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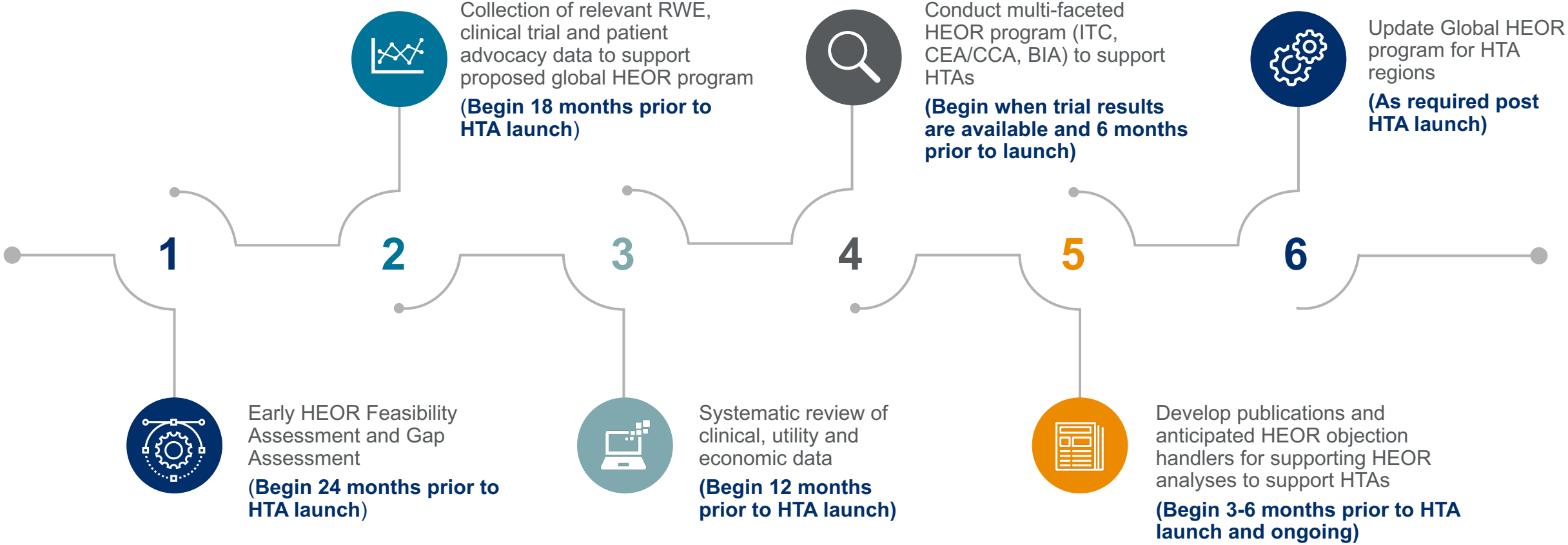
Developing and Implementing HEOR Programs to Support Global HTA and Reimbursement Decisions

A Guide to Key Activities and Timelines

Steps in Developing a Global HEOR Program for Orphan Products

Timelines to implement Global HEOR Program for New Product for Orphan Products



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Global HEOR Program Checklist for Orphan Diseases

- Begin early HEOR Feasibility Assessment and Gap Assessment at least two years before HTA launch
- Find the right partner with Rare/Orphan Disease and global HTA experience
- Begin RWE data collection early to gain a thorough understanding of the patient journey and to develop HEOR material
- Engage regional affiliates and involve them in the HEOR program
- Develop various HEOR analyses to support global HTA requirements and focus on HEOR models that best reflect patient journey
- Develop publication and communication plasn to demonstrate the value of the HEOR program
- Develop strategic partnerships with global patient advocacy organizations to support HEOR program
- Ensure partner is available to adapt regional HEORs and respond to HTAs in timely manner

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Adaptation of Global HEOR Program for Orphan Diseases

Core Global HEOR Program Component	Potential Adaptation for Orphan Product
Systematic Reviews	Initial step to better understand body of information on orphan disease; SLR data may be limited
Indirect Treatment Comparisons	NMAs may not be applicable given limited treatment options; may require access to IPD to conduct ITCs
Real-World Data Activities	Need to build partnerships early given to collect data as *de novo* RWE may not be as accessible
Global Health Economic Activities	Need to build HEOR models that meet HTA requirements, focus on budget impact vs, CE, and also describe patient journey and key outcomes
Value Communication Activities	Need to describe patient journey and convey challenges with cost per QALY estimates using traditional benchmarks
Global HTA Submission Support	Need to understand nuances of HTA frameworks for evaluating drugs or rare or orphan diseases