1º SIMPÓSIO AMÉRICA LATINA
OHDSI 2026

From dispensing **records** to **guideline monitoring: drug eras** enable **scalable assessment** of **treatment-pathway alignment**

6 - Real-world data framework for evaluating therapeutic directives

A proof-of-concept application for ankylosing spondylitis

PRESENTER: **Vinicius Goularte**

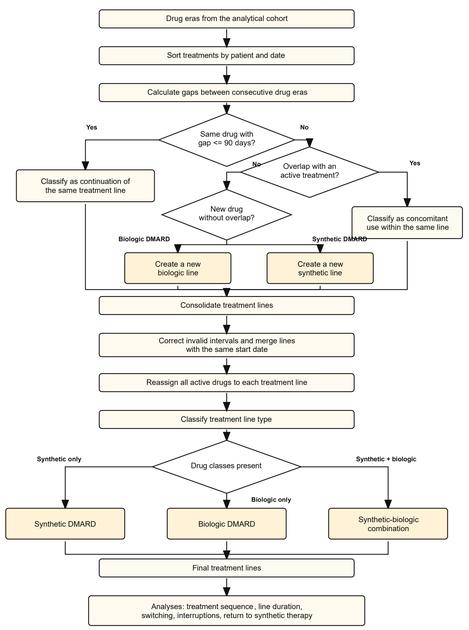
INTRO:

- Ankylosing spondylitis Brazilian PCDT pathways recommend escalation from NSAIDs or synthetic DMARDs to biologics depending on disease pattern.

METHODS

- We used Brazilian Outpatient drug dispensing records (SIA-AM) converted on OMOP-CDM.
- The observation window covered 2019-2025.

Drug Era-Based Treatment Line Algorithm



RESULTS

- 20,993 patients met eligibility criteria. The algorithm reconstructed 39,070 treatment lines.
- Among 19,278 biologic users, 18,121 had a biologic as the first observed line.

1 Initial population
37,245 patients
AS-related ICD-10 codes according to Brazilian PCDT (M45 and M46.8) and at least one study-drug dispensation
Study period: 2018-2025

Retained 86.5% | excluded 5,039

2 Treatment-based eligibility
32,206 patients
Patients with at least 3 drug dispensations

Retained 66.3% | excluded 10,855

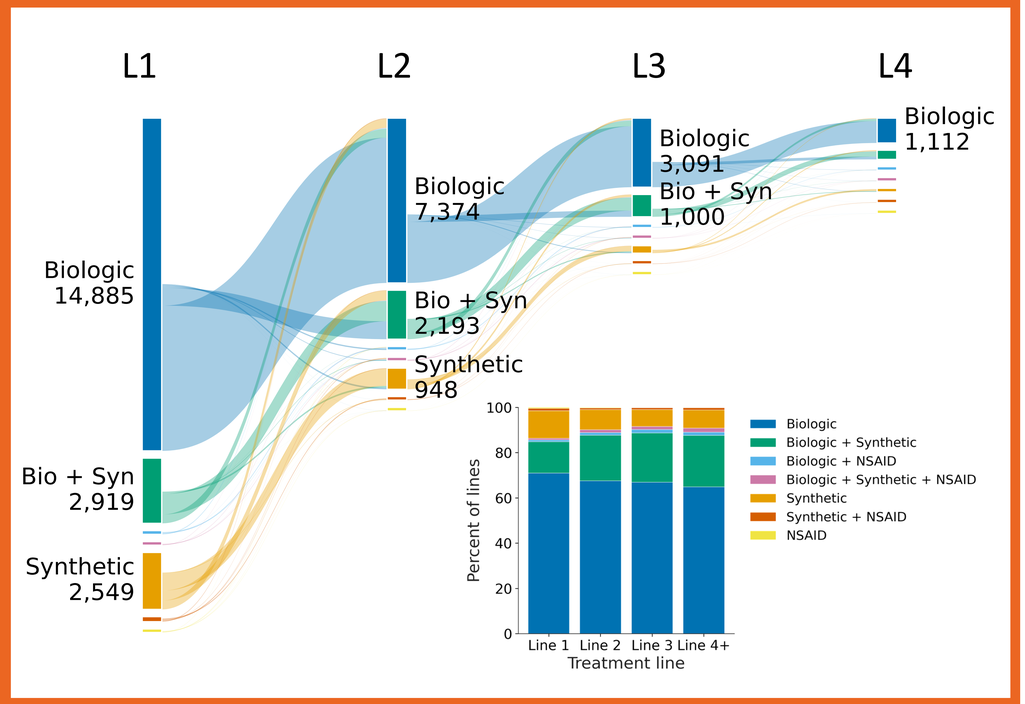
3 Incident treatment cohort
21,351 patients
No observed study-drug use before 2019 (2018 washout period)

Retained 99.0% | excluded 204

4 Minimum follow-up requirement
21,147 patients
Follow-up >= 1 year after cohort entry

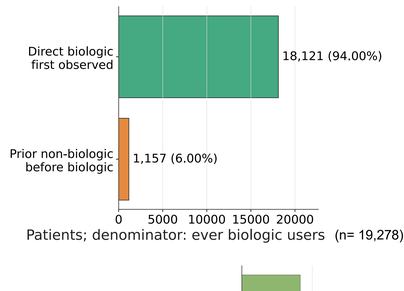
Retained 99.3% | excluded 154

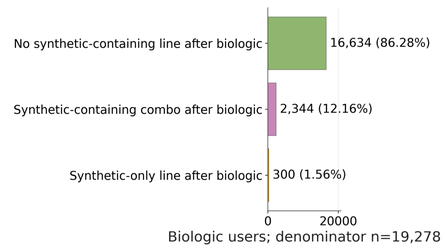
5 Final analytical cohort
20,993 patients
Eligible for OMOP drug_era construction and line-of-therapy (LOT) building



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- Only 1,157 had a clearly observed NSAID or synthetic DMARD line before the first biologic.
- Direct biologic initiation may partly reflect missing capture of out-of-pocket NSAIDs or synthetic DMARDs.
- Return to synthetic therapy after biologic exposure may reflect access barriers, treatment interruption, clinical discontinuation, or supply disruption.





- Findings should be interpreted as observable alignment signals, not definitive measures of clinical compliance.
- Sensitivity definitions matter: strict synthetic-only return differs from any synthetic-containing line after biologic

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