



**WEP**

**With Every Patient.**

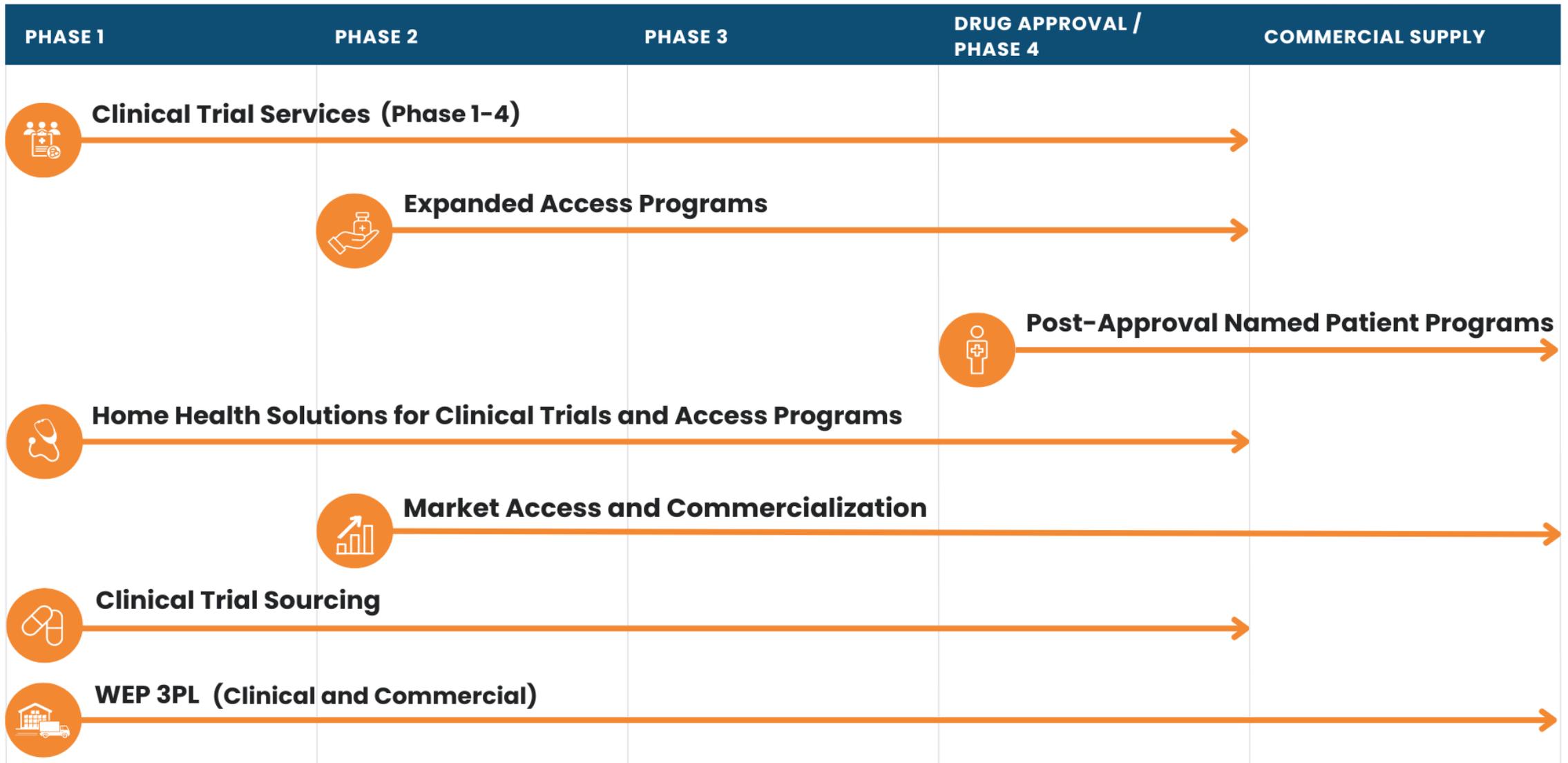
**WEP Market Access**

**The Art of the Possible**

Pre-Licence Access and Funding

Penny Fairmann, Director Market Access

# WEP Core Services



# WEP Market Access Strategic Consulting



Our Market Access team **specialises in providing tailored solutions** for global sustainable access for innovative therapy options with a focus on **Rare Diseases, Advanced therapies, and Oncology**.

By integrating clinically meaningful & patient-centred outcomes, diligent market understanding, and strategic stakeholder engagement, **we drive successful market entry and subsequent commercialisation**.



## Market Research

- Asset profiling & therapeutic positioning
- Competitive landscape, comparators & emerging pipelines
- Payer research
- KOL research
- Global access strategies



## Value Proposition Development

- Payer Advisory Boards
- Establish unmet clinical need
- Clarify potential comparators
- Payer validated endpoints
- Value proposition testing with Payer archetypes\*
- Pricing scenarios based on willingness to pay thresholds



## Price & Reimbursement Strategy

- Pricing strategies
- Price point evaluation, & access arrangements
- Multiple indication pricing strategies
- Health Technology Assessments
- Payer value assessment
- Managed Access agreements



## Commercialisation

- Early access schemes
- HTA & HEOR dossier development
- RWD & RWE generation
- Price negotiations
- Accelerated launch sequencing
- Commercial marketing

\* Cost-effectiveness; comparative effectiveness; cost-comparison

- 1** The value of early access programmes (EAPs)
- 2** Practical considerations when implementing EAPs in commercial strategy
- 3** Early Access - A bridge to commercialisation
- 4** Pre-licence funding opportunities
- 5** Q&A

# Early Strategic Thinking: Value of Early Access Programmes



Meeting patient needs



Opportunity for KOL & patient advocacy



RWD collection opportunity



Pre-license market with full price sales



Accelerated product launch



Global Market Access Strategy

# Practical considerations when implementing EAPs in commercial strategy



## SMALL PATIENT POOLS

- Balance between EAP for small patient populations Vs identifying new patients once Pricing and Reimbursement has been successful and national funding is secured



## COMPETITIVE LANDSCAPE

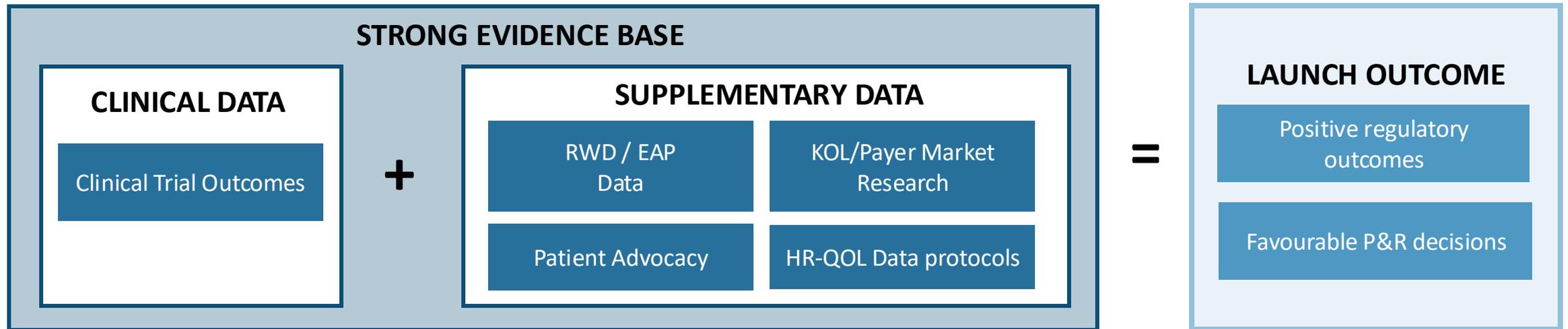
- Requirement to supplement clinical data with Real-world data for positive regulatory and launch outcomes



## REGULATORY COMPLEXITY

- Engaging proactively with regulatory agencies
- Adapting to dynamic regulatory changes
- Risk vs. Opportunity for compliance in diverse markets

# Early Access as a tool for gathering Real-World Data



## OPPORTUNITIES

- Observation of real-world treatment patterns (Adherence, dose modifications, reasons for discontinuation)
- Filling data gaps missing from RCTs to support sustainable access
- Consideration of payer-relevant endpoints



## CONSIDERATIONS

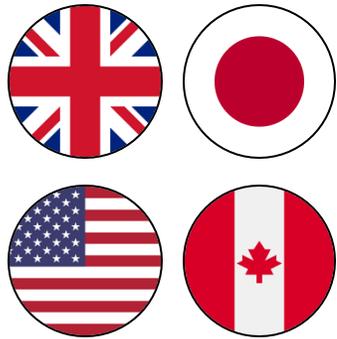
- Data collection must not be burdensome or laborious for sites

# EAP funding opportunities

*Limited to certain markets*

Charged for EAPs are available in specific global markets.  
Regulatory pathway defines therapy area, patient population and possible funded access

## WAVE 1 LAUNCH COUNTRIES



## EU COUNTRIES



## REST OF WORLD



# Key Messages



**Early Access Programmes play a valuable role in an asset's commercialisation strategy**



**Real-world data gathered in an EAP can supplement clinical trial data and should not be burdensome to sites**



**Early Access Programmes offer possibility to gain early patient and clinical experience whilst generation income in some global markets**

# The art of the possible: pre licence access and funding

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## WEP Market Access Strategic Consulting

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- If you are transitioning your asset from Clinical Development to Commercialisation; our team can help you solve this challenge .
  
- If you are planning a RWD collection strategy, for an Expanded Access, Early Access or value proposition please get in touch with us at **[MA@wepclinical.com](mailto:MA@wepclinical.com)**