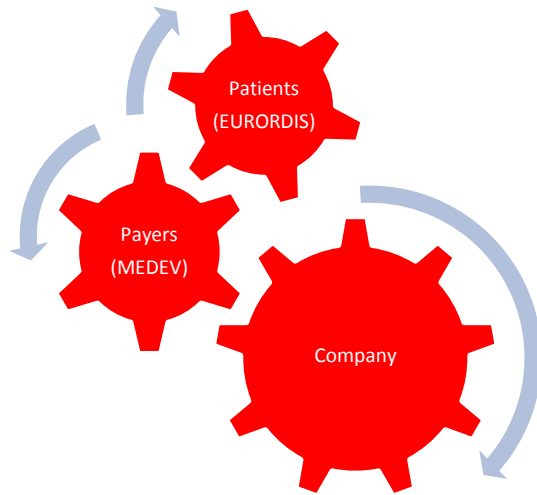


Timelines for MoCA Activity

Color Legend:

Red:	MoCA
Orange:	Company
Blue:	EMA
Green:	HTA, Payer

Mechanism of Coordinated Access to Orphan Medicinal Products



Any company with an OMP/rare disease therapy at any stage of Development can contact MoCA

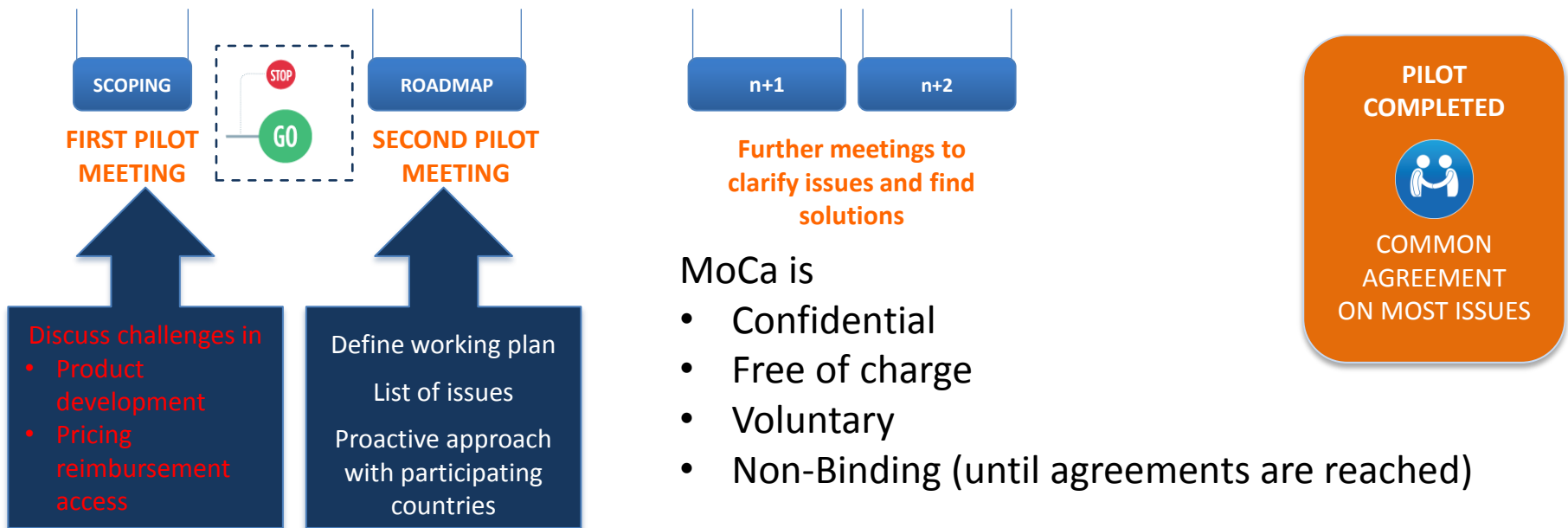


With an orphan designation or not
From non clinical to post-marketing phase

MoCA has patient input at every step of the process and at every stage of the pilot



MoCA TIMELINE

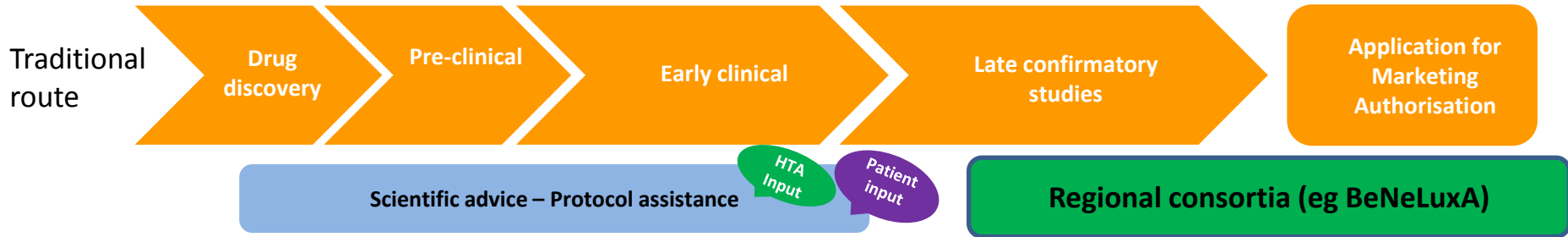


MoCa is

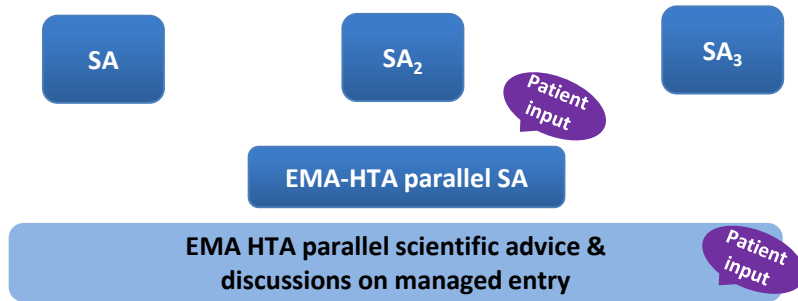
- Confidential
- Free of charge
- Voluntary
- Non-Binding (until agreements are reached)

REGULATORY TOOLS		OTHER TOOLS
TO FACILITATE EARLY ACCESS	TO AVOID FAILURE AT MAA	TO AVOID FAILURE AT PRICING & REIMBURSEMENT
Conditional approval	Scientific advice protocol assistance	MoCA – concrete evaluation
Accelerated assessment	EMA-HTA parallel scientific advice	EUNetHTA – early dialogue
Compassionate use	PRAC Advice	Regional consortia – BeNeLuxA, etc.

PRE- APPROVAL

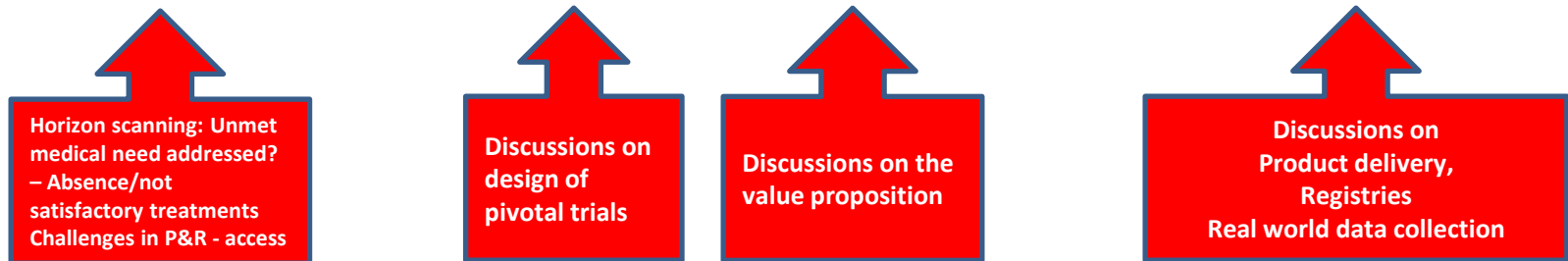


PRIority
MEdicines

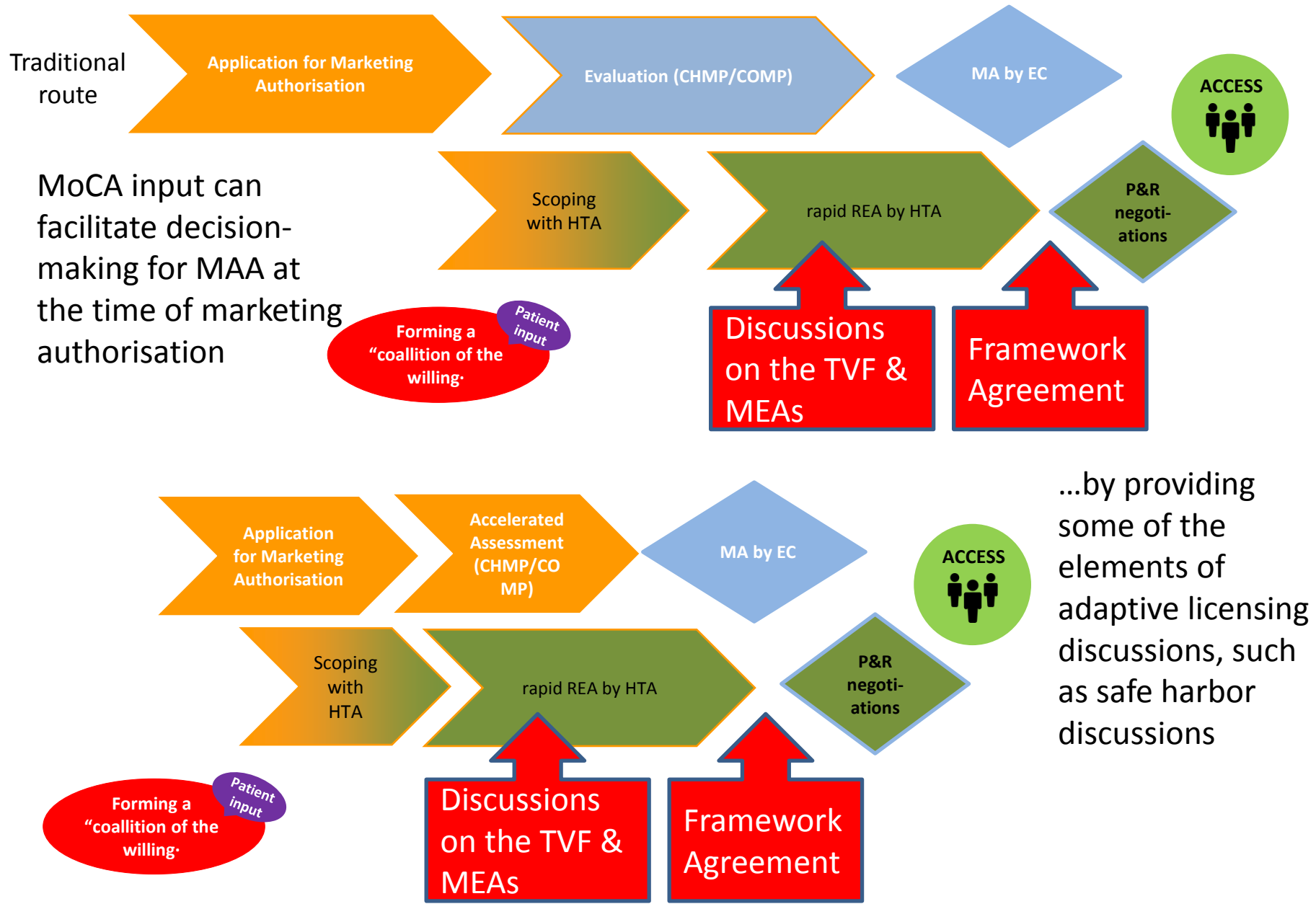


Companies can integrate the input provided by MoCA from patients' and payers' perspectives at any stage of product development

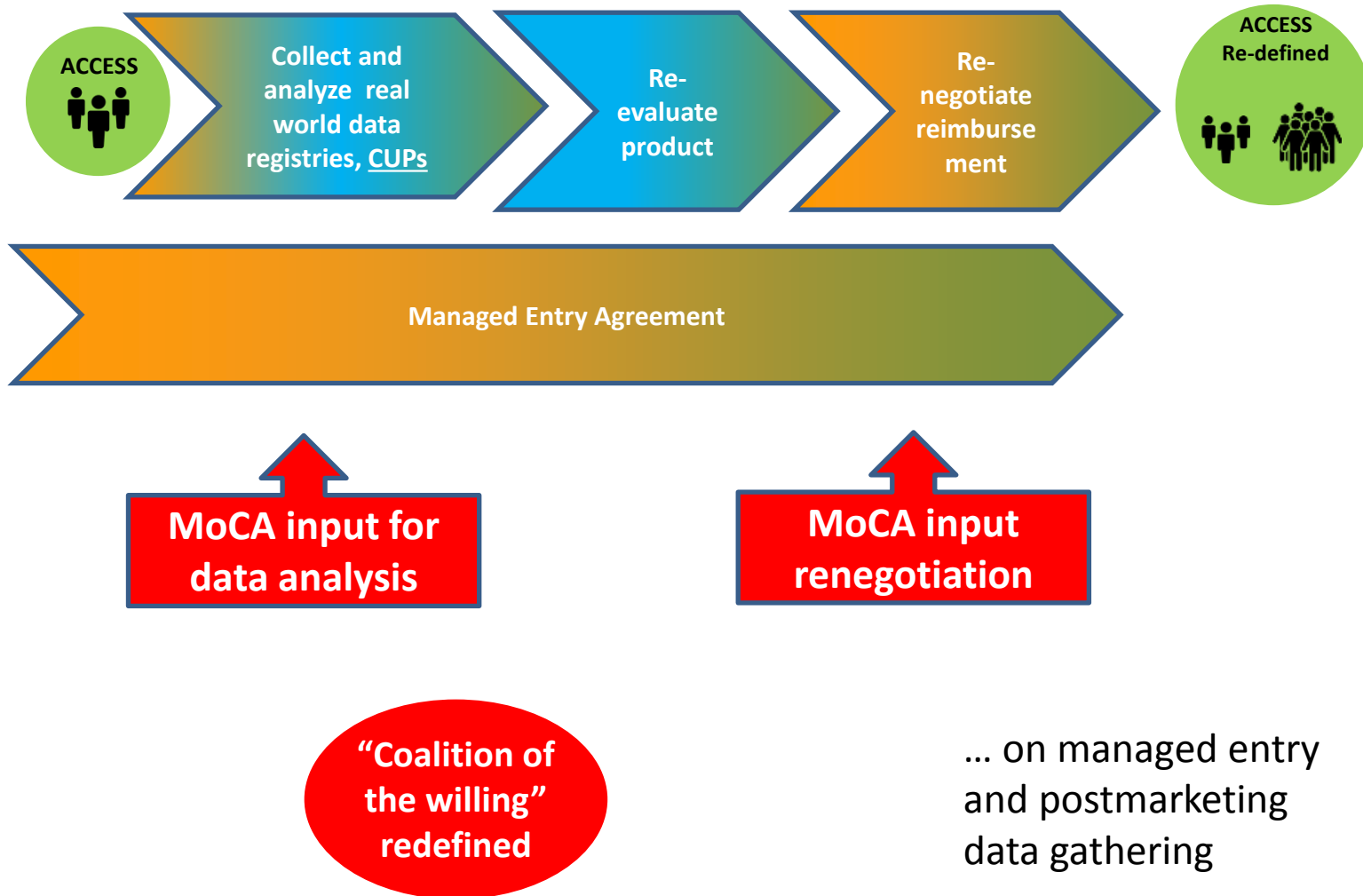
MoCA Pilot
Content

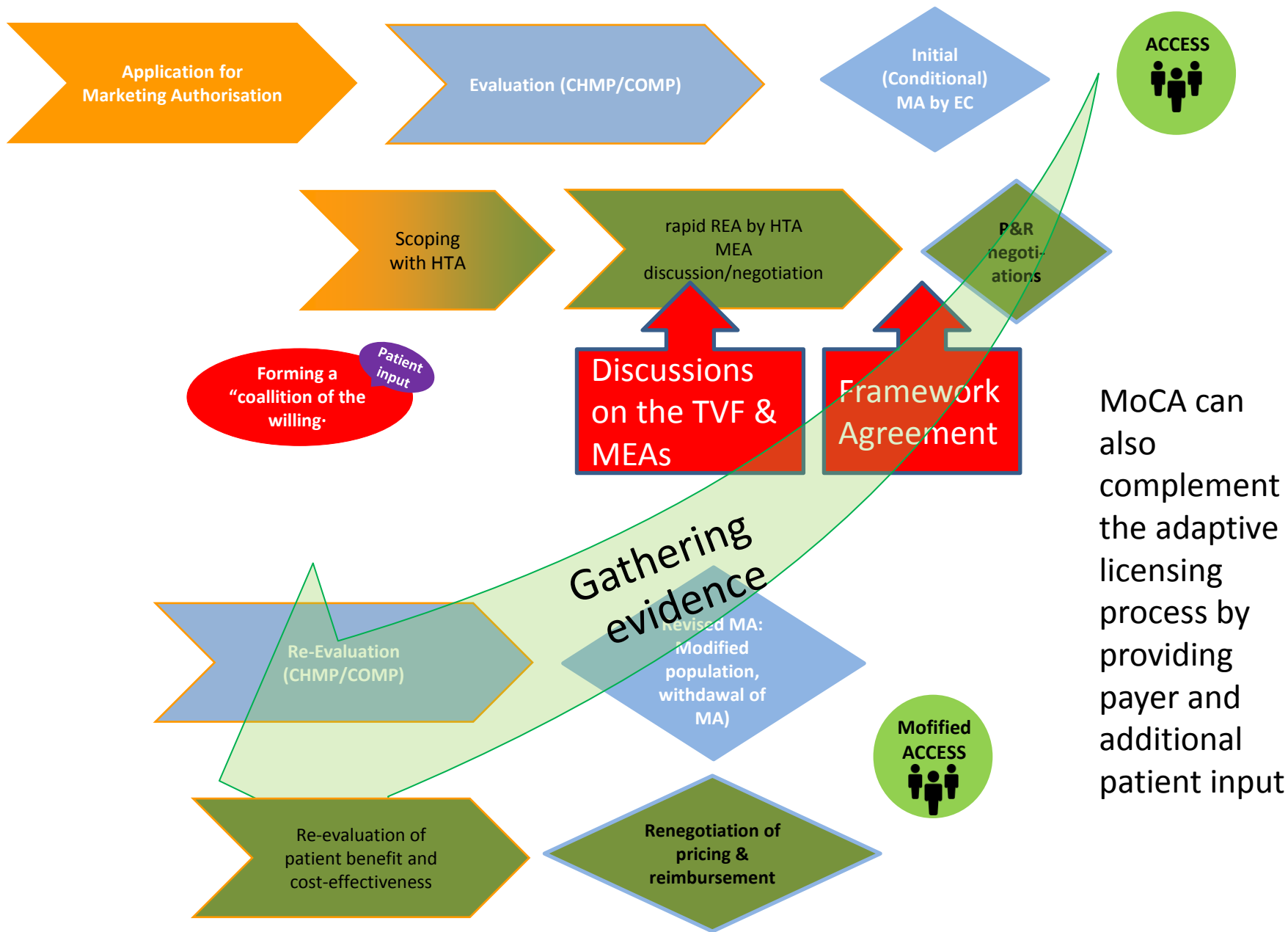


Peri-Approval



POST- APPROVAL





Thank you very much for your attention!