104P Large-Scale Characterization of Real-World Adverse Events (AE) on Immune Checkpoint Inhibitors (ICI)

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BACKGROUND & AIMS

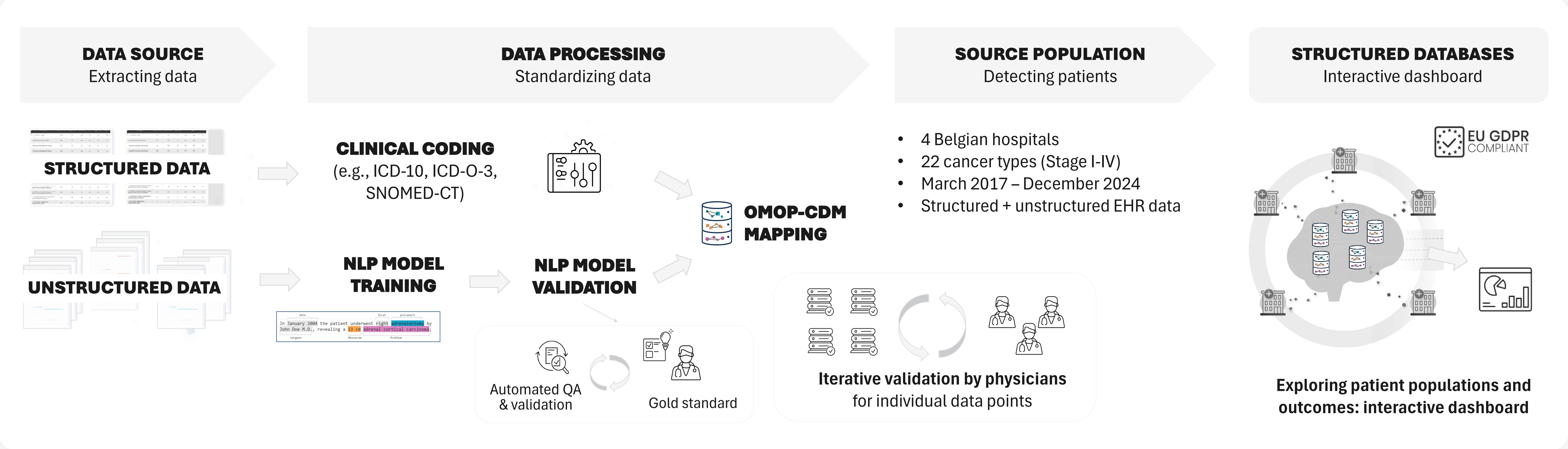
- ICI are used in most cancers but can cause life-long toxicity. Vulnerable populations are understudied in clinical trials.
- **Characterizing real-world ICI AE is a challenge:** treatment-emergent AE are data are fragmented, often free text, and not all AE are ICI-related (e.g. rash may be chemotherapy related or ICI-related).

Aims:

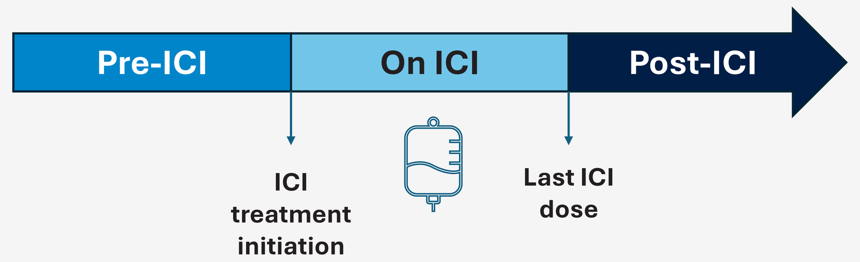
1. Develop **machine-readable phenotypes** of potentially ICI-related AE
2. **Characterize ICI AE** incidence across regimens and tumor types
3. Estimate **toxicity-driven discontinuation** of ICI

METHODS

- **Adults starting ICI** since Mar 2017 across 4 hospitals
- **Structured data + NLP-enriched notes** → OMOP CDM.
- **Computer-readable phenotypes for potential ICI-related events** (concept sets); no causality is assumed.
- **Timing by first mention:** Pre-ICI, On ICI, Post-ICI (>90d after last dose). On ICI AE may be ICI-related.
- **Toxicity-driven ICI discontinuation**: AE or first immunosuppressant <6w after last dose, in absence of progression/death.
- **Privacy:** values n<5 masked.



RESULTS



N=3231

Figure 1. Snapshot of the AE tab of an interactive ICI-treated population dashboard

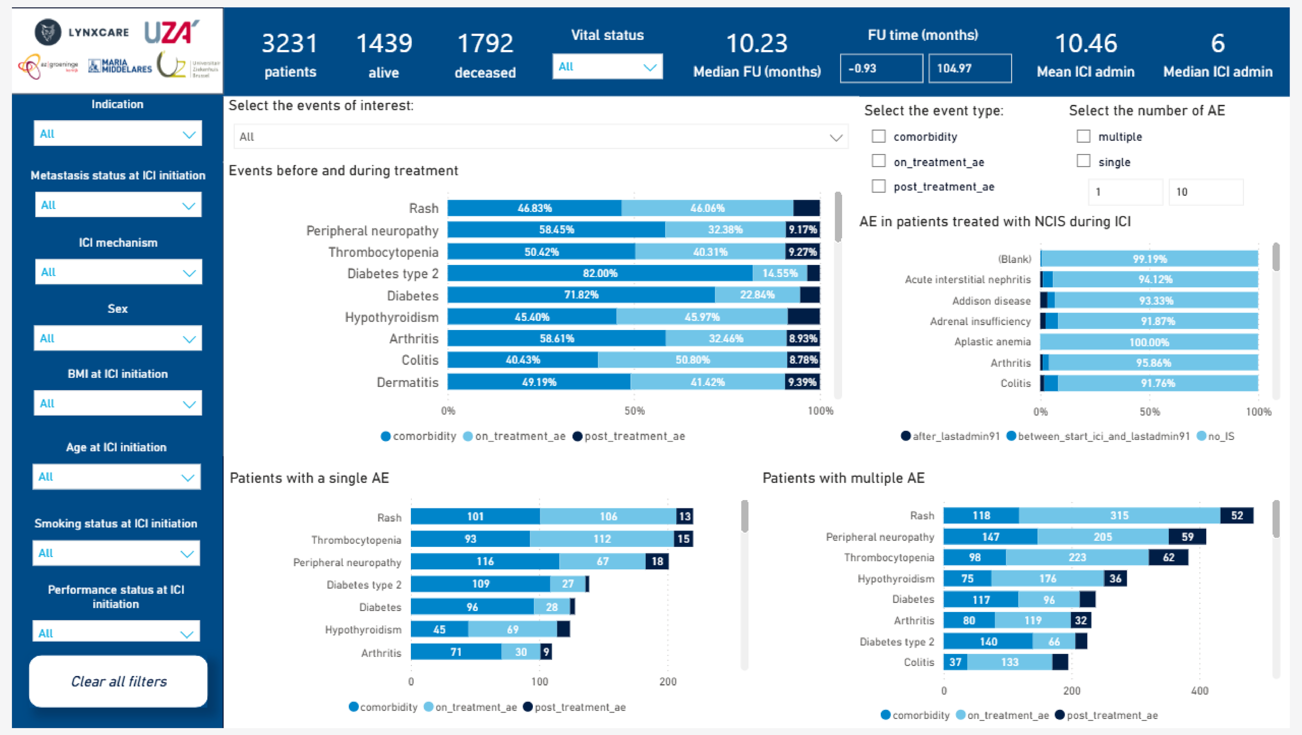


Figure 2. AE by timing on ICI monotherapy

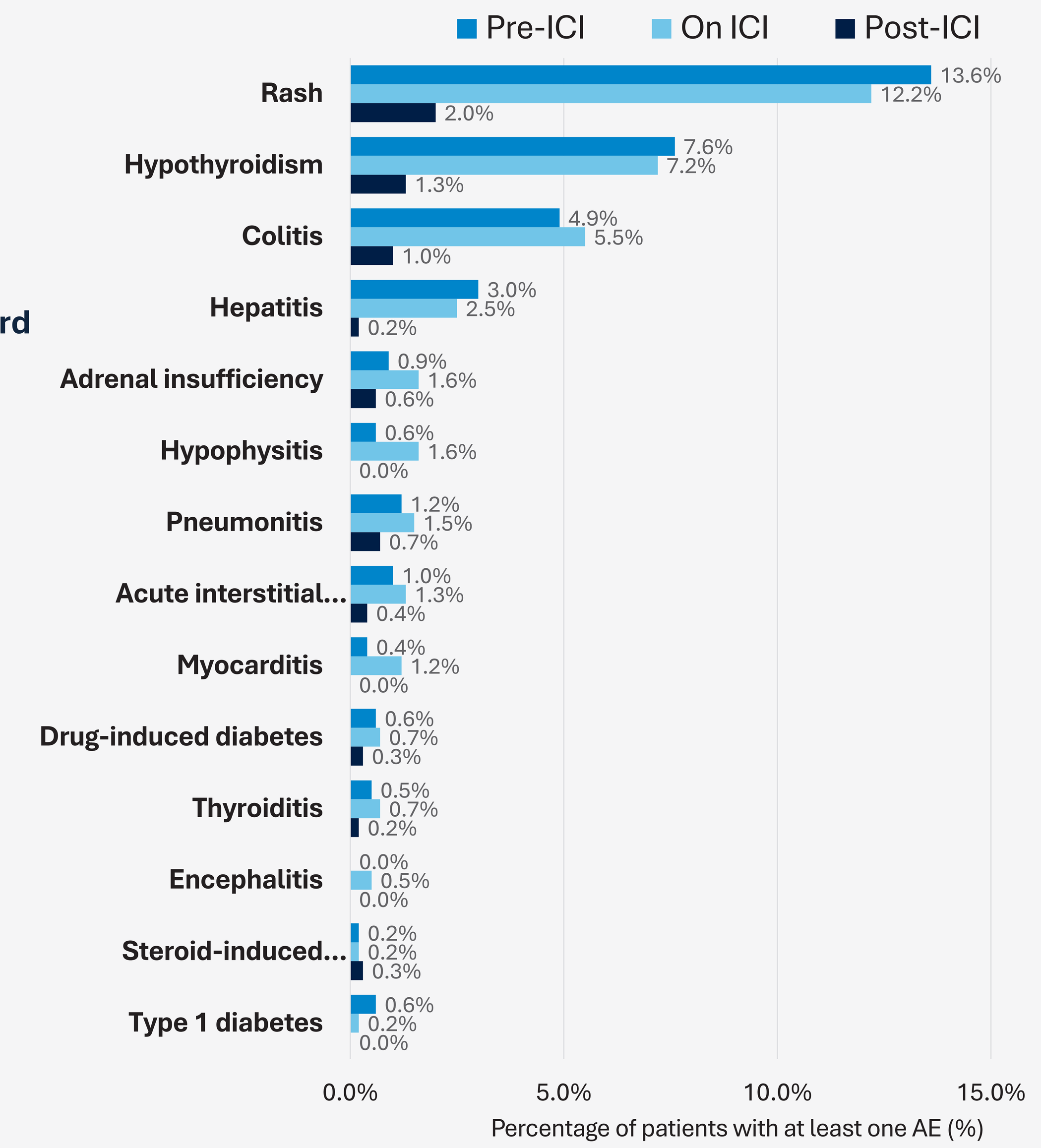


Figure 3. Reasons for ICI treatment discontinuation

Of patients who discontinued ICI, 11% did so due to adverse event

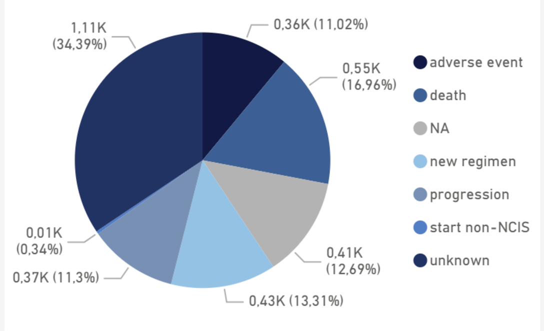


Figure 4. Illustration of dashboard filter function: AE by timing on ipilimumab-nivolumab (n=232)

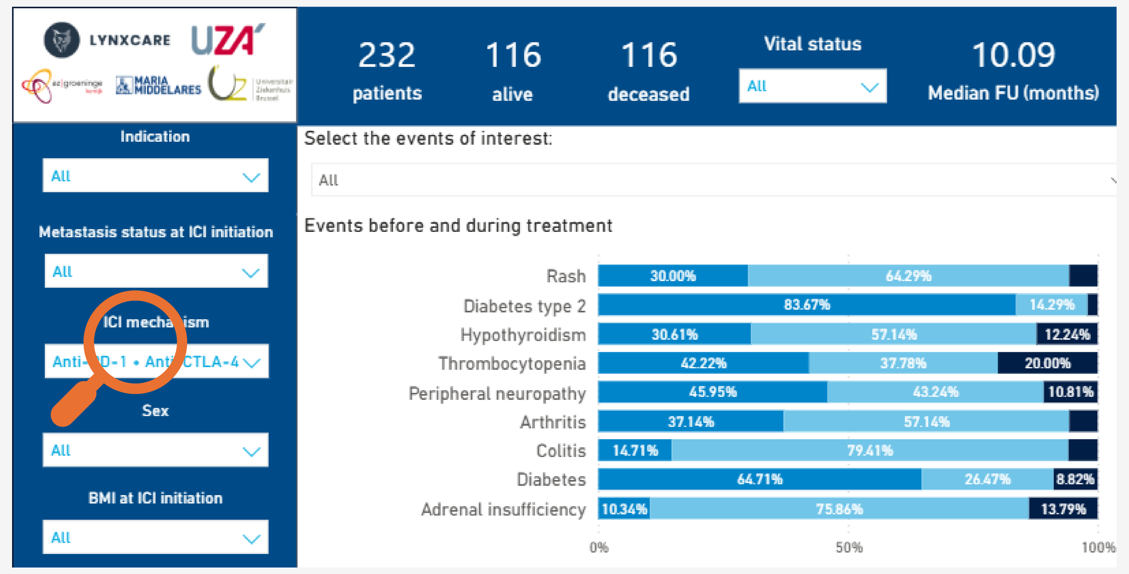
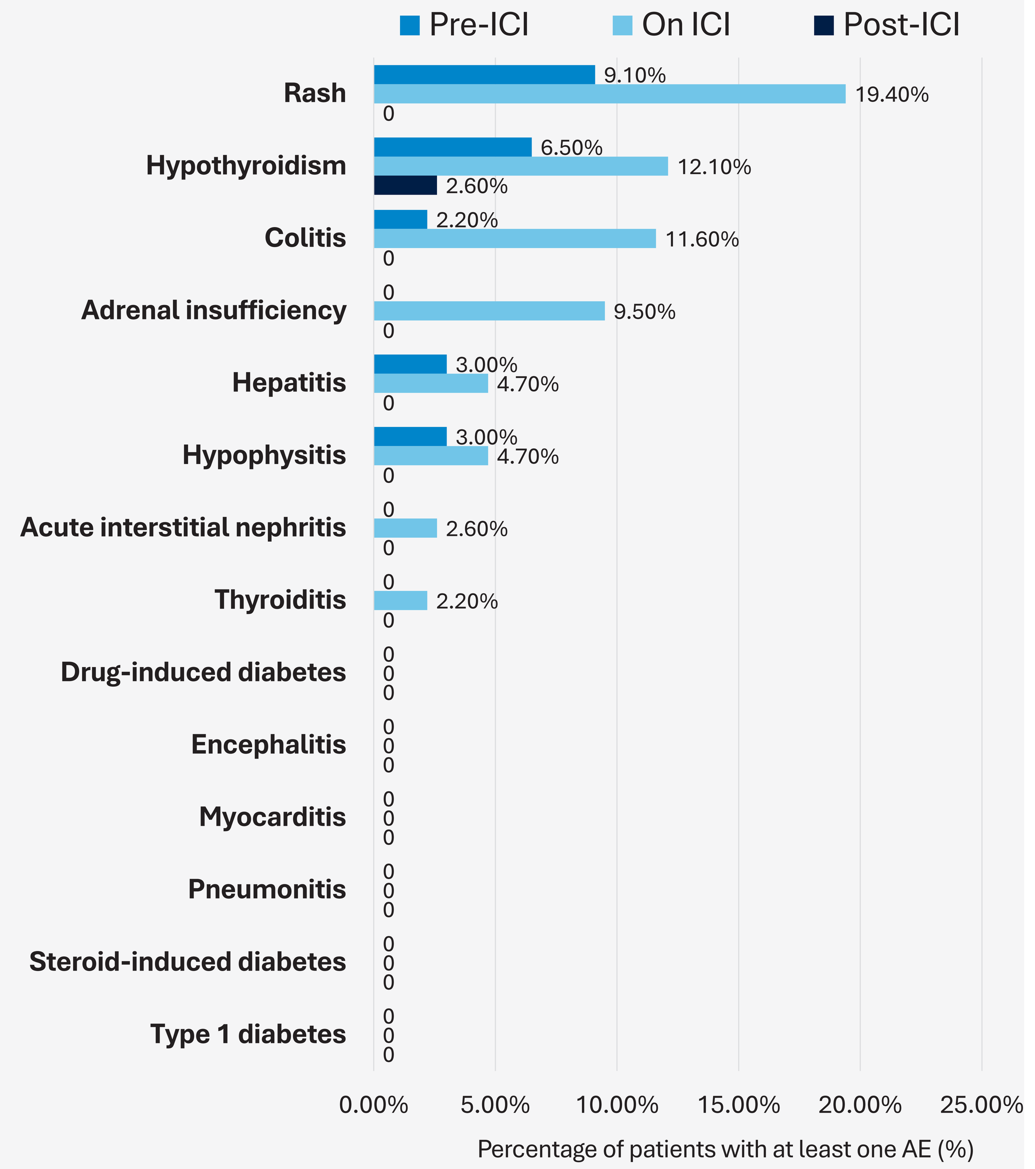


Figure 5. AE by timing on ipilimumab-nivolumab



CONCLUSIONS

- We propose machine-readable ICI AE phenotypes allowing for reproducible research based on OMOP CDM.
- On-ICI AE rates align with published ranges, are higher on ipi-nivo v ICI mono and higher for AE known to be ICI specific (e.g. hypophysitis: this **supports phenotype validity.**
- Background rates of potential ICI-related AE need further quantification to refine estimations of causality
- About **11% of ICI discontinuations appear toxicity-driven**

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Disclosures: A.V. declares speaker fees (Novartis, Ipsen) and advisory board and congress fees (Ipsen), all paid directly to UZA. Spouse works freelance at LynxCare Health Informatics (IT development, no customer contact).