

Overview of Interactions between the EMA and FDA ¹

Clusters

- Orphan Medicinal Products Cluster
- Paediatric Medicinal Products Cluster
 - PDCO's Non-Clinical WG and its Formulation WG
 - International Inflammatory Bowel Disease WG
- Vaccine Cluster
- Oncology Medicinal Products Cluster
- Blood Products Cluster
- Biosimilars Cluster
- Advanced Therapy Medicinal Products Cluster
- Pharmacovigilance Cluster
- Pharmacogenomics Cluster
- Veterinary Medicinal Products Cluster

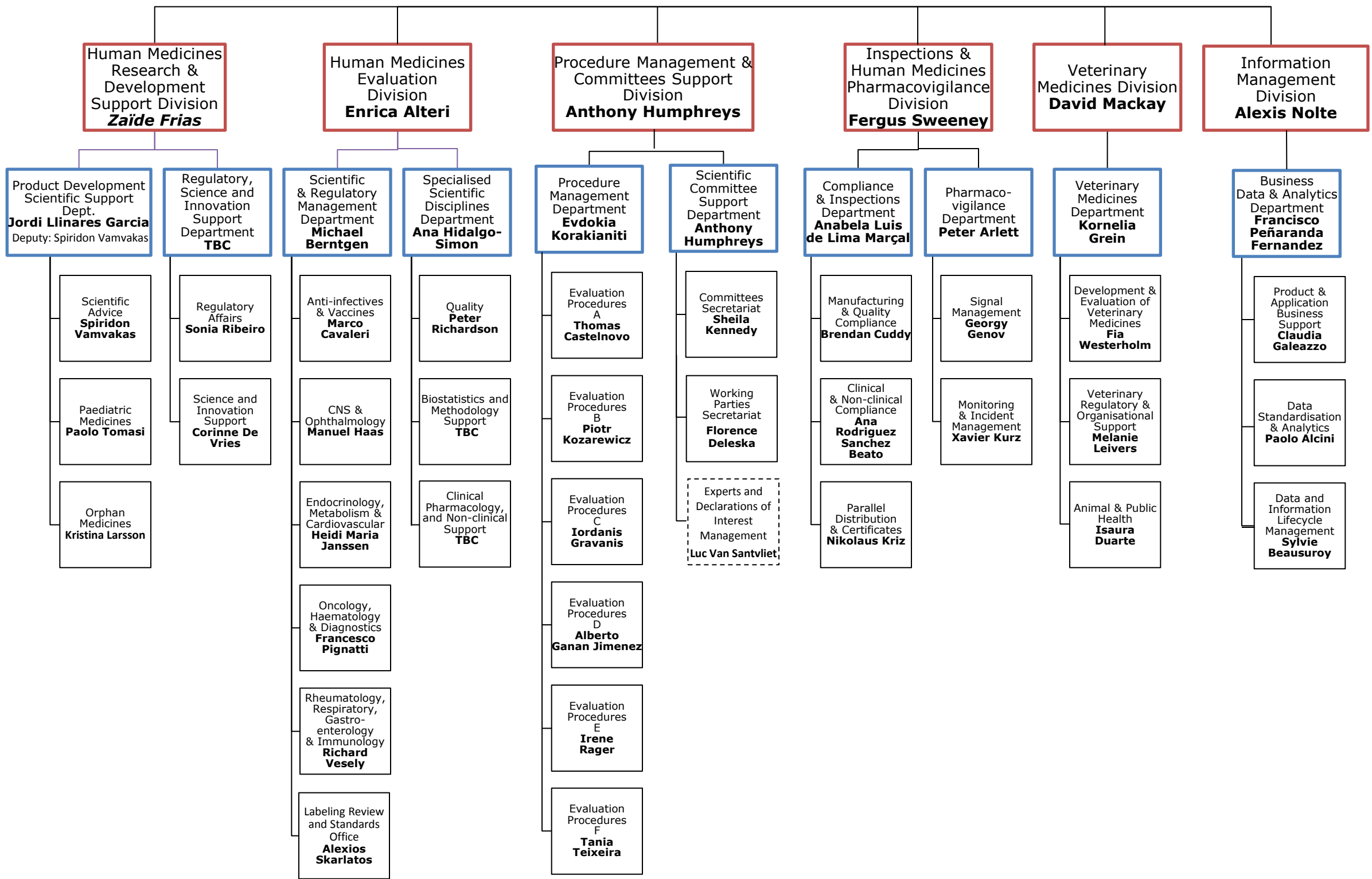
Joint Workshops

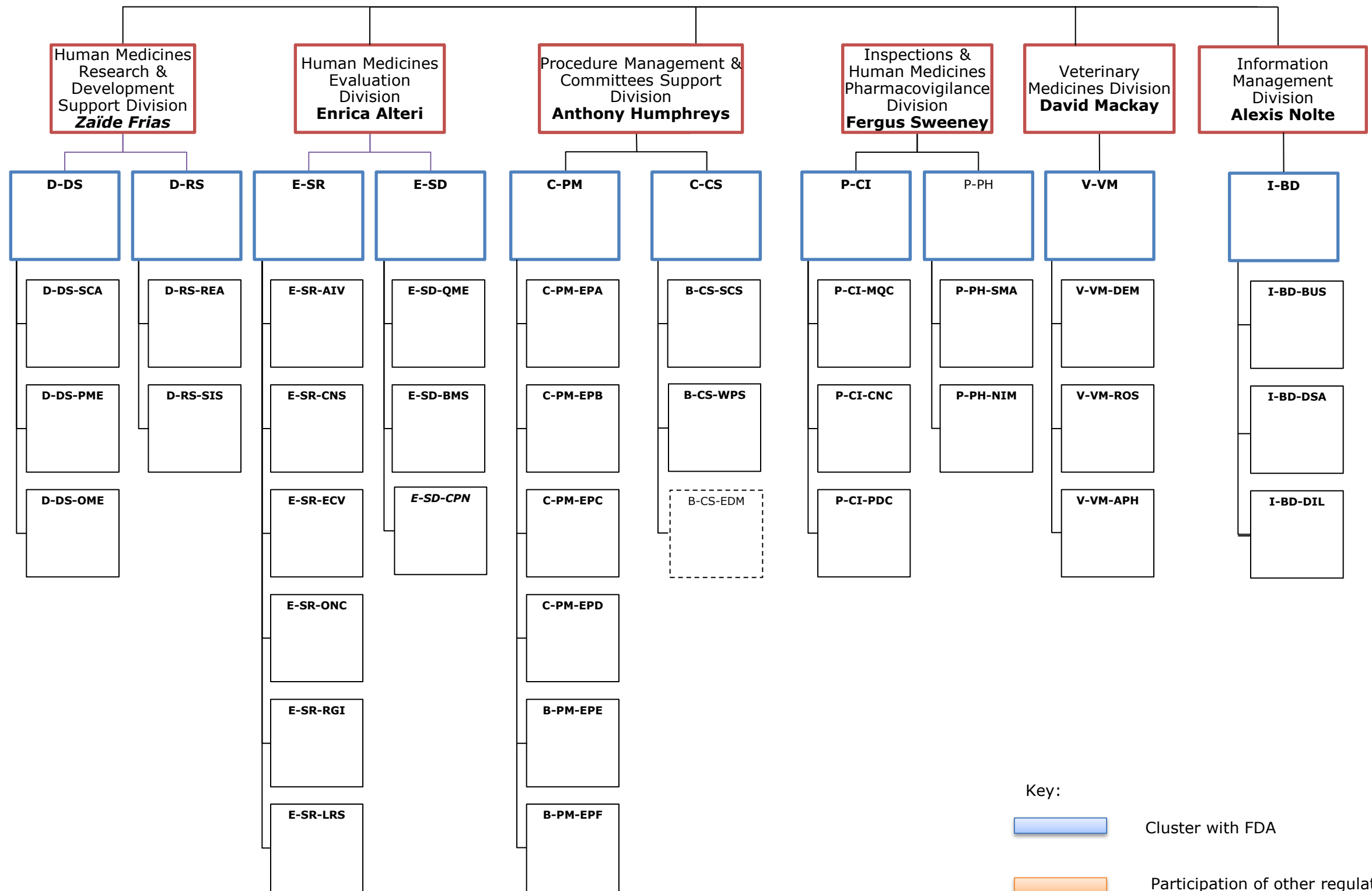
- Orphan Workshops
- CNS Workshops

Other Regular Interactions with FDA:

- Scientific Advice/Parallel Scientific Advice Interactions for medicines of human and veterinary use
- Regular Teleconferences in Cardiovascular, Neurology/Psychiatry and Pulmonary/Allergy/Rheumatology areas
- EU-US Task-force IDMP
- International Standardisation Activities (weekly teleconferences)
- Shortages due to GMP non-compliance and quality defects
- GMP Inspection Report Exchanges
- Joint GMP Inspections
- International API Inspection Programme Telecon
- GCP Inspections Collaboration
- Inspections for Generic Applications (BE)
- Early exchange of Signals (CBER)
- QBD Pilot
- Nanomedicines International Group
- EU-US Mutual Reliance Initiative

¹ Multilateral interactions are included only when the primary interaction was with FDA. Interactions with WHO and ICH are excluded as well as the involvement in ad hoc workshops and product related and communication interactions.





Key:

- Cluster with FDA
- Participation of other regulators in the cluster
- Other regular interactions with FDA
- Other interactions (e.g. IPRF, IMI)

Human Medicines
Research & Development
Support Division
Zaide Frias

D-DS

D-RS

D-DS-SCA
Scientific Advice/Parallel
Scientific Advice
Interactions
Informal discussion on
Scientific Advice

D-DS-PME
Paediatric Medicinal
Products Cluster with
TGA, PMDA and HC
Participation
PDCO's Non-Clinical WG
and its Formulation WG
International
Inflammatory Bowel
Disease WG

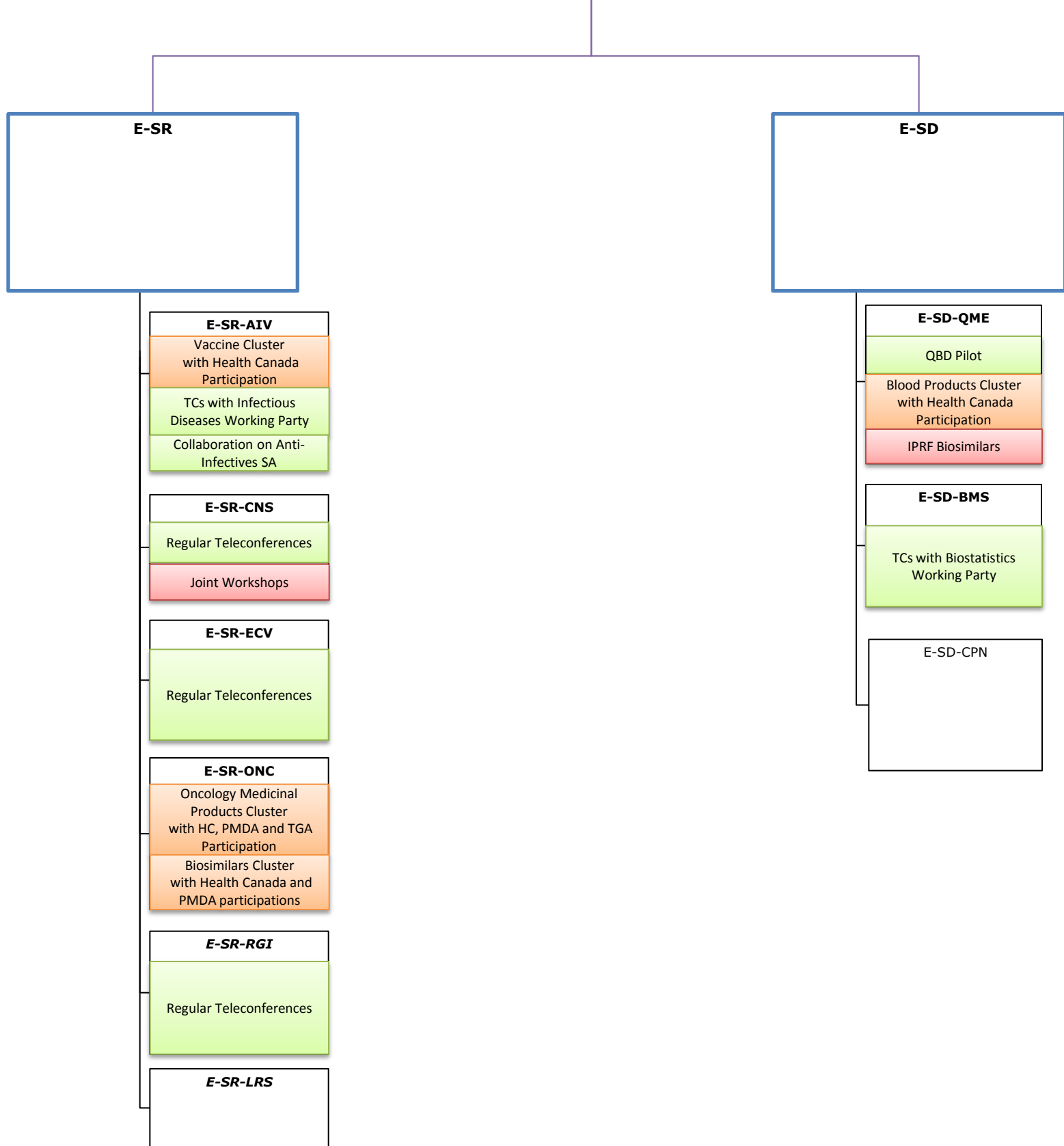
D-DS-OME
Orphan Medicinal
Products Cluster
Orphan Pilot Japan
Joint Workshops

D-RE-REA

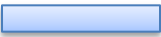
D-RS-SIS
IMI Projects discussions
with PMDA and HC
participation
Nanomedicines
International Group
Pharmacogenomics Cluster

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Human Medicines
Evaluation
Division
Enrica Alteri



Key:



Cluster with FDA



Participation of other regulators in the cluster

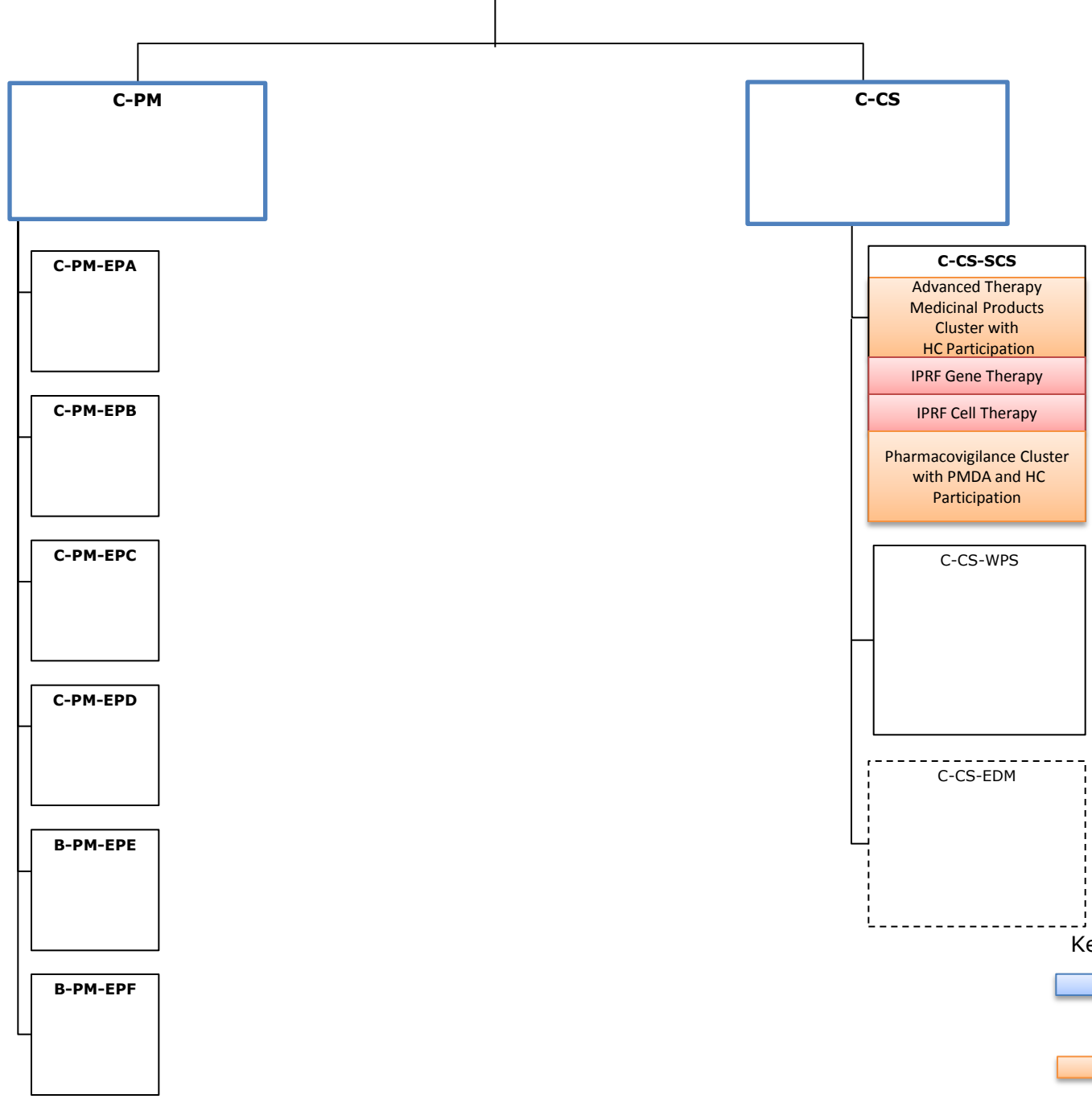


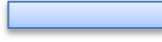



Other regular interactions with FDA



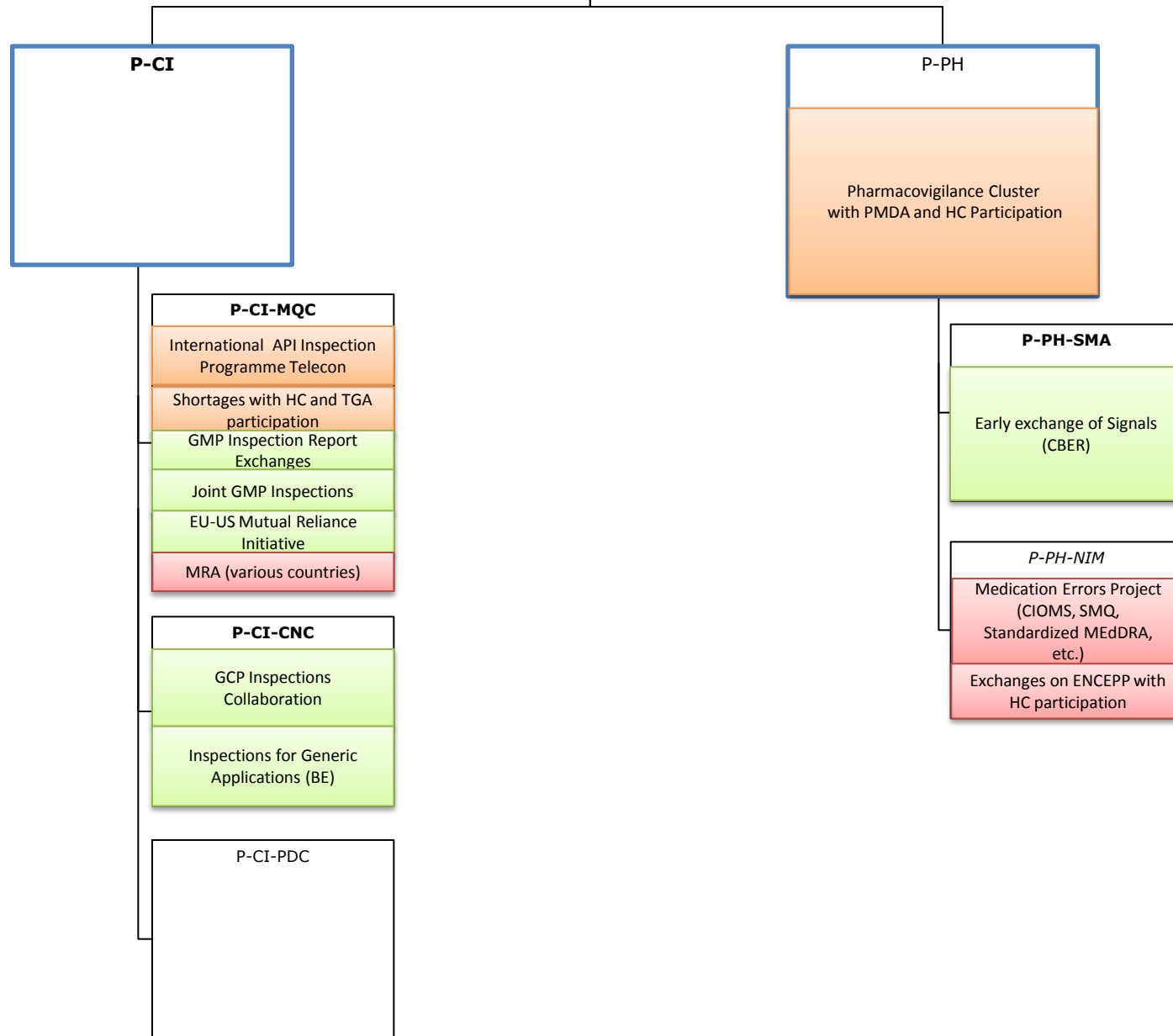
Other interactions (e.g. IPRF, IMI)

Procedure Management &
Committees Support
Division
Anthony Humphreys

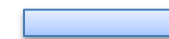


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Inspections & Human Medicines Pharmacovigilance Division
Fergus Sweeney



Key:



Cluster with FDA



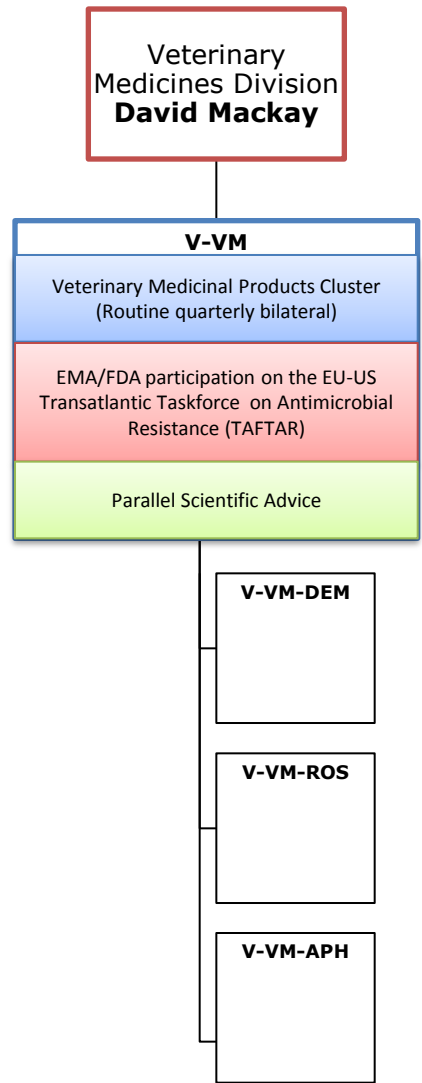
Participation of other regulators in the cluster



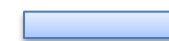
Other regular interactions with FDA



Other interactions (e.g. IPRF, IMI)



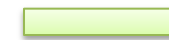
Key:



Cluster with FDA



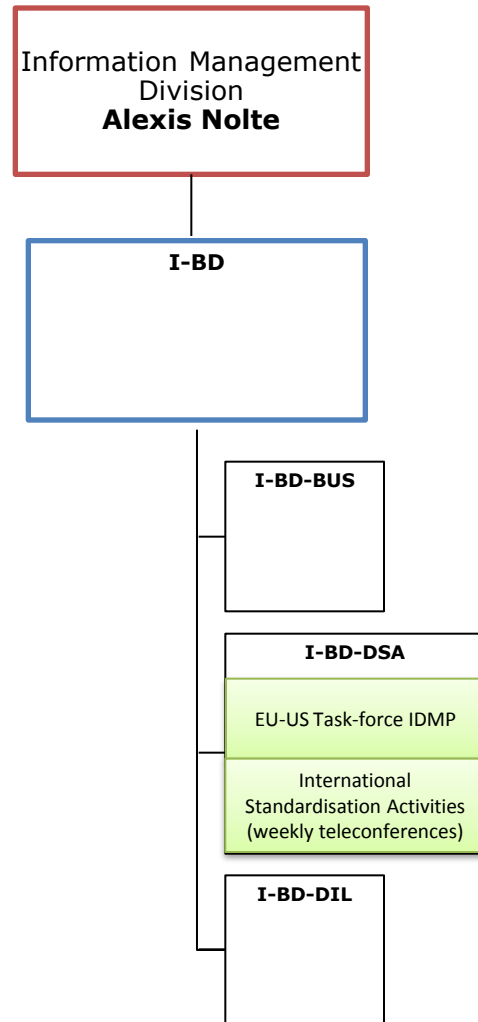
Participation of other regulators
in the cluster



Other regular interactions with FDA



Other interactions (e.g. IPRF, IMI)



Cluster:

Structured working relationship in an agreed public health area, where there is exchange of information through teleconferences in relation to applications for marketing authorisation and extensions of indications, including risk management plans, within a timeframe agreed by both parties (which could range from monthly to quarterly).

(Confidentiality Arrangements Concluded between the EU (EC and EMEA) and the US FDA/DHHS - Implementation Plan for Medicinal Products for Human Use, 2007)

Key:



Cluster with FDA



Participation of other regulators in the cluster



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