

Real World Evidence: Enabling Adaptive Pathways

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Before phase3

Potential Value

Background RWE on disease, treatments, care pathways, unmet need etc

During phase3

Predict Value of new Medicine

Analytical Approach to drivers of real world effectiveness

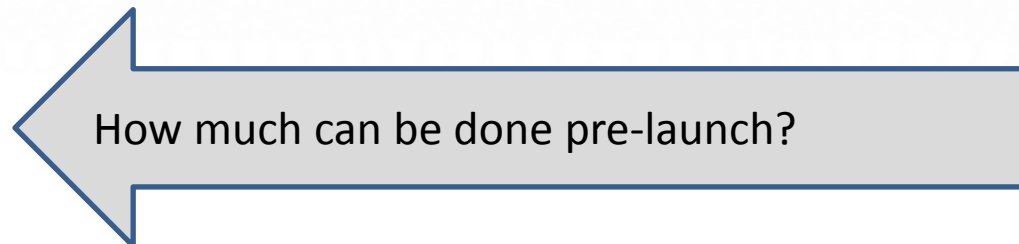
Comparative Trials; Pragmatic Trials, giving information on effectiveness

Evidence Synthesis to combine all sources of information: RCT + PCT + OBS

After Launch

Confirm Value

Post Launch RWE on: use of new medicine, relative effectiveness, longer term outcomes



Before phase3

Potential Value

Background RWE on disease, treatments, care pathways, unmet need etc

During phase3

Predict Value

Analytical Approach to drivers of real world effectiveness

Pragmatic Trials, giving information on effectiveness

combine all sources of information: RCT + PCT + OBS

After Launch

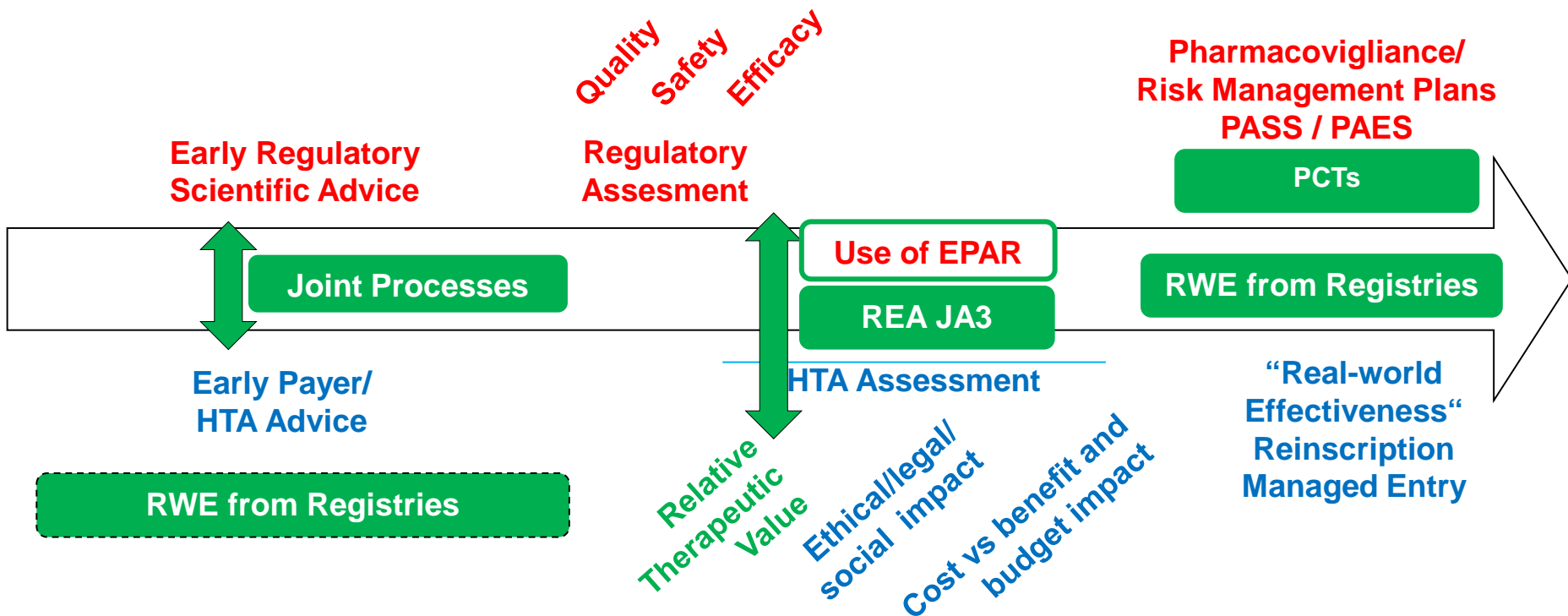
Confirm Value

Post Launch RWE on:

- use of new medicine,
- relative effectiveness,
- longer term outcomes:
- Innovative approaches to investigate next indication

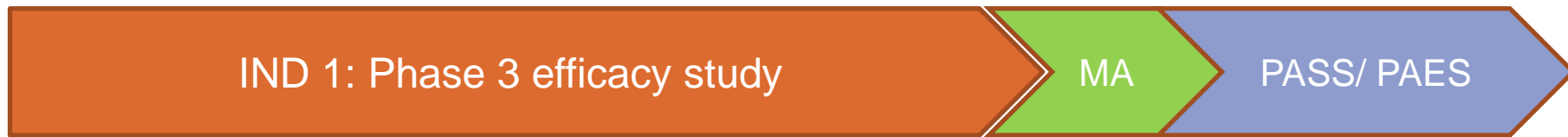
Can we get to Post-Launch Phase earlier?

Evolving Regulatory and HTA processes that inform acceptability of evidence at launch and post launch



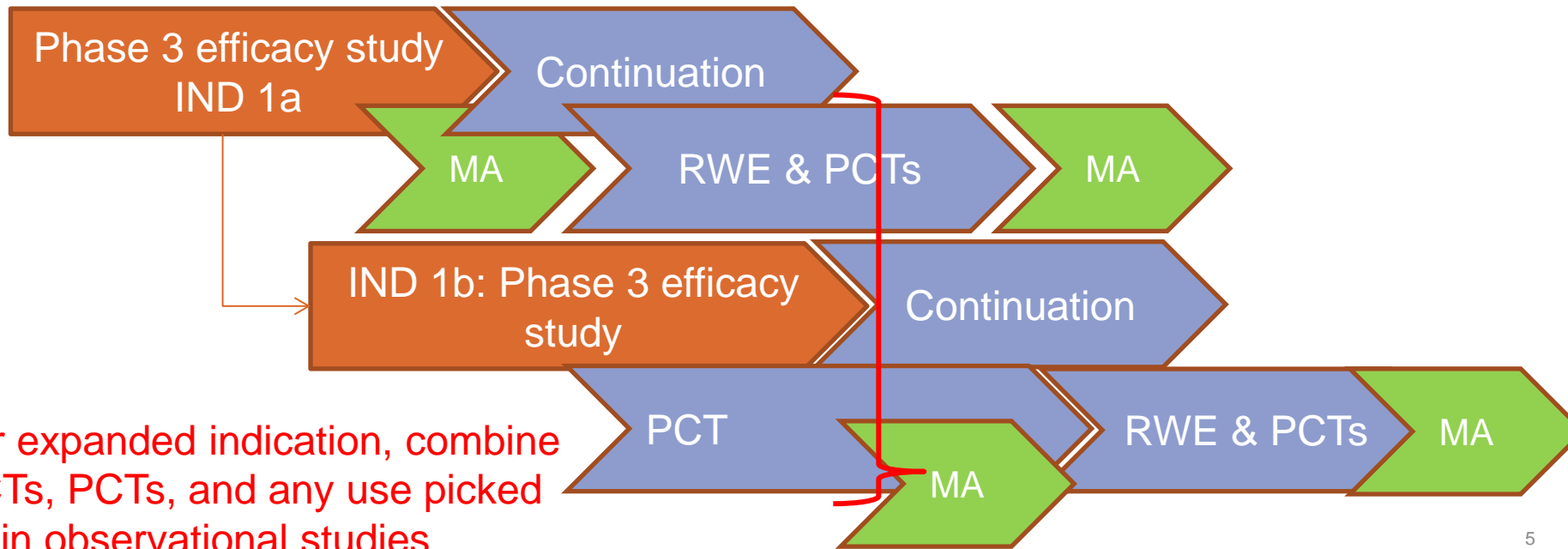
- Existing Regulatory Processes allow for flexibility in sequencing and speed
- Need to pass through HTA and reimbursement to enter post-launch use and RW research
- Scientific Advice needs to be JOINT and cover options for both pre and post launch studies

“Total Evidence” approach



First MA is earlier based on more severe sub-indication; higher event rate, smaller trials, interim endpoint, quicker conditional MA

Intensive and pre-defined post launch RWE: expanded N, longer term endpoint, confirm payer value,



For expanded indication, combine RCTs, PCTs, and any use picked up in observational studies

FOR SUCCESS of MAPPS?

SCIENTIFIC ADVICE

REGISTRY INFRASTRUCTURE

ACCEPTABILITY OF RWE

METHODOLOGY for PCT, TOTAL EVIDENCE SYNTHESIS