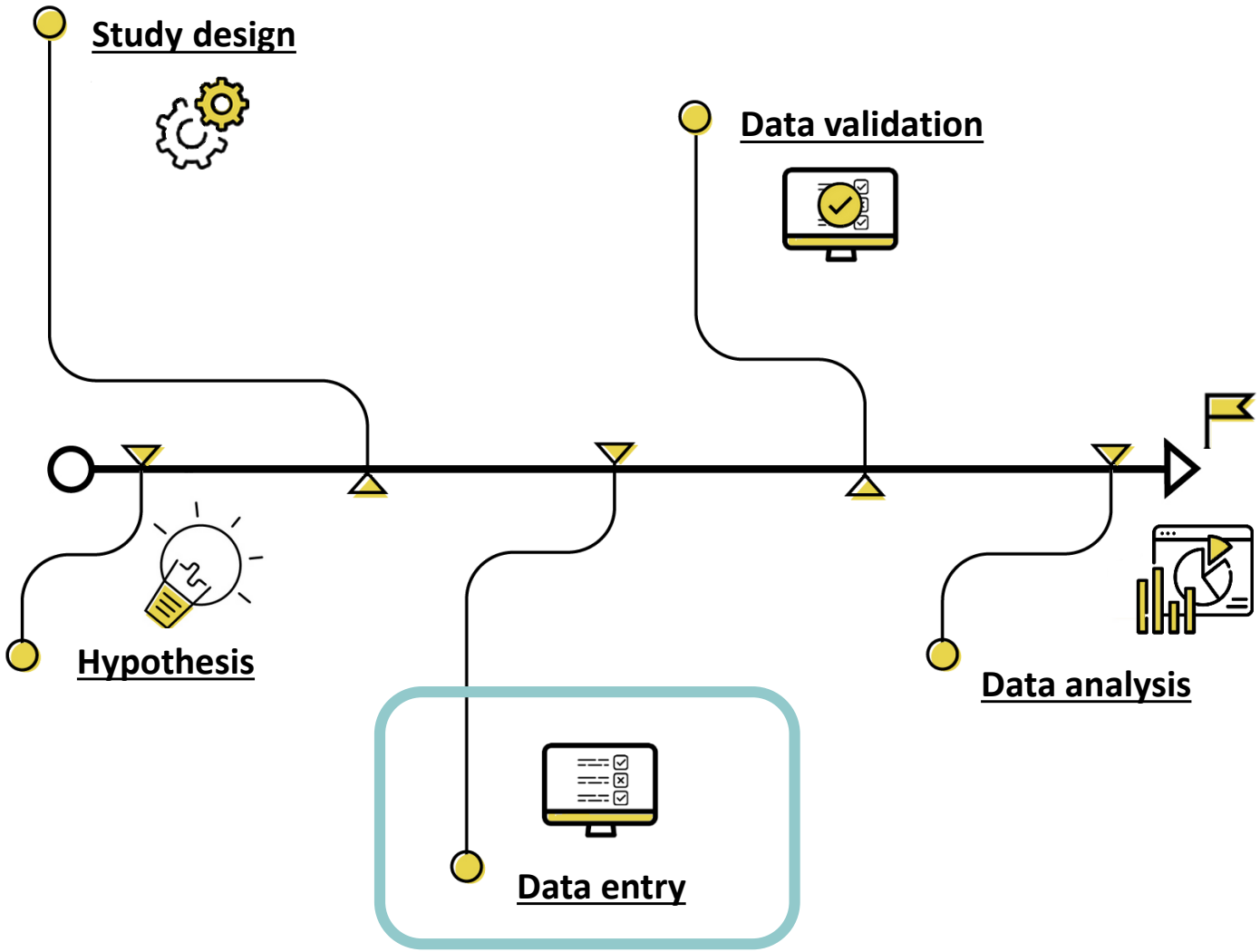
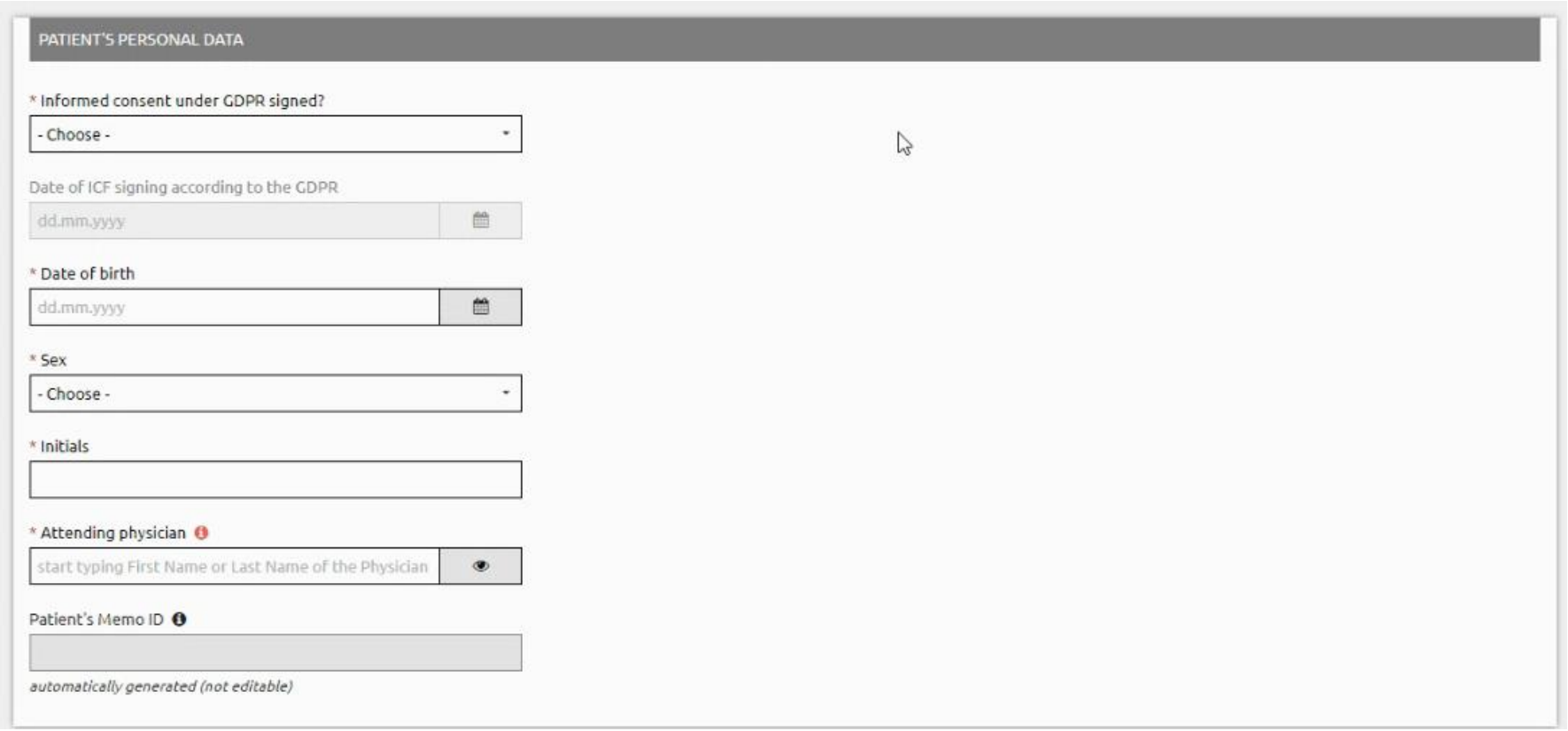


Data entry

Create and edit forms



Who: Healthcare professional

Where: Study

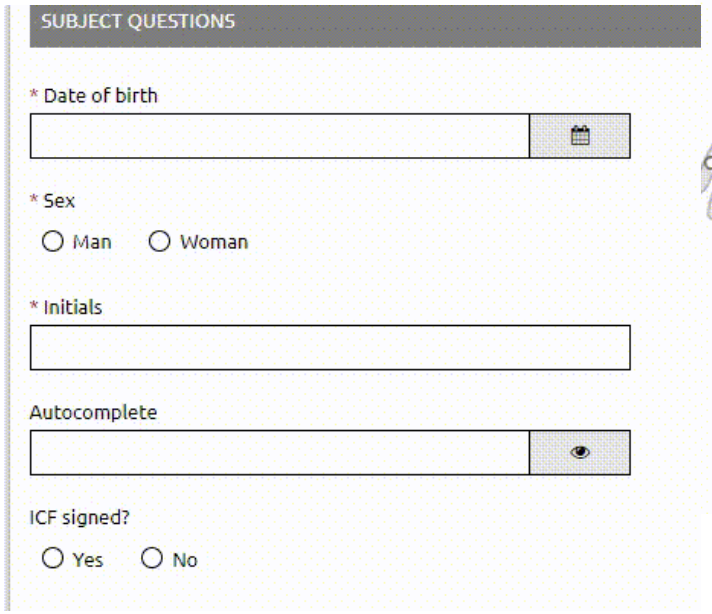
Data entry

Data entry – UX features

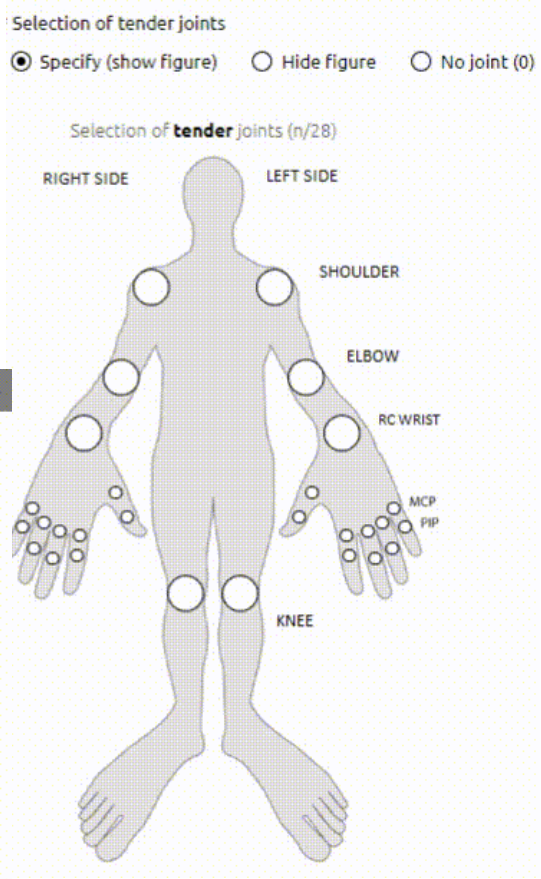
Wide range of data types and question settings

- 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



2



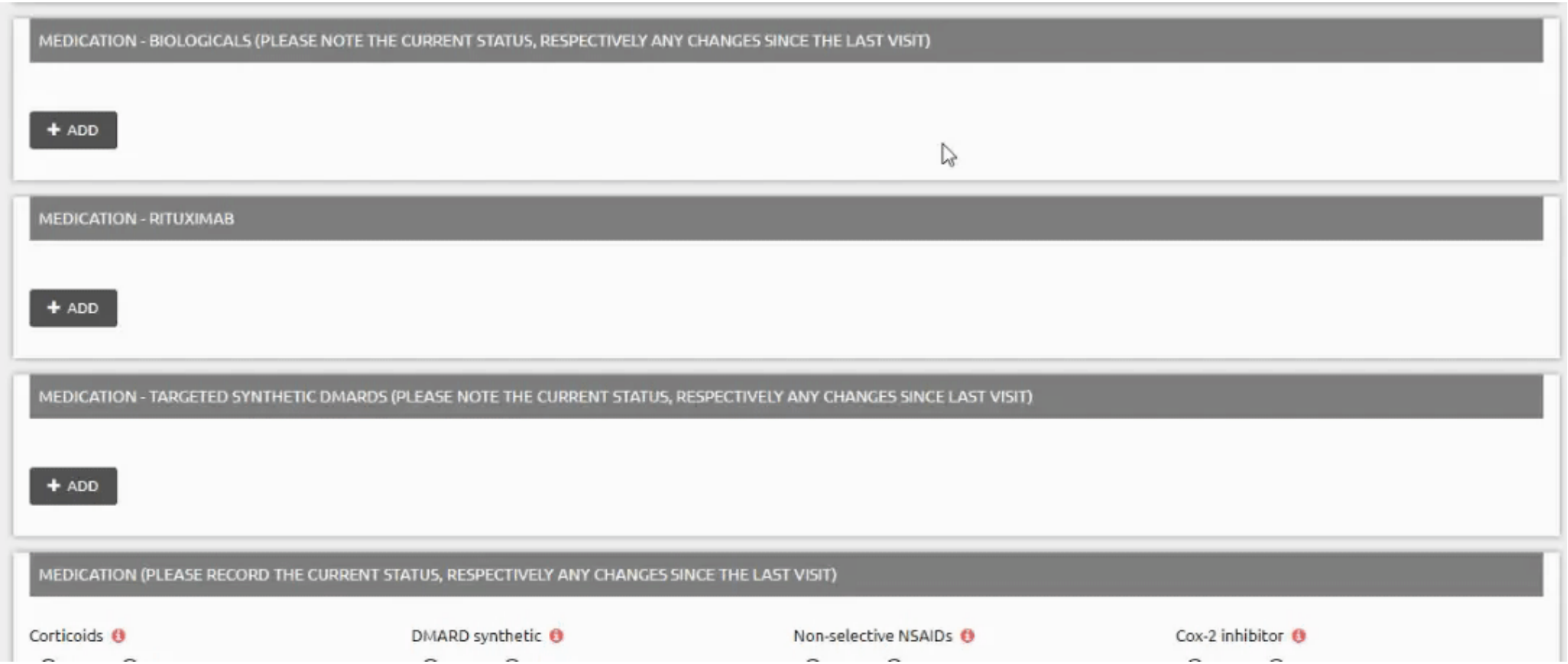
Who: Data manager

Where: Designer

Study design

Data entry - UX features

Edit checks & instant validation

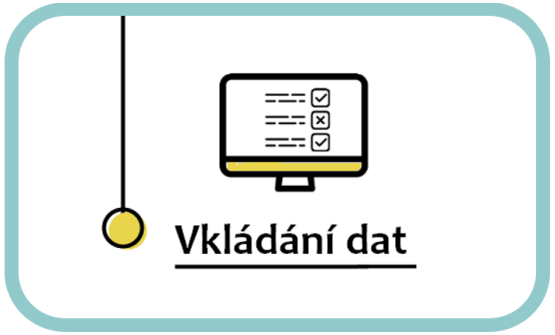


UX features

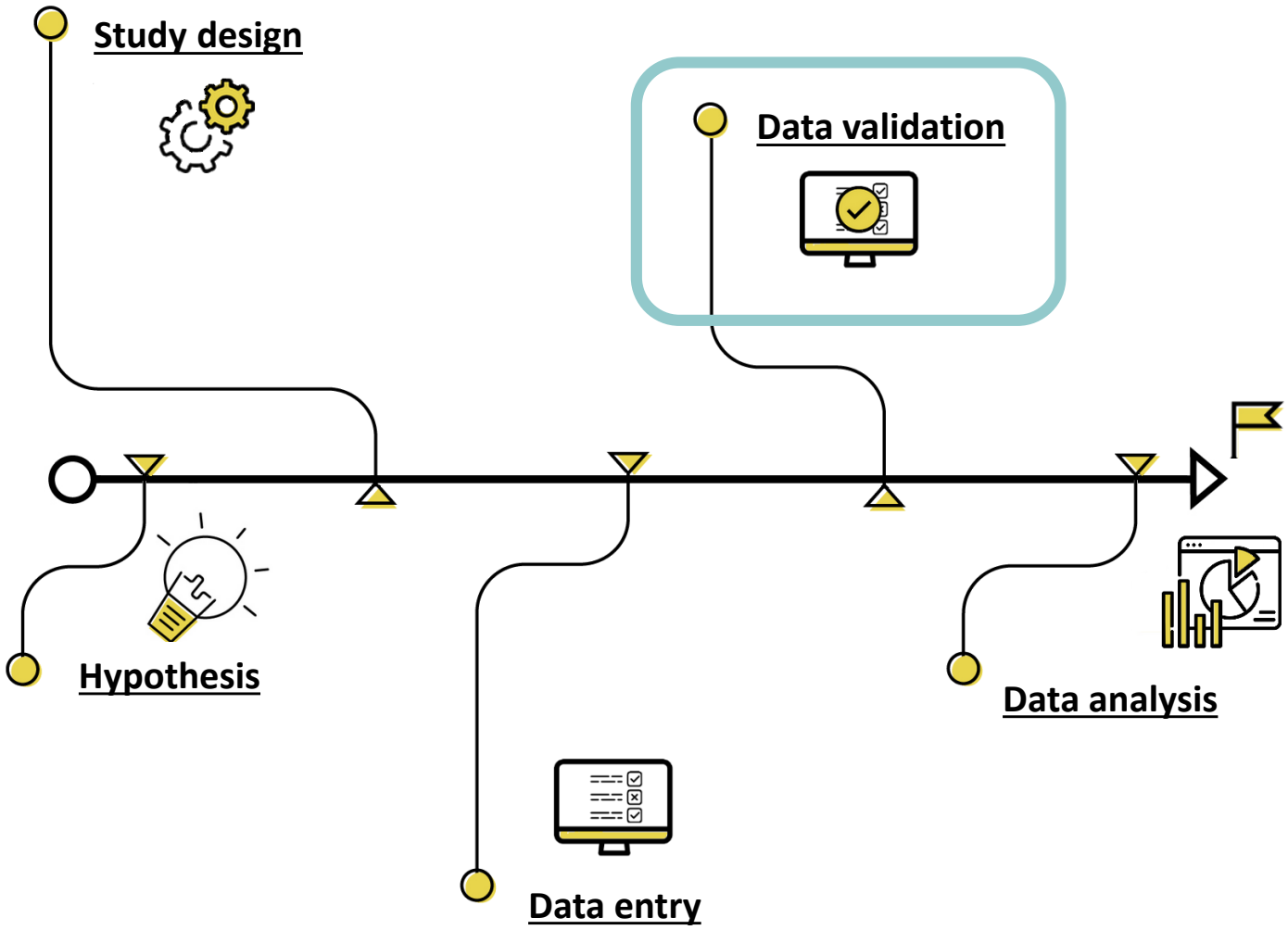
Skip logic

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_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_VS	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	
4770	ATTRA-02790	Quality of life		Two Quality of lif Quality of Life fo		
3180	RA_3007_LH	Termination of monitoring		The patient show indicate in the se		
4248	ATTRA-2090	Termination of monitoring		The patient show indicate in the se		
6300	ATTRA-02773	Follow-up		The first Follow-u register at all. Pl or add missing e patient started t form (Evaluation		

Who: Monitor

Where: Study

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

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

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

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

[redacted], 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 an all visits, please explain the reduction or correct answer.

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

[redacted], 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

Treatment type (main)

														O
														empty
														empty
														empty
														empty
														empty
														empty
												atm		empty
														empty
														empty
												n		empty
												nal		empty
												nal		empty
														empty
														empty
27	132120	30/05/2018 09:26:		23628	INF-0001	INF-8201	Yes	Change to question		Q125	Data con	Data control		empty
28	132120	30/05/2018 09:26:		23628	INF-0001	INF-8201	Yes	Change to question		Q126	Note	Data control		empty
29	132121	30/05/20	Petra Joba	23628	INF-0001	INF-8201	Yes	Change to question		Q673	Date of in	Informed	empty	skipped
30	132121	30/05/20	Petra Joba	23628	INF-0001	INF-8201	Yes	Change to question		Q620	Date of la	Survival	empty	skipped
31	132121	30/05/20	Petra Joba	23628	INF-0001	INF-8201	Yes	Change to question		Q627	Date of d	Survival	empty	skipped
32	132121	30/05/20	Petra Joba	23628	INF-0001	INF-8201	Yes	Change to question		Q628	Phase of	Survival	empty	skipped

Who: QA manager

Where: Study

Data entry

Data insights

Dashboard

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

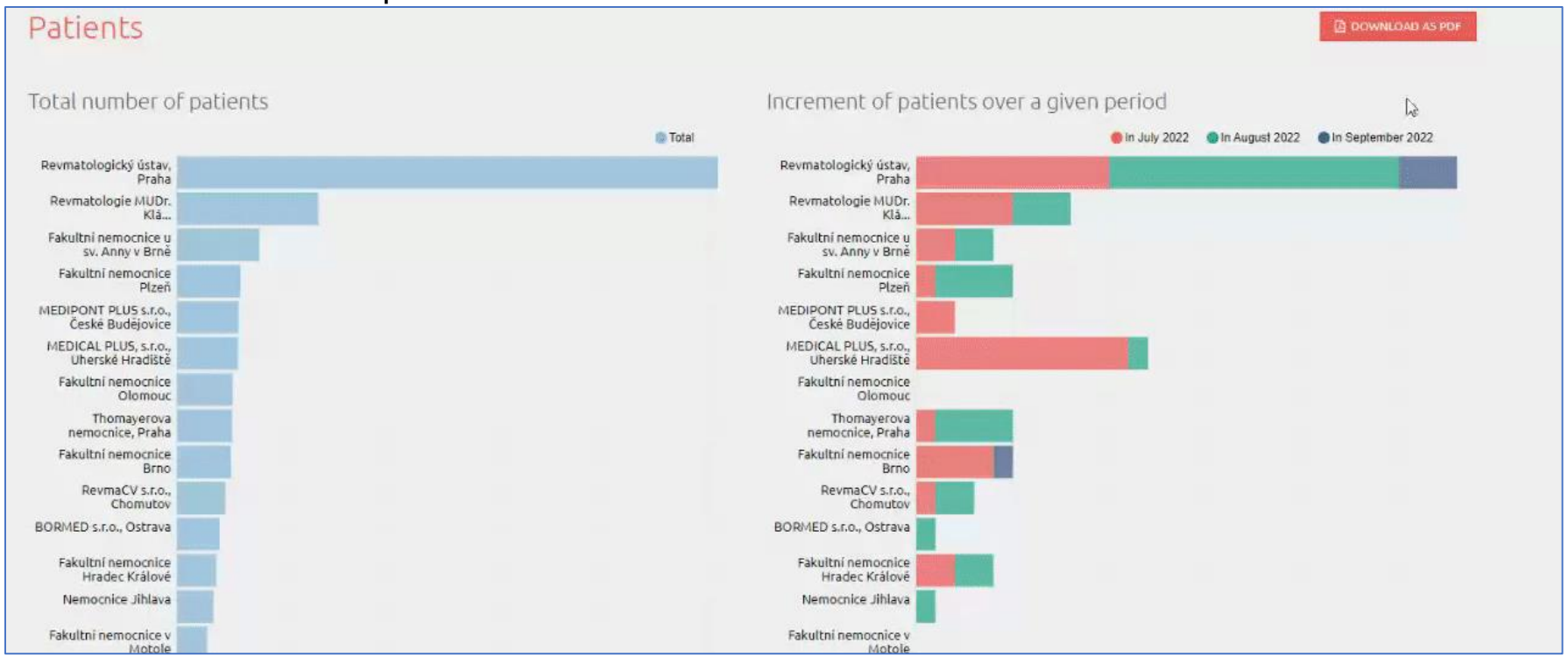
Who: Coordinator

Where: Study

Data validation

Data insights

Interactive reports



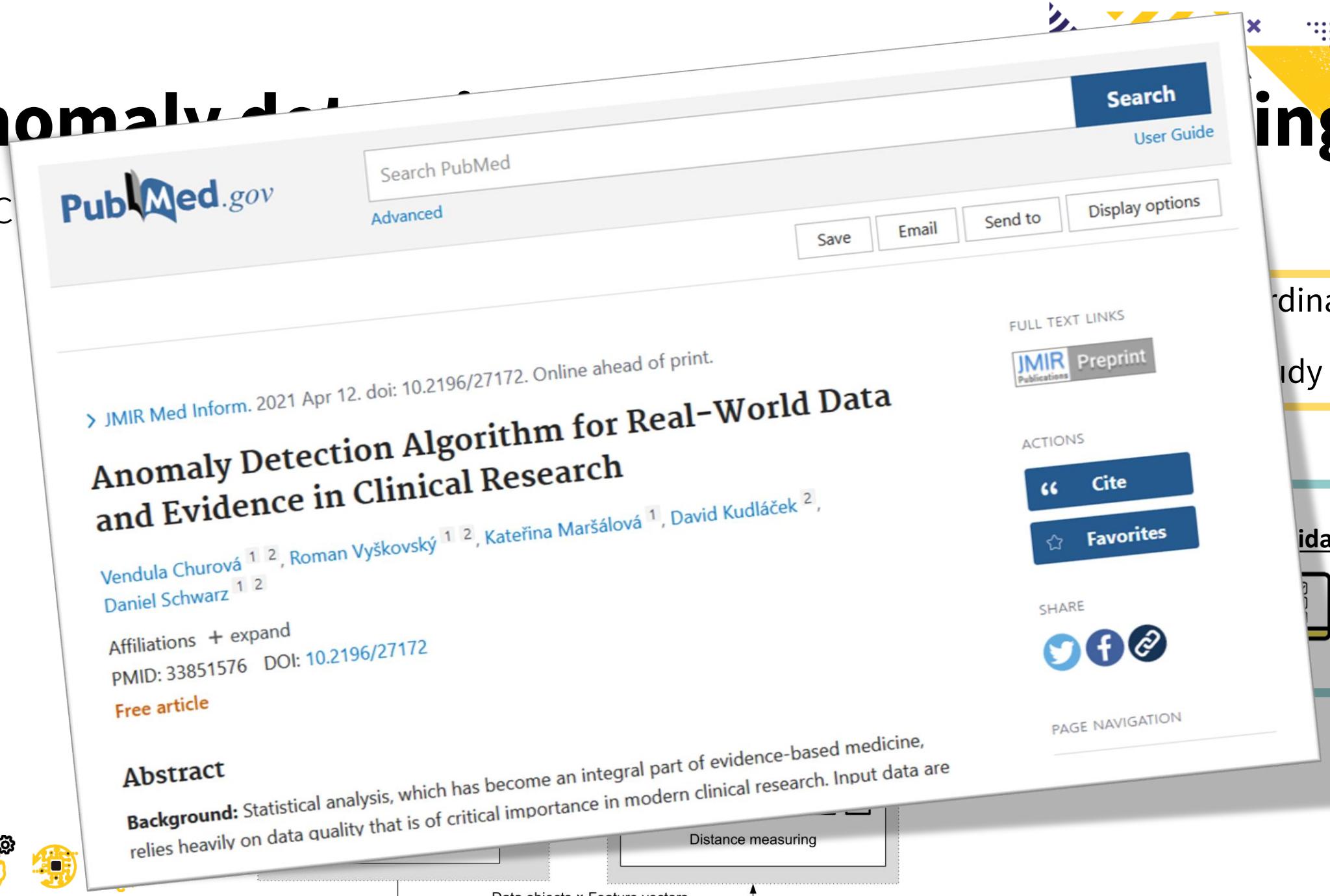
Who: Coordinator

Where: Study

Data validation

Anomaly de ing

Effic



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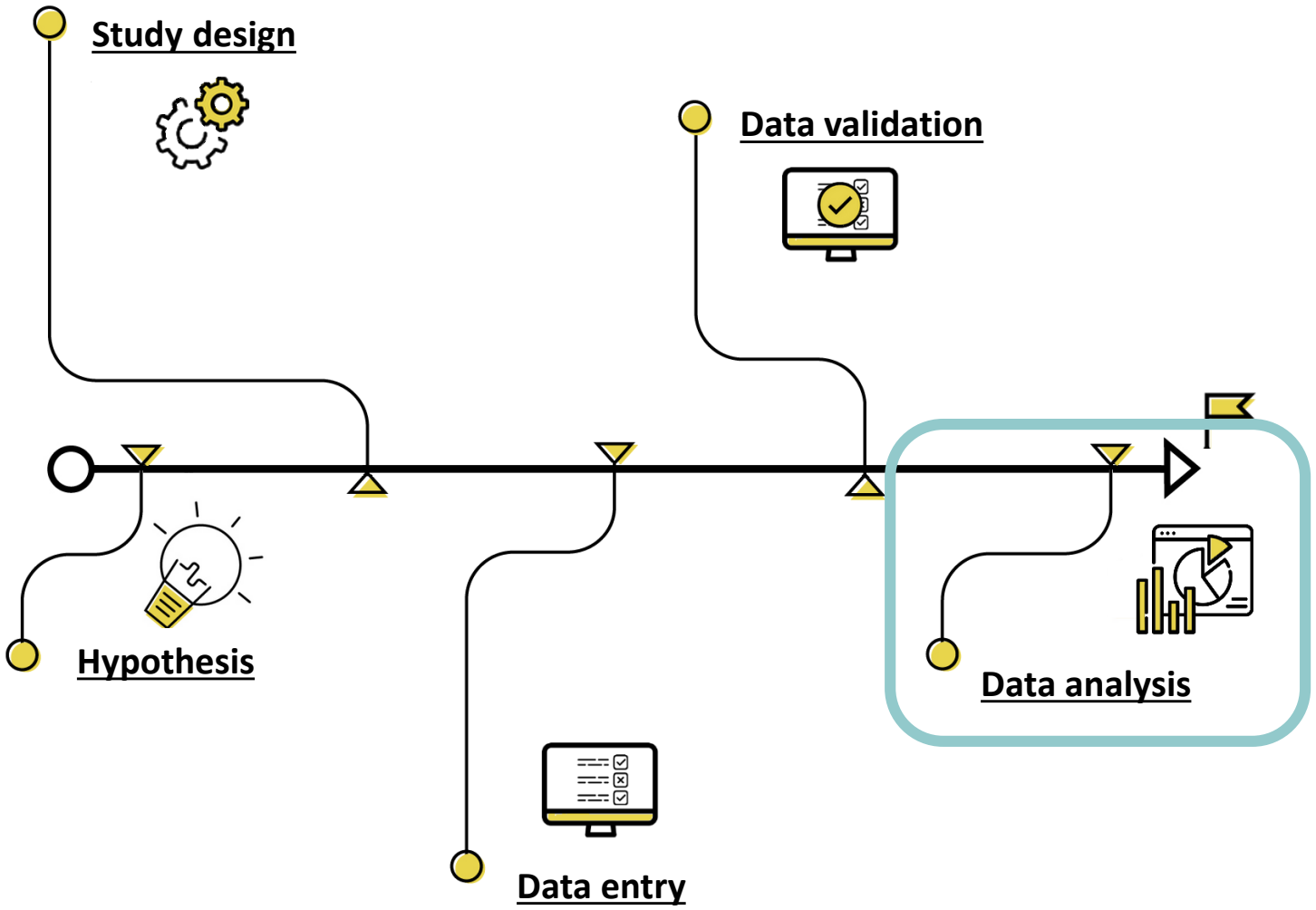
Distance measuring

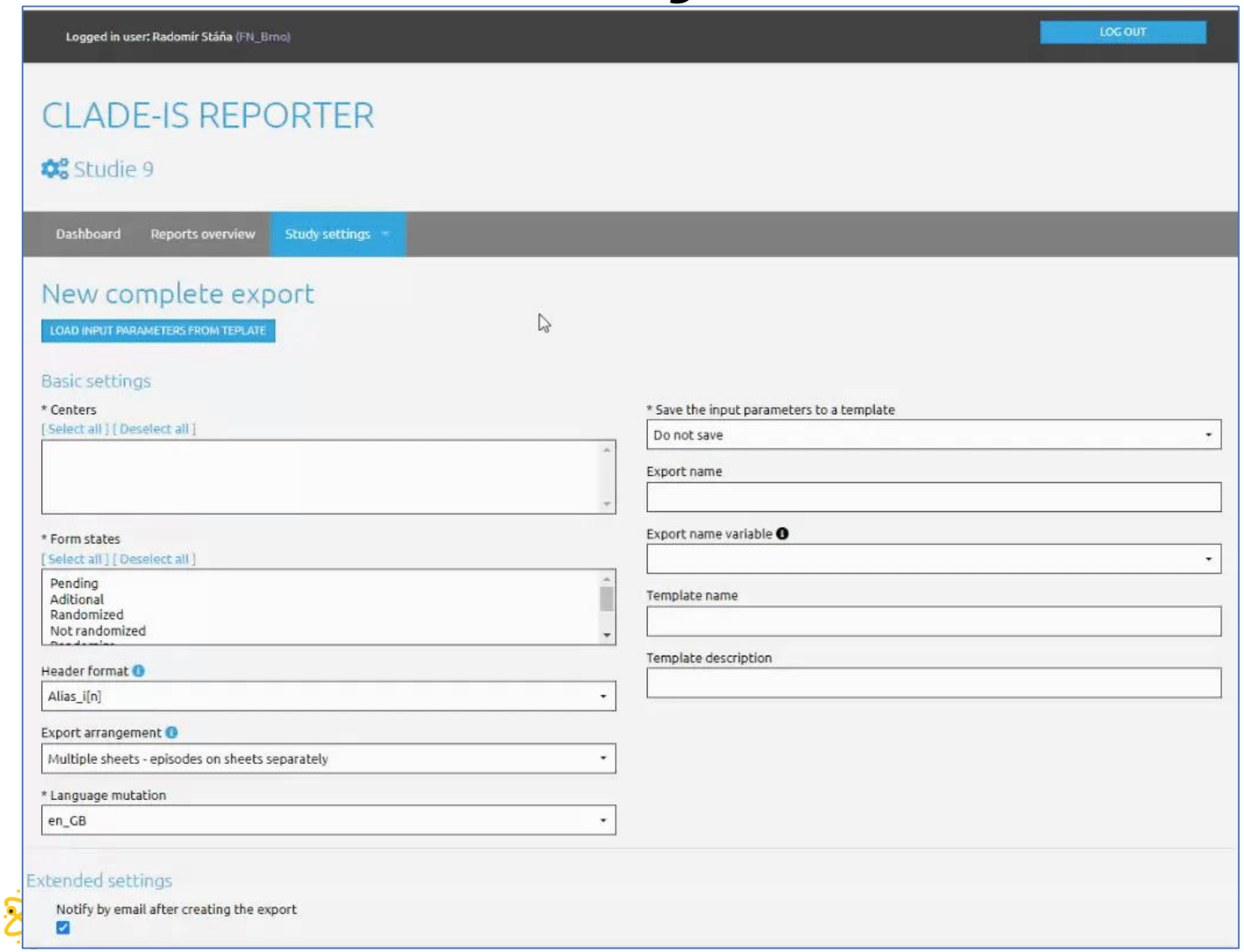
Data objects × Feature vectors

From a hypothesis to an outcome



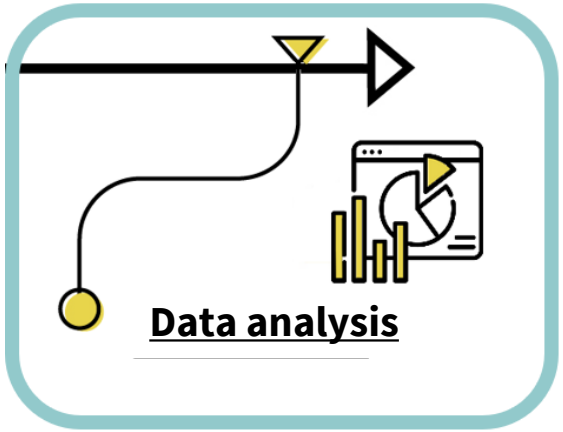
Toolkit for data analysis

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

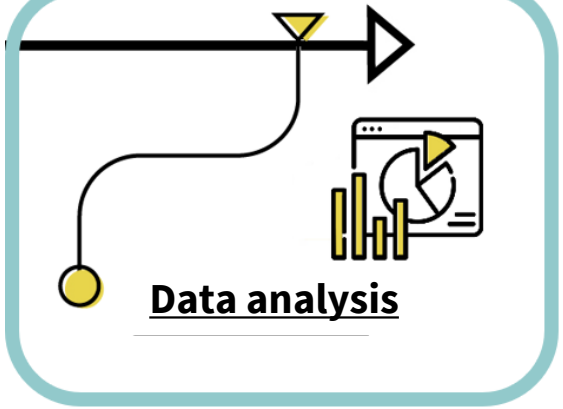
Registr HARM - [redacted]

Aktuální přehled pacientů v registru

Centrum	Pacienti			Léčba (probíhající a ukončená)			Léčba (ukončená)					
				Terapeutický postup			Terapeutický postup			SVR		
	Celkem	Léčení	Neléčení	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
[redacted]	124	124	0	33	15	13	33	15	11	55	1	3
[redacted]	328	328	0	64	27	80	64	27	44	121	1	13
[redacted]	46	46	0	4	2	5	4	2	5	11	0	0
[redacted]	100	88	12	13	3	13	12	3	7	19	1	2
[redacted]	101	101	0	24	1	26	22	0	26	41	0	7
[redacted]	73	73	0	4	5	19	4	5	13	21	0	1
[redacted]	211	211	0	30	2	25	30	2	8	38	1	1
[redacted]	264	264	0	37	18	32	37	18	32	83	3	1
[redacted]	24	24	0	6	0	0	6	0	0	5	0	1
[redacted]	52	52	0	29	2	0	28	2	0	30	0	0
[redacted]	299	268	31	49	12	68	48	10	52	104	1	5
[redacted]	0	0	0	0	0	0	0	0	0	0	0	0
[redacted]	167	156	11	6	0	35	6	0	18	23	1	0
[redacted]	19	19	0	2	0	9	1	0	6	4	0	3
[redacted]	0	0	0	0	0	0	0	0	0	0	0	0
[redacted]	132	132	0	22	1	8	22	1	8	31	0	0
[redacted]	9	9	0	0	0	3	0	0	3	3	0	0
[redacted]	74	74	0	7	2	12	7	1	8	13	2	1
[redacted]	63	63	0	1	19	0	1	17	0	15	0	3
[redacted]	50	50	0	6	5	11	5	4	10	19	0	0
[redacted]	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

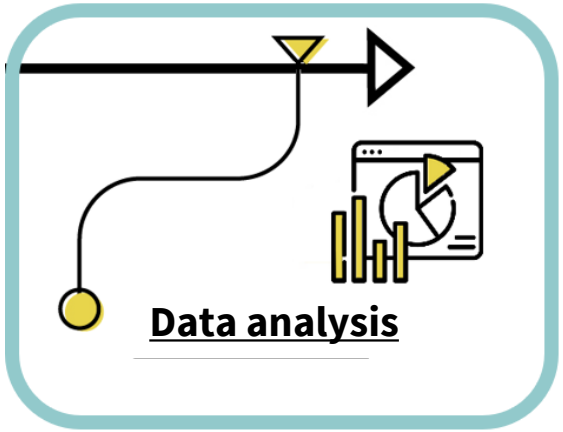
Form status

Valid

BACK

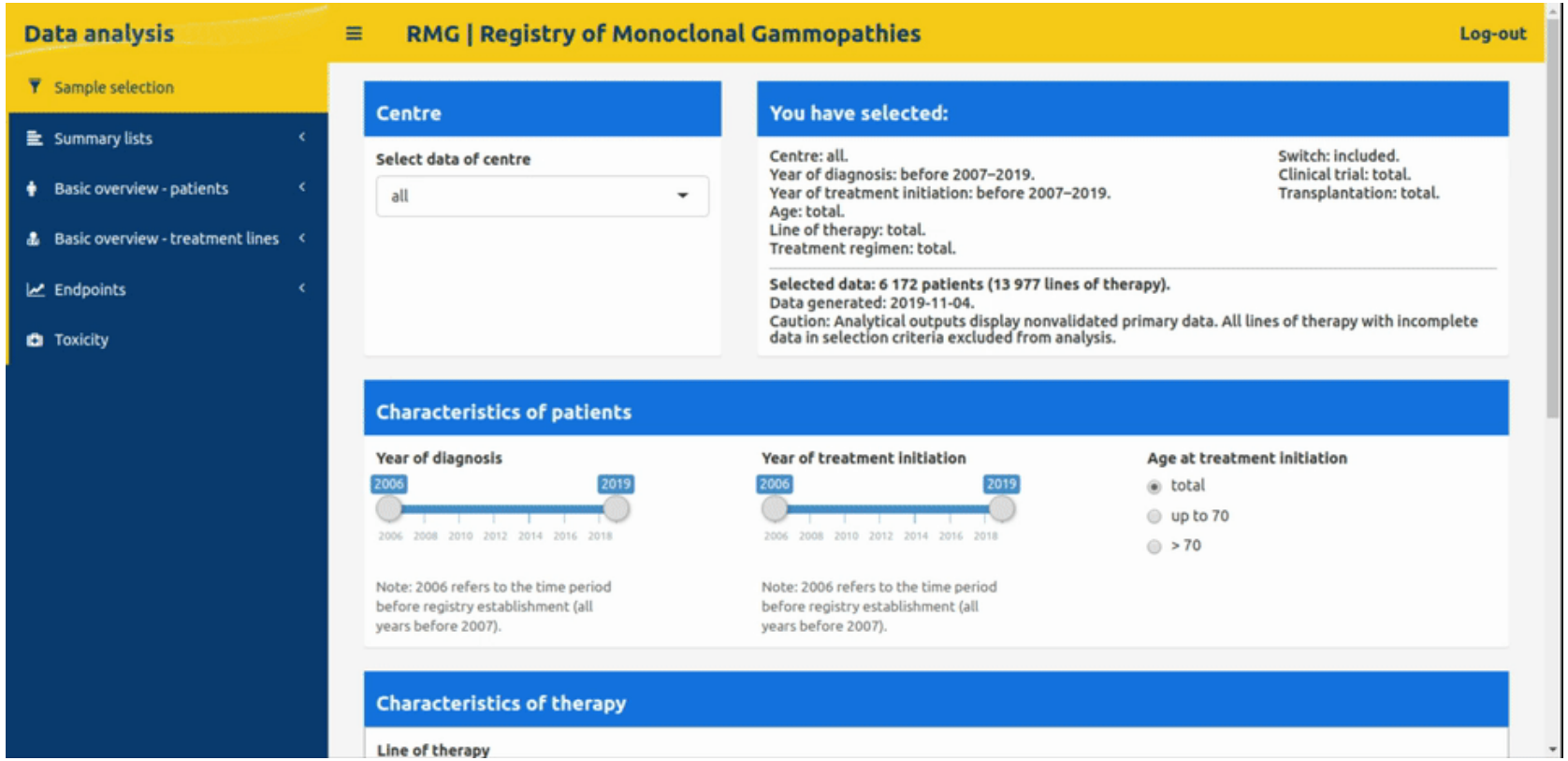
Who: Healthcare professional

Where: Study



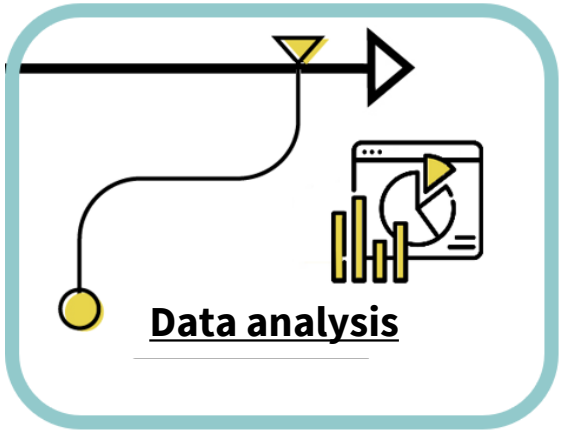
Toolkit for data analysis

Visual analytics on a project website



Who: Biostatistician

Where: Ext. website



Toolkit for data analysis

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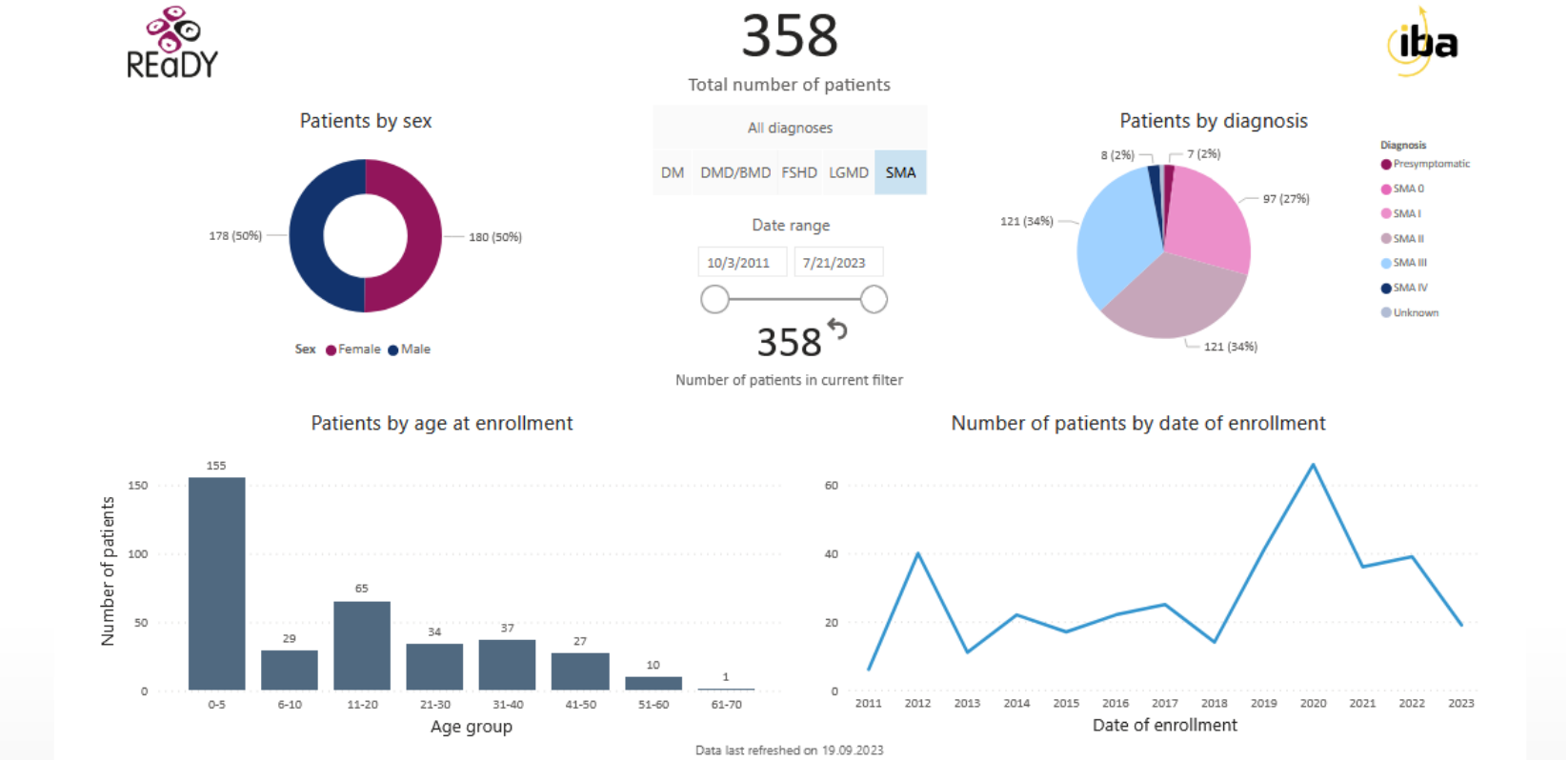

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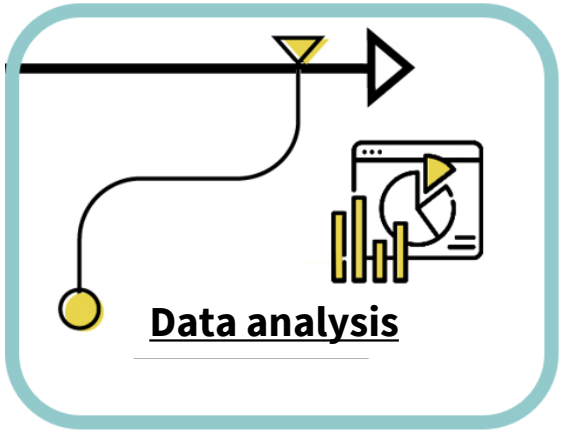

Jak dobrá je AI?

..:: Kvalitní data jsou klíčem k úspěchu AI

Zdroje „nekvality“ dat:

1. **Šum a anomálie:**
   chyby měření, překlepy, fraud
2. **Zkreslení v datech**
   bias, předsudky
3. **Chybějící nebo neúplná data**
   nevyplněné hodnoty

Nesprávné závěry a predikce.

Ztráta důvěry ve výsledky.
Náklady na opravy.
Etické důsledky.

„Data is the new electricity“
--- Andrew Ng (Coursera, Google Brain)

Zkreslení a předsudky

..:: Bias ve statistice a v AI/ML modelech

SYSTEMATICKÁ CHYBA

Overcoming Racial Bias In AI Systems And Startlingly Even In AI Self-Driving Cars

Racial bias in a medical algorithm favors white patients over sicker black patients

AI expert calls for end to UK use of 'racially biased' algorithms

AI Bias Could Put Women's Lives At Risk - A Challenge For Regulators

Gender bias in AI: building fairer algorithms

Bias in AI: A problem recognized but still unresolved

Amazon, Apple, Google, IBM, and Microsoft worse at transcribing black people's voices than white people's with AI voice recognition, study finds

Millions of black people affected by racial bias in health-care algorithms

Study reveals rampant racism in decision-making software used by US hospitals – and highlights ways to correct it.

When It Comes to Gorillas, Google Photos Remains Blind

Google promised a fix after its photo-categorization software labeled black people as gorillas in 2015. More than two years later, it hasn't found one.

The Week in Tech: Algorithmic Bias Is Bad. Uncovering It Is Good.

Google 'fixed' its racist algorithm by removing gorillas from its image-labeling tech

Artificial Intelligence has a gender bias problem – just ask Siri

The Best Algorithms Struggle to Recognize Black Faces Equally

US government tests find even top-performing facial recognition systems misidentify blacks at rates five to 10 times higher than they do whites.

Jak bojovat s předsudky

..:: (nejen) při tvorbě AI modelů

1. Pre-processing datového souboru
2. Post-processing na úrovni výstupu z modelu

3. Generování syntetických dat
   - Generative Adversarial Networks (GANs) – Generativní „protivní“ sítě
   - Variational Auto-Encoders (VAEs) – Variační autoenkodéry
   - Synthetic Minority Over-sampling Technique (SMOTE) – Technika syntetického pře-vzorkování menšin
   - …

- Kvak D, Březinová E, Biroš M, & Hrubý, R. Synthetic Data as a Tool to Combat Racial Bias in Medical AI: Utilizing Generative Models for Optimizing Early Detection of Melanoma in Fitzpatrick Skin Types IV–VI. In International Conference on Medical Imaging and Computer-Aided Diagnosis, 2022, pp:317-330).
- Shahul Hameed MA, Qureshi AM, Kaushik A. Bias Mitigation via Synthetic Data Generation: A Review. *Electronics*. 2024; 13(19):3909.
- Draghi B, Wang Z, Myles P, Tucker A. Identifying and handling data bias within primary healthcare data using synthetic data generators. *Heliyon*. 2024; 10(2):e24164.

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Jak dobrá je AI?

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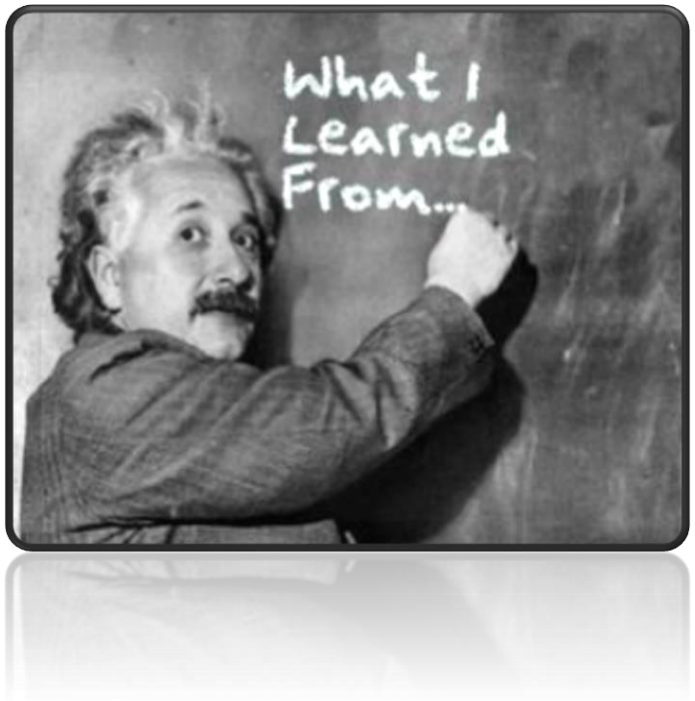
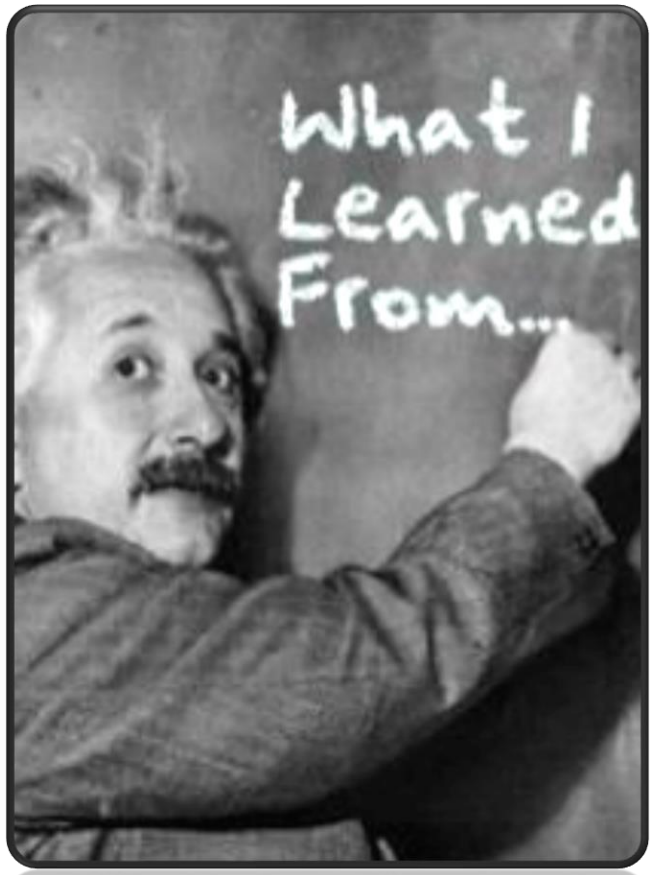


Algoritmy a technologie AI/ML můžete použít pro zlepšení kvality dat, a tedy předcházet chybným výsledkům analýzy.

Co si z toho odnést

..:: Pár drobných „poučení“



1. **Pozor na dlouhodobé predikce** (a taky na neférová MEMEčka)
   …technologie neexistuje ve vakuu
2. **Regulace mohou stimulovat inovace**
   …účinnost – bezpečnost – transparentnost => důvěra
3. **Demokratizace AI:**
   …kontrast s Watsonem - uzavřený systém vs. každodenní nástroj
4. **AI/ML aplikace pomáhají v řešení lidských limitů:**
   …máte kognitivní úzké hrdlo a potřebujete přestávky!
5. **Nepodceňujte kvalitu dat:**
   …odstraňte anomálie a zkreslení pomocí ML algoritmů

Pozvánka

CLINICAL DATA MANAGEMENT
best practices

iba Institute of Biostatistics and Analyses

CDM best practices

..:: Pohledy expertů na problematiku správy klinických dat

“Data is the second most important thing in the clinical trials,
where the first thing is obviously subject wellbeing and health.”

--- Tomáš Machulka, CZECRIN & PremierResearch

“Bleeding as a concept is different between clinical trials and health care.”

--- Adam Chee, WHO & National University of Singapoure

“In population studies which maintain a lot of health records and sensitive data,
nobody will provide you the data in one common database.”

--- Richard Hůlek, RECETOX PřF MU

“For me data management is really about finding the right balance
between data as an asset and data as reliability.“

--- Luke Woodham, St George’s University in London

iba Institute of Biostatistics and Analyses

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https://ibapodcast.podbean.com/

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CLINICAL DATAWAREHOUSE

3DIAMOND

healthy data