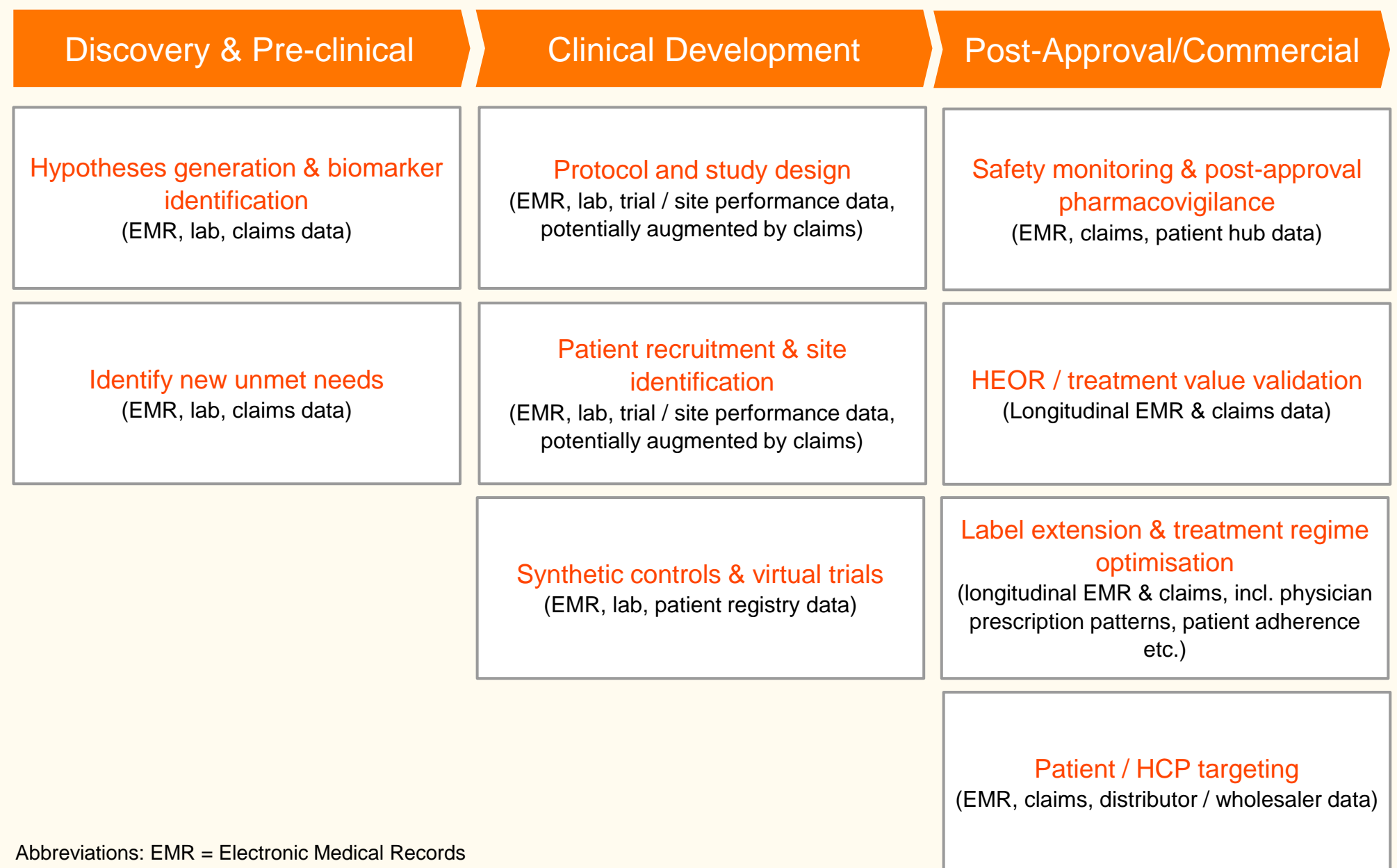# RWE ACROSS THE PRODUCT LIFECYCLE

RWE has many potential use cases along value chain, each with different data requirements

Main use cases, not exhaustive

Discovery & Pre-clinical	Clinical Development	Post-Approval/Commercial
Hypotheses generation & biomarker identification (EMR, lab, claims data)	**Protocol and study design** (EMR, lab, trial / site performance data, potentially augmented by claims)	**Safety monitoring & post-approval pharmacovigilance** (EMR, claims, patient hub data)
Identify new unmet needs (EMR, lab, claims data)	**Patient recruitment & site identification** (EMR, lab, trial / site performance data, potentially augmented by claims)	**HEOR / treatment value validation** (Longitudinal EMR & claims data)
	Synthetic controls & virtual trials (EMR, lab, patient registry data)	**Label extension & treatment regime optimisation** (longitudinal EMR & claims, incl. physician prescription patterns, patient adherence etc.)
		Patient / HCP targeting (EMR, claims, distributor / wholesaler data)

Abbreviations: EMR = Electronic Medical Records

The use of RWE is now expanding across the entire product lifecycle

Development → **Growth phase** → **Mature phase**

Evidence Required

Understand SoC · TPP design · Trial design · Patient recruitment · Payer/provider cost offsets · Unmet need · Budget impact · Post-marketing commitments (safety, etc.) · Risk sharing (e.g., pay for performance) · Adherence · Utilisation/prescribing patterns · Long-term clinical outcomes · Head-to-head comparative effectiveness · Differentiation in sub-populations · Target populations · Usage difference · Effects of switching on outcomes · Differentiate with or vs. protected galenics

Traditional focus

Launch · Conditional Pricing Review · New Competition · New Formulation/Indication · Competitor Goes Generic

From the *Generating RWE for Optimising Market/Patient Access* course with Prof. Dr. Thomas Wilke