Real-world studies with biosimilars

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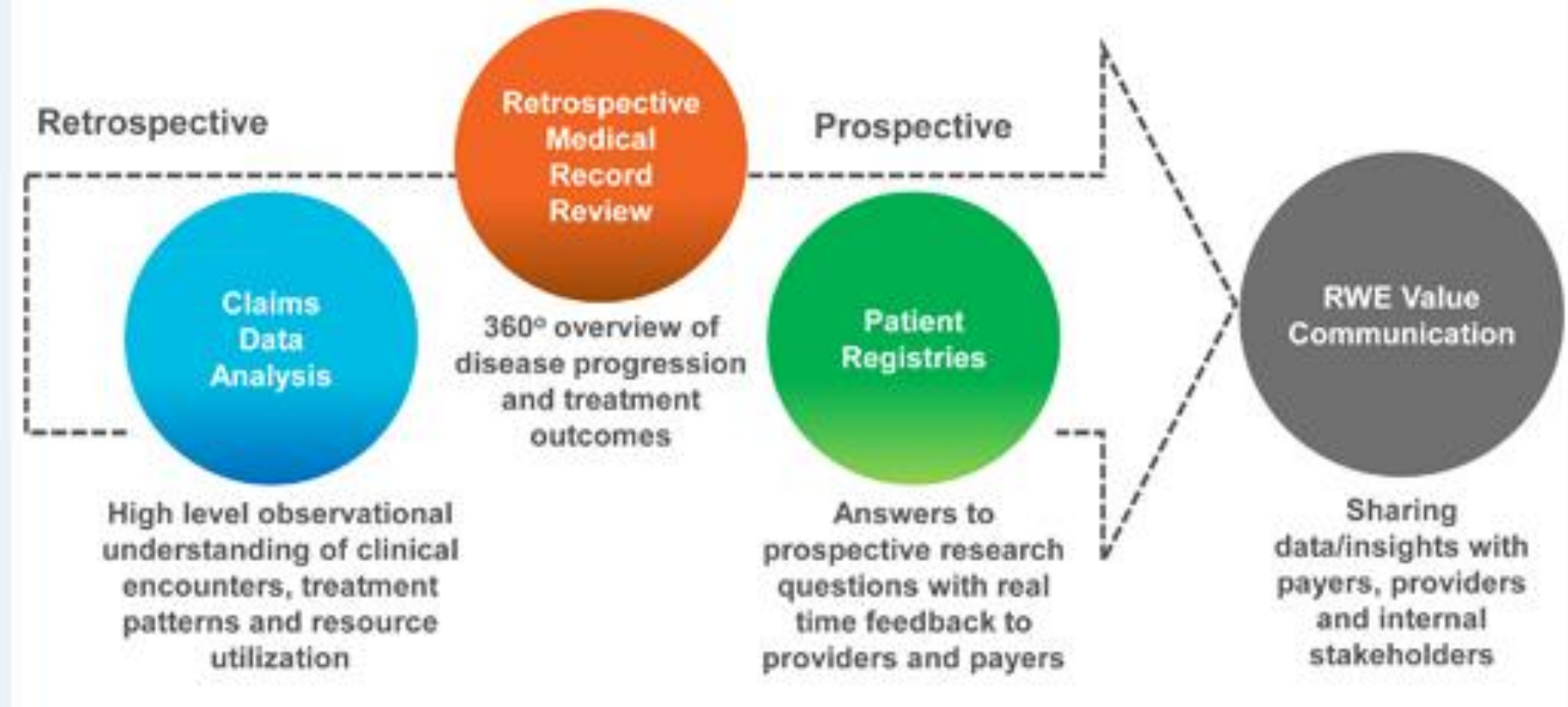
Continuum of real-world evidence



Biosimilar example 1

- **Prospective observational** study in patients with CD or UC treated with CT-P13. Patients were naive or switched to anti-TNF treatment from the reference infliximab (Remicade®) to CT-P13.
- "… demonstrated effectiveness and safety at 3 and 6 months, and support to continue long-term therapy studies."

Dig Dis Sci. 2017 May;62(5):1305-1312.

Biosimilar example 2

- A descriptive analysis of real-world treatment patterns of innovator infliximab (REMICADE) and biosimilar infliximab.
- “Discontinuation in 55% of the IFX cohort…with 8% initially switching to CT-P13. In the CT-P13 cohort, a confirmed discontinuation was observed in 63% …20% initially switched to IFX”

Ann Rheum Dis. 2017; Volume 76, Issue Suppl 2.

Challenges

- What RWE would be useful to guide clinical decisions?
- What RWE would be useful to inform payers?
- What study design for biosimilars?