

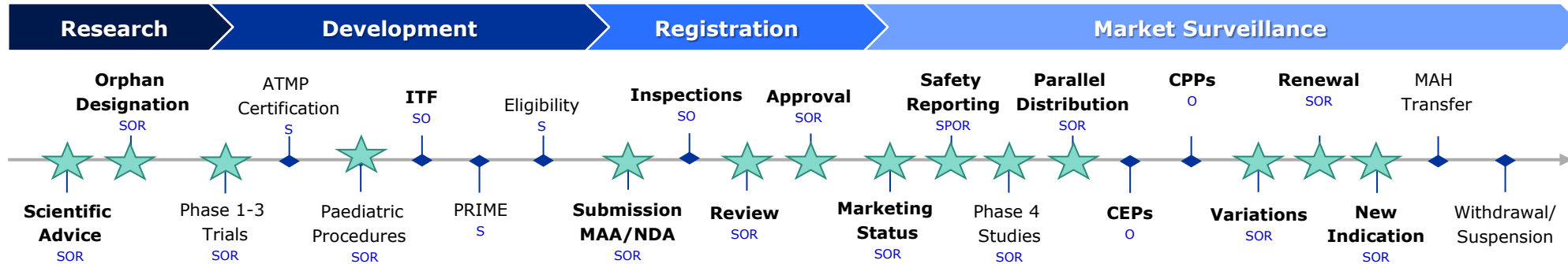
# Organisation Management Service (OMS) in processes & systems



System	Domain	Process
<b>EMA Account Management &amp; EV registration</b>	H&V	User registration, identity and access management
EudraCT & CTIS	H	Phase 1-4 Trials
<b>EudraGMDP</b>	H&V	Inspections + Manufacturing Import Authorisation + Wholesale Distribution Authorisation
<b>EnprEMA</b>	H	Research networks and centres with recognised expertise in performing clinical studies in children
<b>IRIS</b>	H&V – CAPs only	Scientific Advice + Orphan Designation + ITF + Marketing Status + Inspections + Parallel Distribution + Shortage (iSPOC) + PRIME + Paediatric procedure
<b>eAF (PDF) &amp; eAF webform &amp; PLM Portal &amp; PMS (just H)</b>	H&V	Submission MAA, Variations, Renewal
<b>SIAMED</b> via ECD	H&V – CAPs only	Review, Approval
<b>UPD</b>	V	Approval
<b>XEVMPD &amp; EV vet</b>	H&V	Safety reporting

Legend	
	Implemented
	Planned
	Not planned yet

# RMS in processes & systems



System	Domain	Process
<b>EudraCT &amp; CTIS</b>	H	Phase 1-4 Trials
<b>IRIS</b>	H&V	Scientific Advice + Orphan Designation + Inspections + Parallel Distribution
<b>eAF &amp; PMS</b>	H&V	Submission MAA, Variations, Renewal
<b>SIAMED II</b>	H&V	Review, Approval
<b>UPD</b>	V	Approval
<b>CorpGXP/EudraGMDP</b>	H&V	Inspections + Manufacturing Import Authorisation + Wholesale Distribution Authorisation
<b>EVVET3 &amp; ESVAC</b>	V	Safety reporting
<b>PSUR repository &amp; EU PAS &amp; xEVMPD</b>	H	Safety reporting
<b>ASU</b>	V	Antimicrobial sales and use
<b>Real World Data (Healthcare Data)</b>	H	Pharmacovigilance

**Legend**

- Implemented
- Planned
- Not planned yet