EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

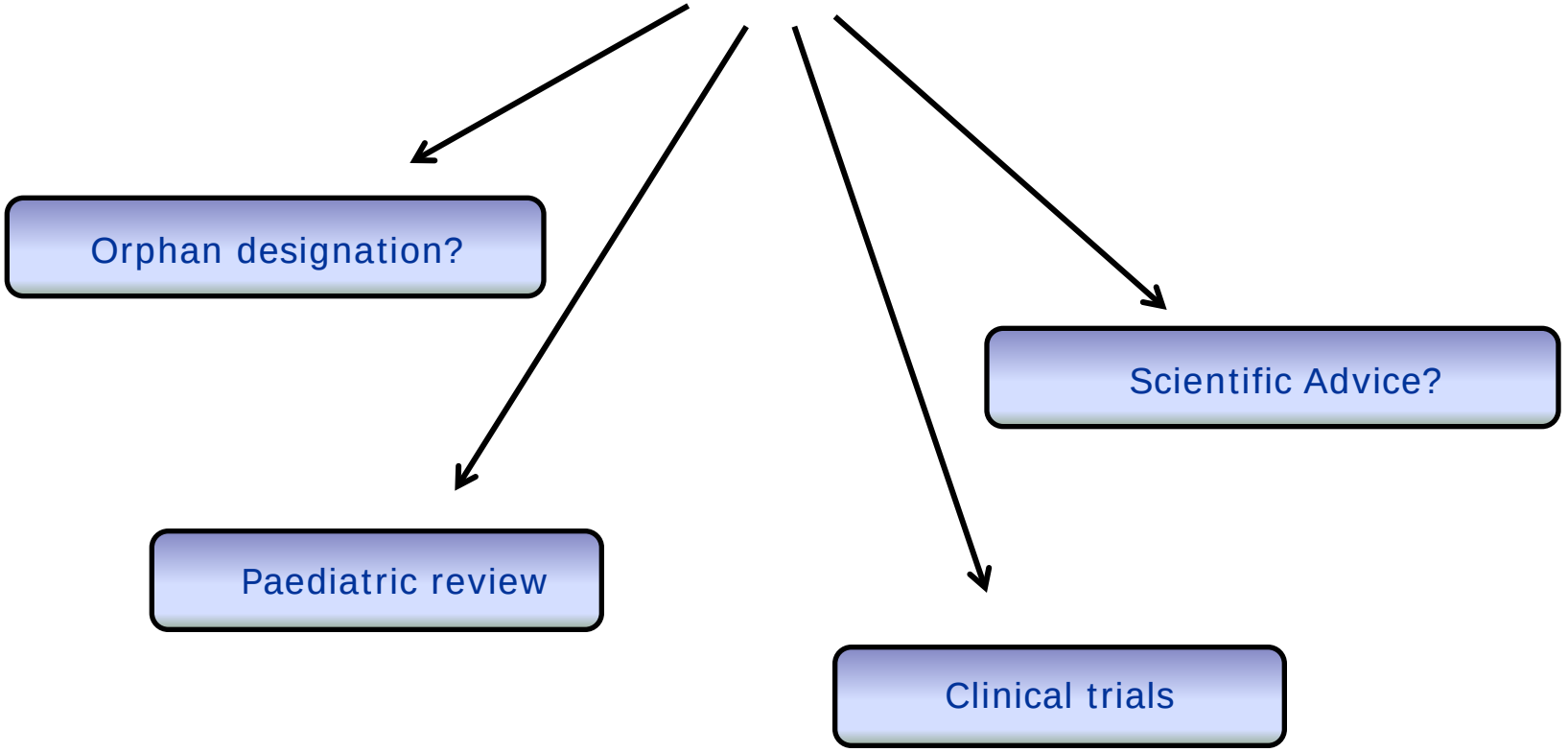
Lifecycle of a new medicinal product

with emphasis on pharmacovigilance

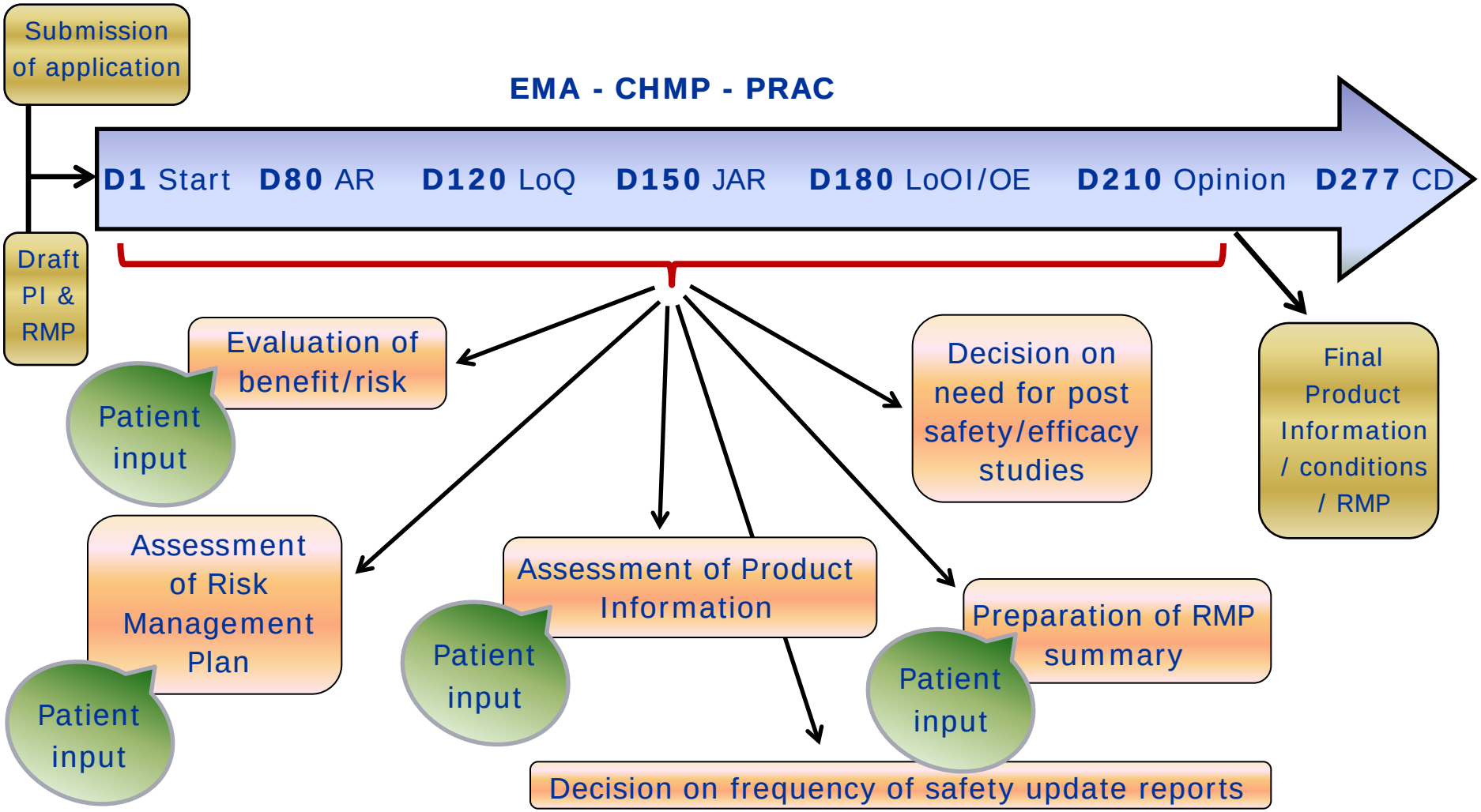
Presented by: Nathalie Bere
Patient interaction / Medical Information Sector

An agency of the European Union

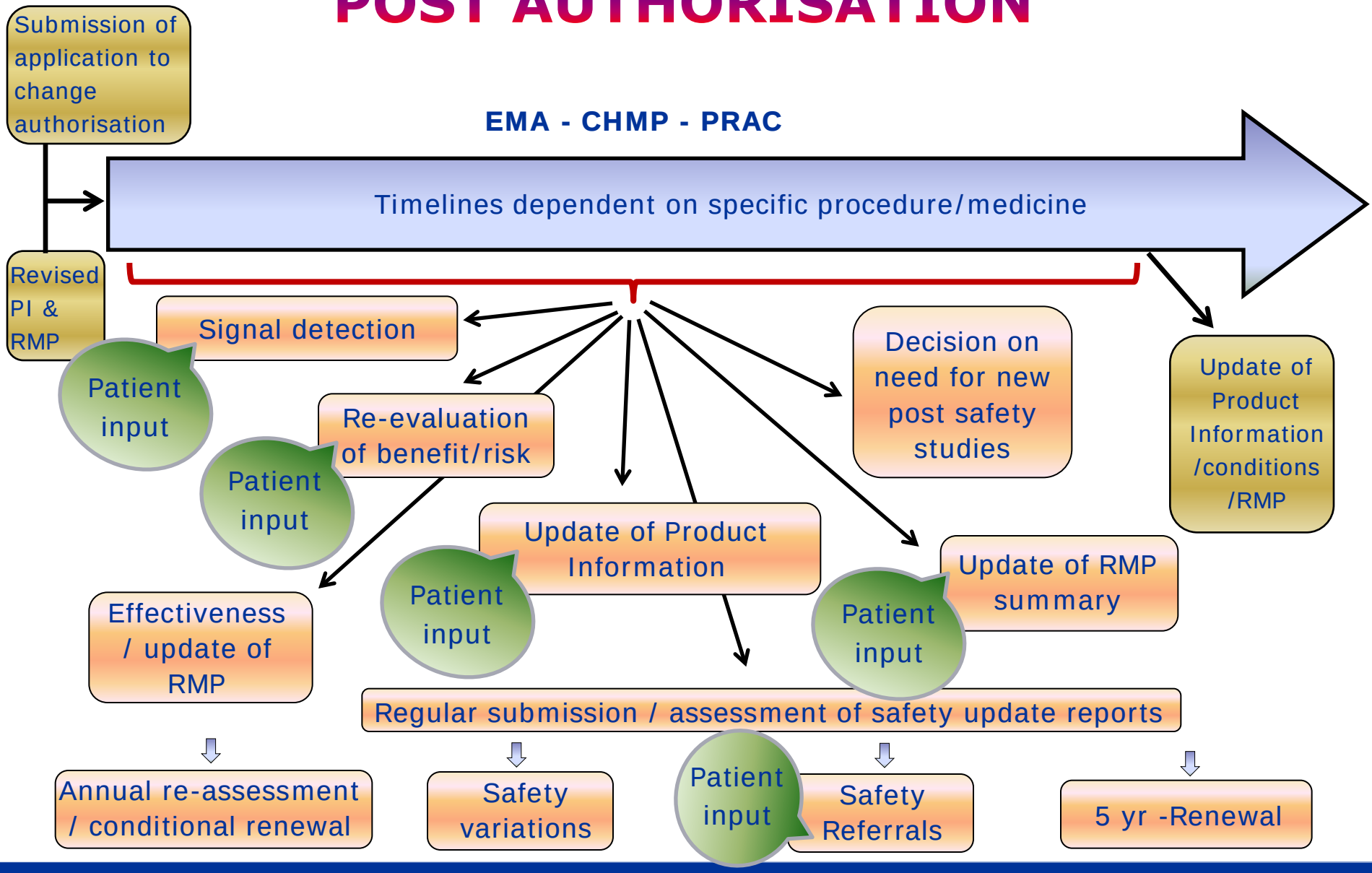
PRE-SUBMISSION



EVALUATION


Submission of application
EMA - CHMP - PRAC
D1 Start
D80 AR
D120 LoQ
D150 JAR
D180 LoOI/OE
D210 Opinion
D277 CD
Draft PI & RMP
Evaluation of benefit/risk
Patient input
Decision on need for post safety/efficacy studies
Final Product Information / conditions / RMP
Assessment of Risk Management Plan
Patient input
Assessment of Product Information
Patient input
Preparation of RMP summary
Patient input
Decision on frequency of safety update reports

POST AUTHORISATION



Acronyms

- CHMP = Committee for Medicinal Products for Human Use
- PRAC = Pharmacovigilance Risk Assessment Committee
- RMP – Risk Management Plan
- PSUR = Periodic Safety Update Report
- PASS = Post Authorisation Safety Study
- PI = product information
- D1, D80, etc = Day 1, Day 80, (procedural timeline)
- AR = Assessment Report
- LoQ = List of Questions
- LoOIs = List of Outstanding Issues
- OE = Oral explanation
- CD = Commission Decision