From practice to evidence: Leveraging unique Czech RWD to support regulatory documentation

BioBridges, 26/09/2025

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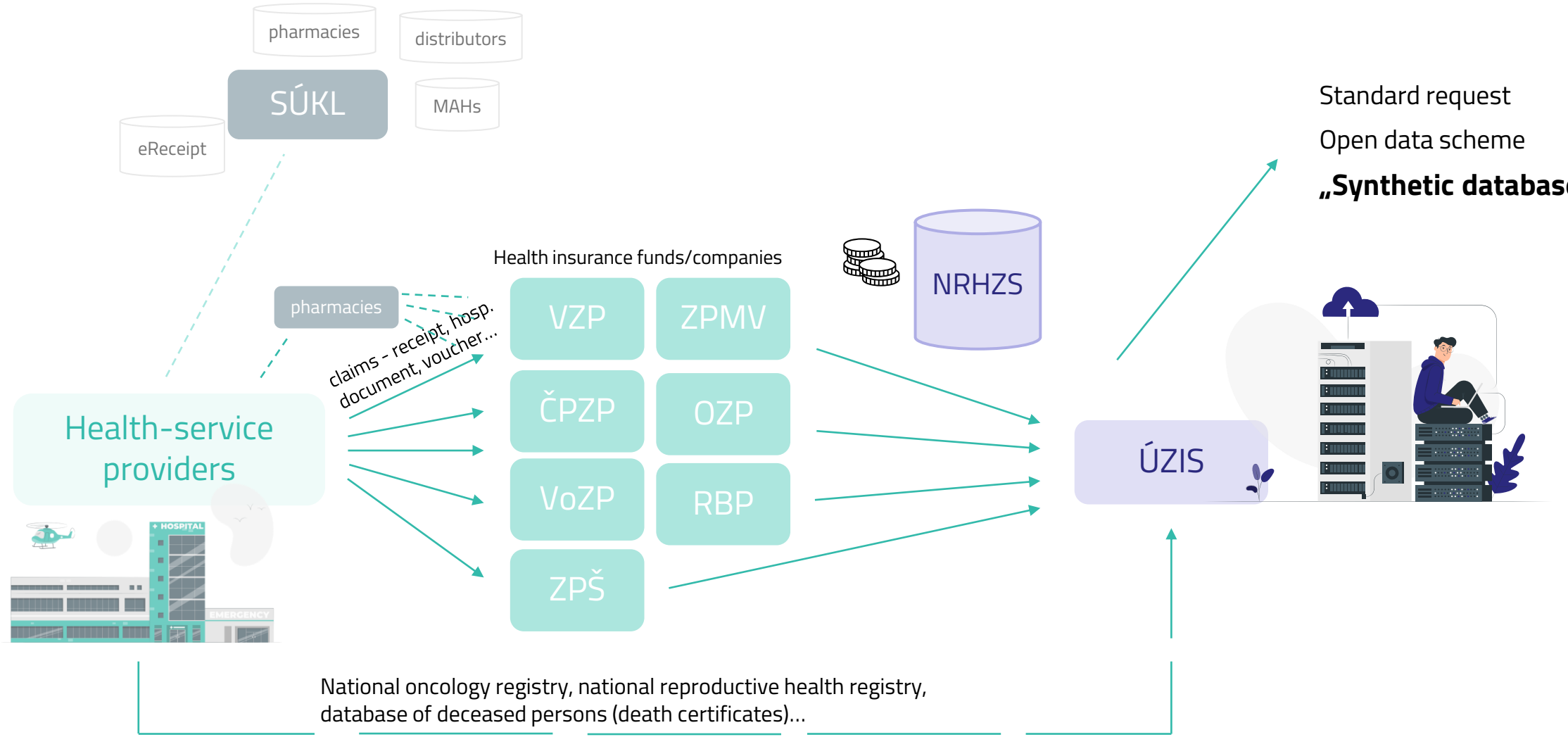
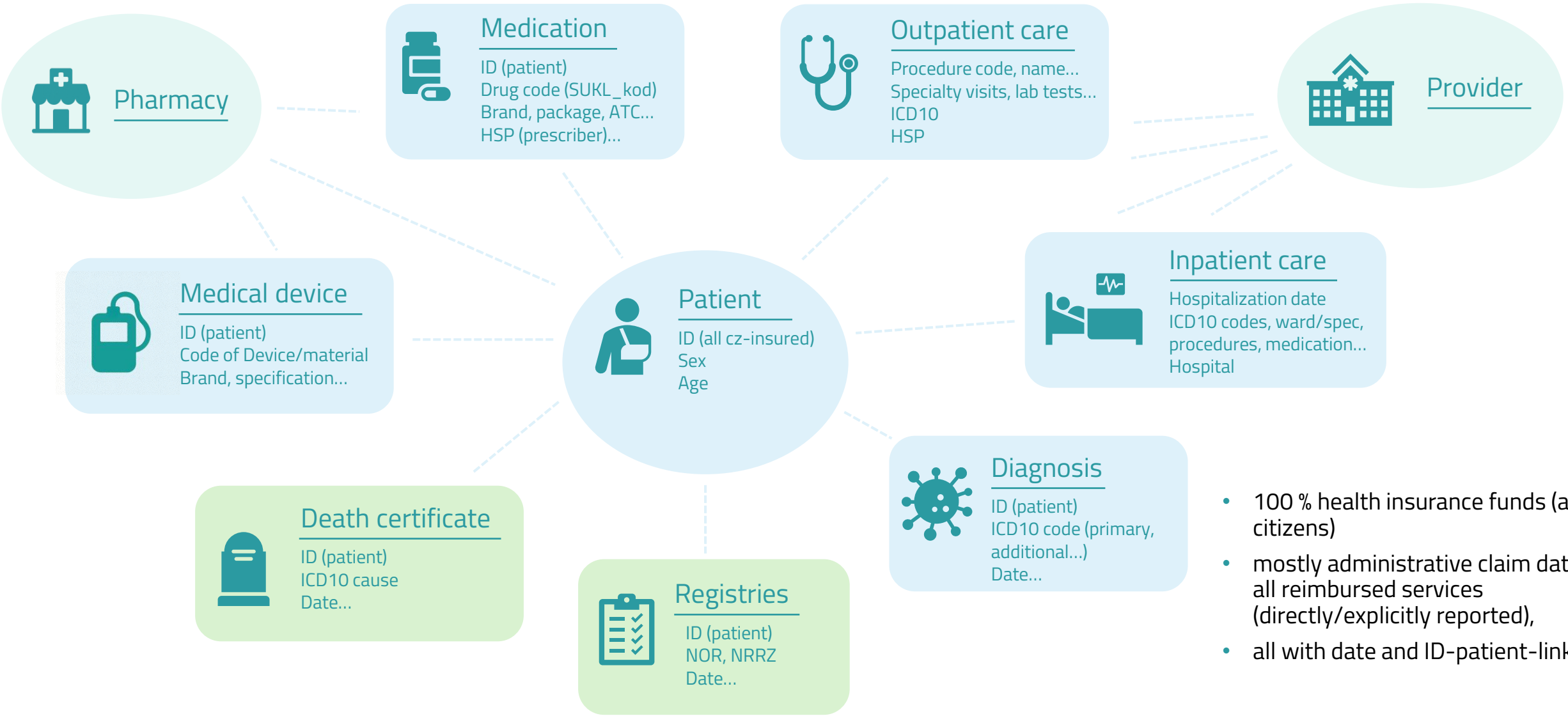
TME solutions

Scheme of (administrative) data in the czech health system



Data we can work with



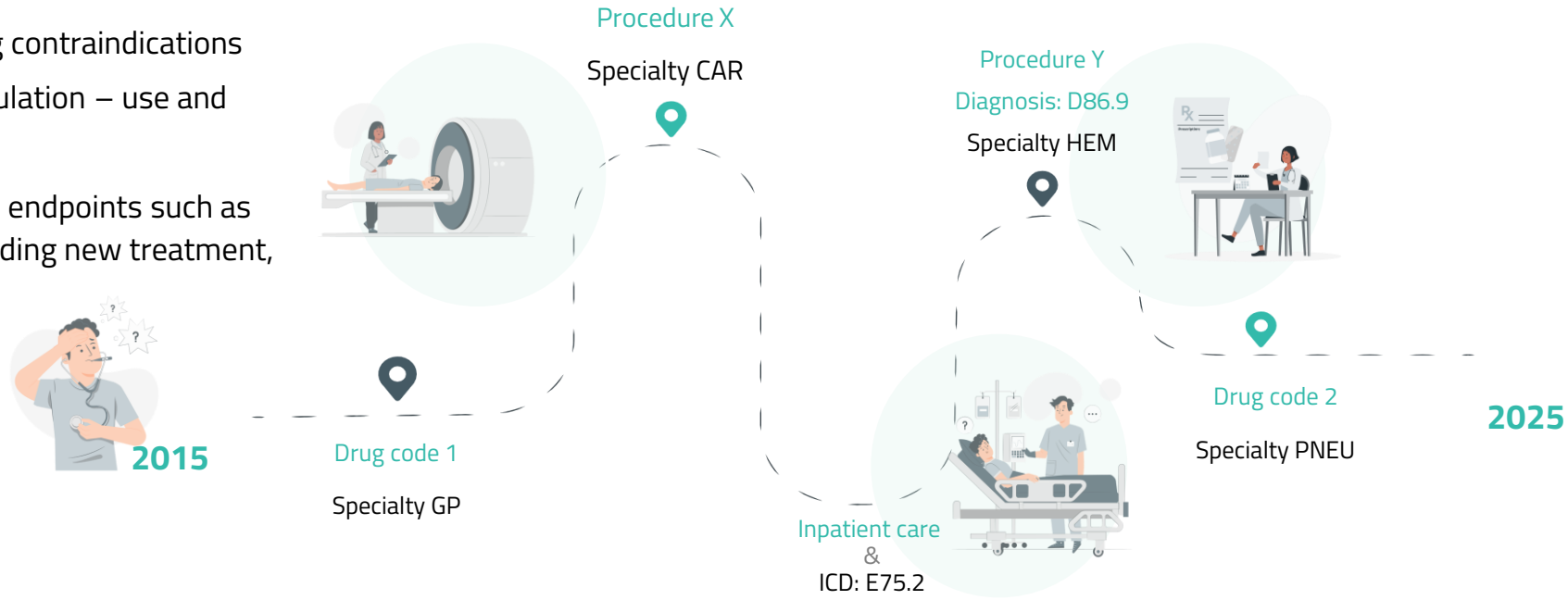
- 100 % health insurance funds (all cz citizens)
- mostly administrative claim data, all reimbursed services (directly/explicitly reported),
- all with date and ID-patient-linked!

What is not included (at least yet)

- Primary EHR from HIS/AIS in general (either structured or un-structured)
- Laboratory and clinical values – some laboratory values hopefully coming during next year, some laboratory and clinical values is possible to link to NRHZS (at least in theory)
- Some hospital-administrated drugs (reimbursed as lump-sum, not directly)
- Prescription but not reimbursed drugs
- OTCs
- No parents-children link
- Data from National social information system (disability pension etc.) – hopefully during nex year as well

Patient-level analysis – a few use-cases

- Concomitant therapy used by a specific patient:
  - Potential drug interactions
  - Duplicated prescription
  - Multiple monotherapies vs fixed combinations
  - Polypharmacy
- Adherence to treatment (proportion of days covered, medical possession ratio etc.)
  - Dosage
  - Duration of treatment
  - Gaps in treatment
- Comorbidities for assessment of potential drug contraindications
  - Drug administration in the pediatric population – use and dosage
- Clinical outcomes are missing, but we still have endpoints such as mortality, hospitalizations, dosage increase, adding new treatment, stopping the treatment
- Estimation of adverse effects
- Drug forms



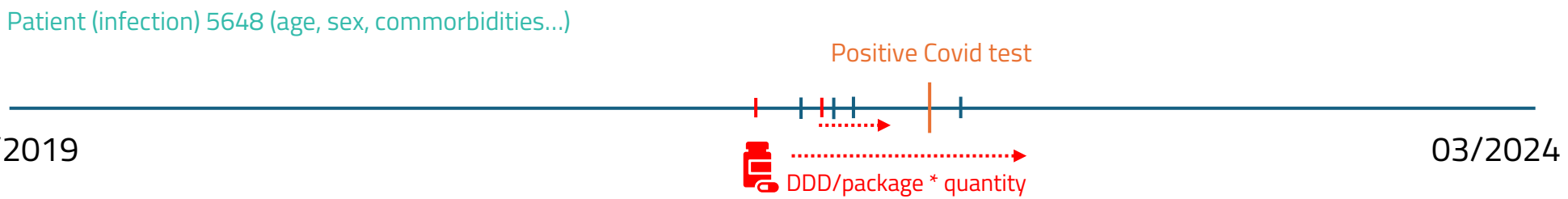
Data quality

- ICD10 quality (suspections, errors…) – combining with other data and metrics such a multiple ICD10 codes, medication, procedures, spec visits etc. if possible
- Dispensation = ! Usage
- Self-payments
- Specific reimbursement (§16) not reliable (not complete)
- Delay – cca 3.5-4 months for NRHZS, longer for registries and death certificates
- And much more…

Drug interactions case – nirmatrelvir+ritonavir (Covid)

- What proportion of COVID infections were accompanied by concomitant treatment with a potential severe interaction with nirmatrelvir+ritonavir?
- All covid infections, 2020-1Q2024 (4.761 mio infections, cca 4.3 mio patients)

- Selecting active substance with potentialy high-severity interaction („Do Not Coadminister" label within Liverpool covid19 interaction checker)
- Identification of all ATCs (and drug codes) containing at least one of these substances
- Selecting all infections (patient-date of positive test)
- Selecting relevant higher-risk population (65+) and date since the drug was available on the market
  - What dispensed medicines do we see before and do they overlap (DDD-based) with potential nirmatrelvir+ritonavir treament?



Drug interactions case – nirmatrelvir+ritonavir (Covid)

- Infection_ID
- Infection date
- Paxlovid
- Lagevrio
- Veklury
- Other treatment
- Age group
- Sex
- Infection rank
- Conflicted treatment – „Do not coadminister“ – based on Liverpool COVID-19 interaction checker
- ATC – „Do not coadminister“
- Conflicted treatment – „Potential interaction“
- ATC – „Potential interaction“
- DCCI

Drug interactions case – nirmatrelvir+ritonavir (Covid)

Results

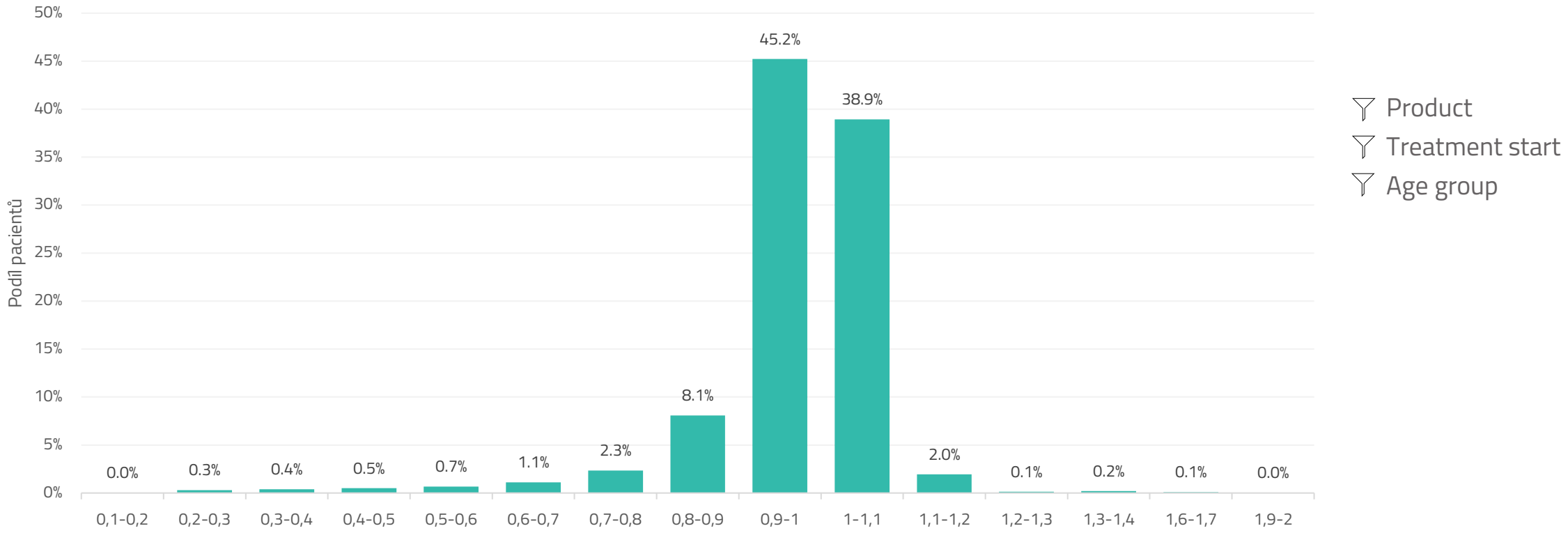
Out of **99 771** relevant covid19 infections, **13 761 (13.79%)** had overlapping expected use of drug with potentially severe interaction with nirmatrelvir+ritonavir

- Out of these 13.79%, how many patients could get the covid treatment because of…
  - Switching to other treatment with no/lower risk? (simvastatin?)
  - Pausing the treatment
  - Decreasing the dosing
  - ??

Average/typical WHO-based daily defined dosages vs. modelling expected dosing on patient-drug level (could be done with some limitations

Average consumption compared to expected (SPC-based) dosing - migraine

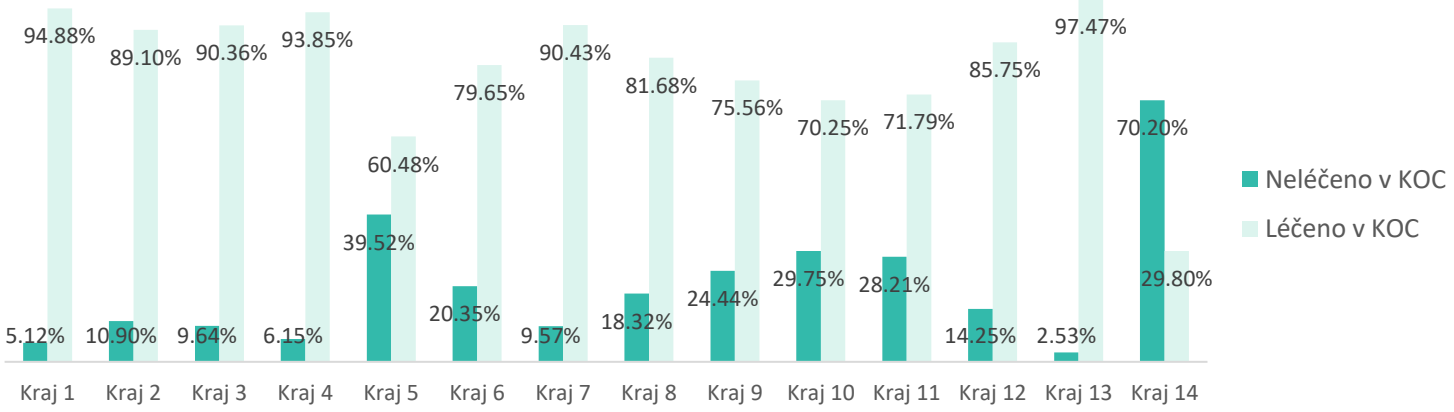
Migraine biological treatment (eptinezumab, erenumab, fremanezumab, galkanezumab), medical possession ratio like metric – slightly over 90%



Breast cancer treatment – KOC vs ROC (complex and regional oncology centres)

Analysis objective:

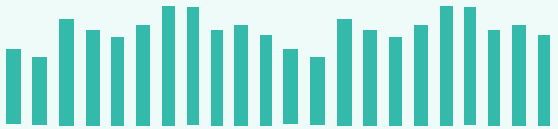
- Determine whether patients are reaching KOC
- Determine the time between diagnosis and treatment in KOC depending on:
  - Stage of disease at diagnosis
  - Region of primary treatment
  - Also mortality as outcome…



KOC treatment

85 %

Of patients were treated at least one in KOC



„Feasibility" – screening for eligibility of potential participating centers in clinical trial

- Assumptions:
  - Current situation in screening of center eligibility for clinical trials is time consuming process based on assumptions
  - Currently wide range of healthcare data available from insurance companies here in the Czech Republic with granularity to centers of treatment

- What we can get on the specific Centre (Healthcare Provider) detail:
  - Number of patients with a certain diagnosis
  - Number of patients with a certain diagnosis who were also treated with some previous treatment (for some time)
  - Patients who are still actively treated in the given area (we see visits / outpatient procedures within the relevant department)
  - Provider uses similar treatment as standard ("advanced" provider)
  - Provider performs certain operations/procedures in a significant volume
  - Devices and technology equipment
  - Personal capacities (?)

Screening for eligibility of potential participating center in clinical trial through available RWE data

Item	Old attitude	New RWD-based attitude
Quality system	OK	OK
Material equipment	OK	OK
Patients meeting inclusion/exclusion criteria	estimation	OK
Personal capacities	OK	OK
Other studies in center	„estimation“	OK
Financial and contractual aspects	OK	Necessity for personal visit (vs „empiric“ knowledge)

List of publications

- R. Kubeš et al. Predicting the development of hemophilic arthropathy in patients with hemophilia based on patient age: a retrospective single-center database study. Expert Review of Hematology, 2023;16:12, 1099-1105.
- S. Gkalpakiotis et al. Management of Moderate to Severe Plaque Psoriasis with Brodalumab in Daily Practice: Real-World Evidence from the LIBERO Study in the Czech Republic. Dermatology and Therapy, 2023, https://doi.org/10.1007/s13555-023-01066-z.
- Zatovkaňuková P. et al. Evaluating Drug Interaction Risks: Nirmatrelvir & Ritonavir Combination (PAXLOVID®) with Concomitant Medications in Real-World Clinical Settings. Pathogens 2024;13.12: 1055
- Petroušová L. et al. Analýza účinnosti perorálních antivirotik u onemocnění covid-19 v České republice. Vakcinologie 2024;4:176-183
- M. Lapka. Lékové formy perorálního mesalazinu a jejich klinické využití. Gastroent Hepatol 2023; 77(4): 342–346. doi: 10.48095/ccgh2023342
- J. Slíva. Potenciál lékových interakcí kombinace nirmatrelvir+ ritonavir v reálné klinické praxi. Medicina po Promoci 2023; 24(2): 176-186.
- E. Tůmová, et al. Výsledky neintervenčního hodnocení z reálné praxe (EZRA): fixní kombinace rosuvastatinu s ezetimibem u pacientů s primární hypercholesterolemií. AtheroRev 2022; 7(1): 39-46.
- E. Seberová, Holá B. Fixní kombinace flutikason propionátu a azelastin hydrochloridu v reálné klinické praxi v České republice (studie RECIPE-D). Farmakoterapie 2021;17(4): 591-598
- P. Salaj et al. Identifying risk factors and optimizing standard of care for patients with acquired haemophilia A: Results from a Czech patient cohort. Haemophilia 2020; 26(4): 643-651.
- T. Milota et al. Czech Hizentra noninterventional study with rapid push: efficacy, safety, tolerability, and convenience of therapy with 20% subcutaneous immunoglobulin. Clinical Therapeutics 2019; 41(11): 2231-2238.
- R. Kubeš et al. Range of motion after total knee arthroplasty in hemophilic arthropathy. BMC musculoskeletal disorders 2018; 19(1): 1-7.

THANK YOU VERY MUCH

LET'S DISCUSS!

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TME solutions

BACK-UP SLIDES

TME solutions

„Synthetic database“

- Artificial database („testing database“)
- More detail while maintaining GDPR aspects (detailed and extensive data, outputs are more aggregated)
- Most of the analytical work is transferred to the applicant (sql script and documentation)
- Limitations (GDPR, computing capacity)
- Process: designing the project -> writing sql script on testing database and writing documentation -> requesting ÚZIS -> getting the real data if everything is ok -> cleaning, wrangling, doing analysis and statistics

„standard request“ – before

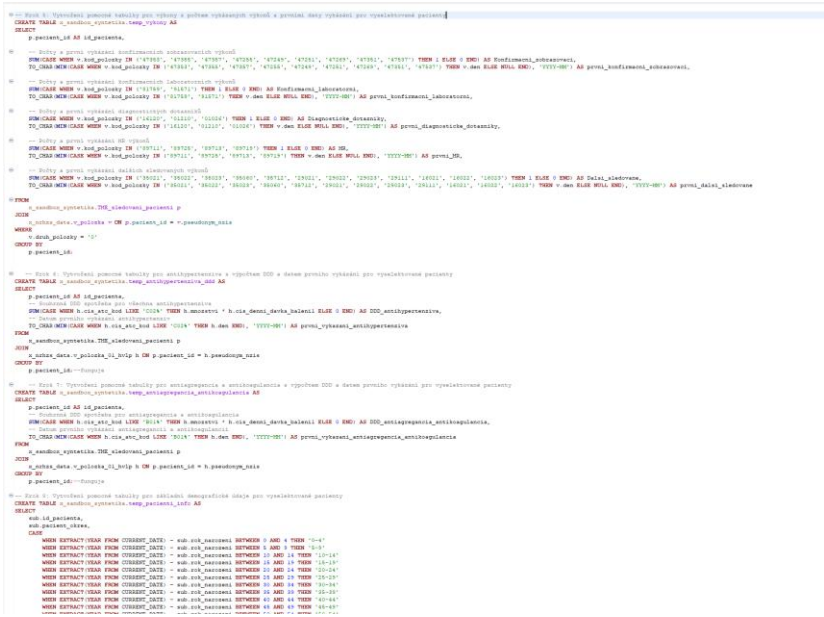
Medikace (ZÚLP, recept) předpis - MKN detailní 4znaková

Atribut	Popis
Rok	Rok, kdy došlo k vydání/aplikaci léku. Prosíme o zahrnutí období 2018-2023. Počítáme s mírným podhodnocením z důvodu nedoreportovaného konce 2023.
IČZ	Identifikační číslo zařízení (předepisující)
Název IČZ	Název IČZ (předepisující)
Odbornost	Odbornost předepisujícího pracoviště
Diagnóza dle MKN - detailní	Detailní diagnóza - maximálně však 4znaková, tj. v případě 5znakové seskupit dle 4znakové (ev. "neuvedeno")
ATC	

Medikace (ZÚLP, recept) předpis - 3znaková MKN, bez IČZ a odbornosti

Atribut	Popis
Rok	Rok, kdy došlo k vydání/aplikaci léku. Prosíme o zahrnutí období 2018-2023. Počítáme s mírným podhodnocením z důvodu nedoreportovaného konce 2023.
ATC	
Název ATC	
Diagnóza dle MKN - 3znaková	3znaková diagnóza dle MKN (ev. "neuvedeno")
Věková skupina	10letá věková skupina v době aplikace/vydání
Kraj pacienta	Kraj dle trvalého bydliště pacienta (ke konci sledovaného období).
Počet balení	Počet vykázaných balení
Počet pacientů	Počet unikátních pacientů

„synthetic data“ – now



CTEPH – where are the patients?

Chronic thromboembolic pulmonary hypertension as a specific form of PH

Objective: Where are the patients with CTEPH risk? Who is treating them (what specialty)?

Specialty	Packages – PE yes	Packages – PE no	PE/Total	PE patients %
všeobecné praktické lékařství	1 346	29 397	4.4%	**28.8%**
vnitřní lékařství - interna	1 084	17 757	5.8%	**23.2%**
onkologie	562	6 578	7.9%	12.0%
hematologie	453	25 601	1.7%	9.7%
kardiologie	255	5 791	4.2%	5.5%
angiologie	231	4 861	4.5%	5.0%
chirurgie	206	22 013	0.9%	4.4%
pneumologie a ftizeologie	120	1 234	**8.9%**	**2.6%**
…	…	…	…	…
Celkem	**4 667**	**177 025**	**2.6%**	**100.0%**

n = 1.3 mil. pojištěnců