1056P Real-world usage and adverse events (AE) of immune checkpoint inhibitors (ICI): A large-scale, automated, GDPR-compliant analysis of hospital records

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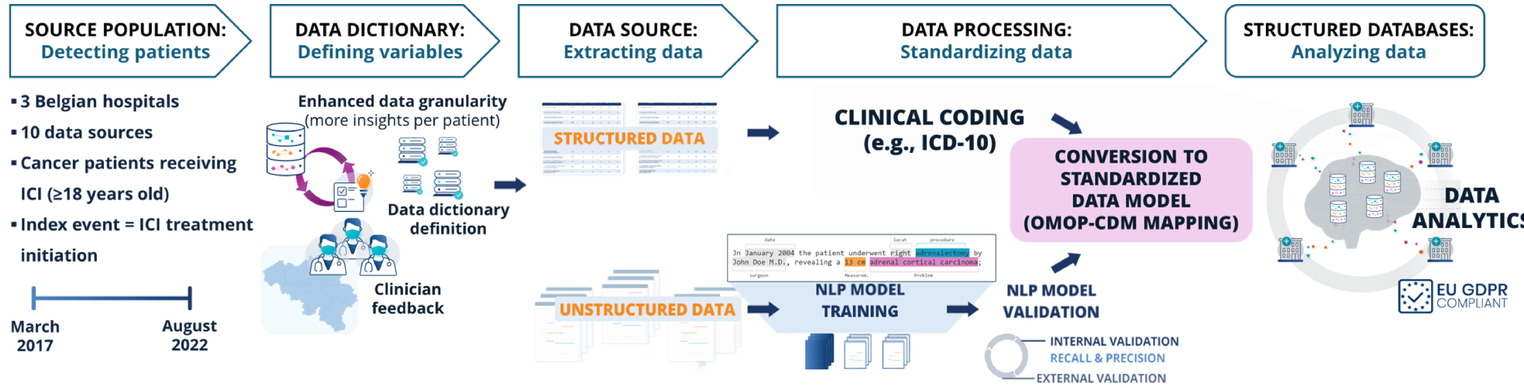
BACKGROUND AND AIMS

- **Immune checkpoint inhibitors (ICI)** form a backbone of curative and non-curative treatment across cancer types, yielding **survival benefits as well as costs and AEs**.
- The interplay between these is **challenging to estimate from trial data and classical real-world data** (claims, registries), because of the heterogeneity of patient populations and outcomes.
- The **Observational Medical Outcomes Partnership Common Data Model** (OMOP CDM) is designed for analysis of cross-domain observational health data.

METHODS

- **Retrospective multicenter** study
- Processed anonymized **electronic health records** (EHR) using **natural language processing** (NLP) and machine learning.
- The pipeline mapped 597 variables to **SNOMED-CT**
- Detected **adverse events** (AE) on ICI treatment and **comorbidities** before ICI
- The resulting **OMOP CDM databases** were validated per hospital, ensuring patient privacy.



RESULTS AND CONCLUSIONS

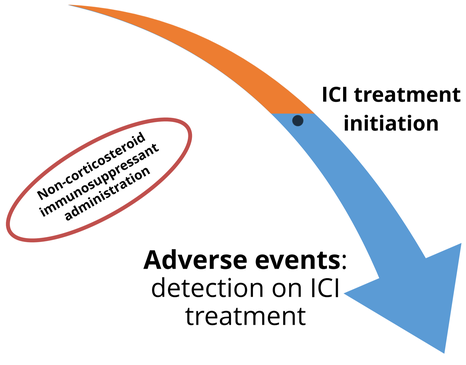


Table 1. Patient demographics. The sex, age, and performance status are shown for the total population.

Patients, n (%)	
Total	1574
Female	537 (34)
Age (median)	67y
Performance status	
0	255 (26)
1	484 (50)
2-4	229 (24)
Unknown	606

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Figure 1. Events detected before and during ICI treatment. Event distribution is shown as detected before ICI treatment (i.e., comorbidities, in orange) or on ICI treatment (i.e., adverse events, AEs, in blue) for total and specific events. The time of onset for specific AEs is shown in violin plots on the right (from first ICI administration to 3 months after last ICI administration). Red dots and numbers represent patients with administration of non-corticoid immunosuppressants (ncIS) and its timing (if within the first 12 months).

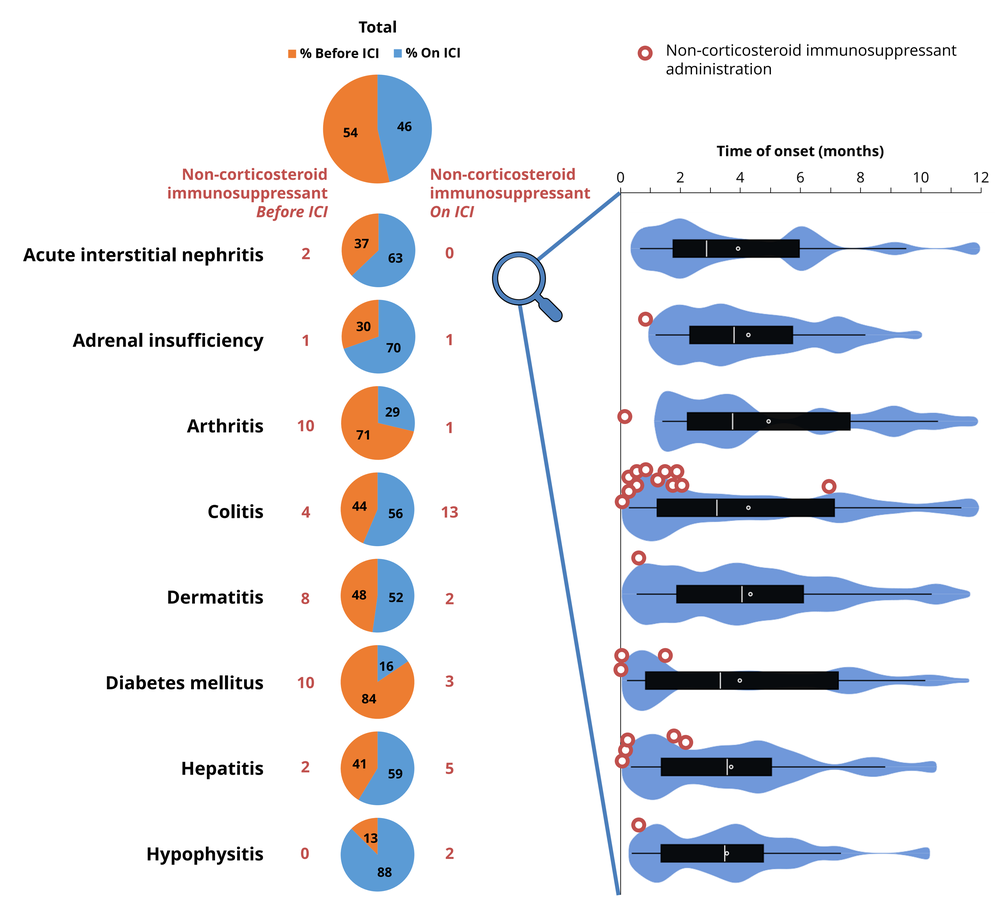

Table 2. ICI treatment characteristics per primary cancer type. The number of patients, ICI administrations, and median (95% CI) real-world time on treatment (rwToT) are shown per primary cancer type.

Primary cancer	Patients, n (%)	ICI administrations, n (%)	rwToT, median (95% CI) in days*
TOTAL	1574	18584	-
Lung	730 (46)	8145 (44)	-
NSCLC	607 (39)	7231 (39)	147 (132 – 175)
SCLC	72 (5)	485 (3)	126 (88 – 147)
Unspecified	51 (3)	429 (2)	106 (73 – 181)
Melanoma	229 (15)	3580 (19)	252 (168 – 336)
Head and neck	139 (9)	1481 (8)	84 (70 – 124)
Urothelial	137 (9)	1451 (8)	105 (63 – 147)
Renal cell	133 (9)	2169 (12)	203 (160 – 336)
Mesothelioma	59 (4)	684 (4)	126 (105 – 210)
Hepatocellular	34 (2)	308 (2)	85 (42 – 560)
Breast	32 (2)	326 (2)	168 (114 – not reached)
Esophageal	26 (2)	206 (1)	91 (67 – 141)
Endometrial	16 (1)	123 (1)	85.5 (42 - not reached)
Colorectal	13 (1)	160 (1)	971 (70 – not reached)
Other (cervical, gastric, biliary, cutaneous squamous cell carcinoma, basal cell carcinoma, Merkel cell carcinoma, Hodgkin lymphoma)	26 (2)	427 (2)	-

*rwTOT is aggregated by cancer type and includes various treatment indications, such as different treatment lines, settings, and regimens (monotherapy and combination). This grouping is intended to provide an overview and may reflect a range of clinical contexts.

CONCLUSIONS:

- We were able to build **granular real-world data warehouses** across hospitals on **>1500 ICI patients**.
- **Lung carcinoma constituted 46% of ICI-indications**.
- Among AEs that can be ICI-related, **diabetes mellitus was the main AE detected before start of ICI** (21% patients)
- **AEs detected on ICI-treatment varied**.