

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

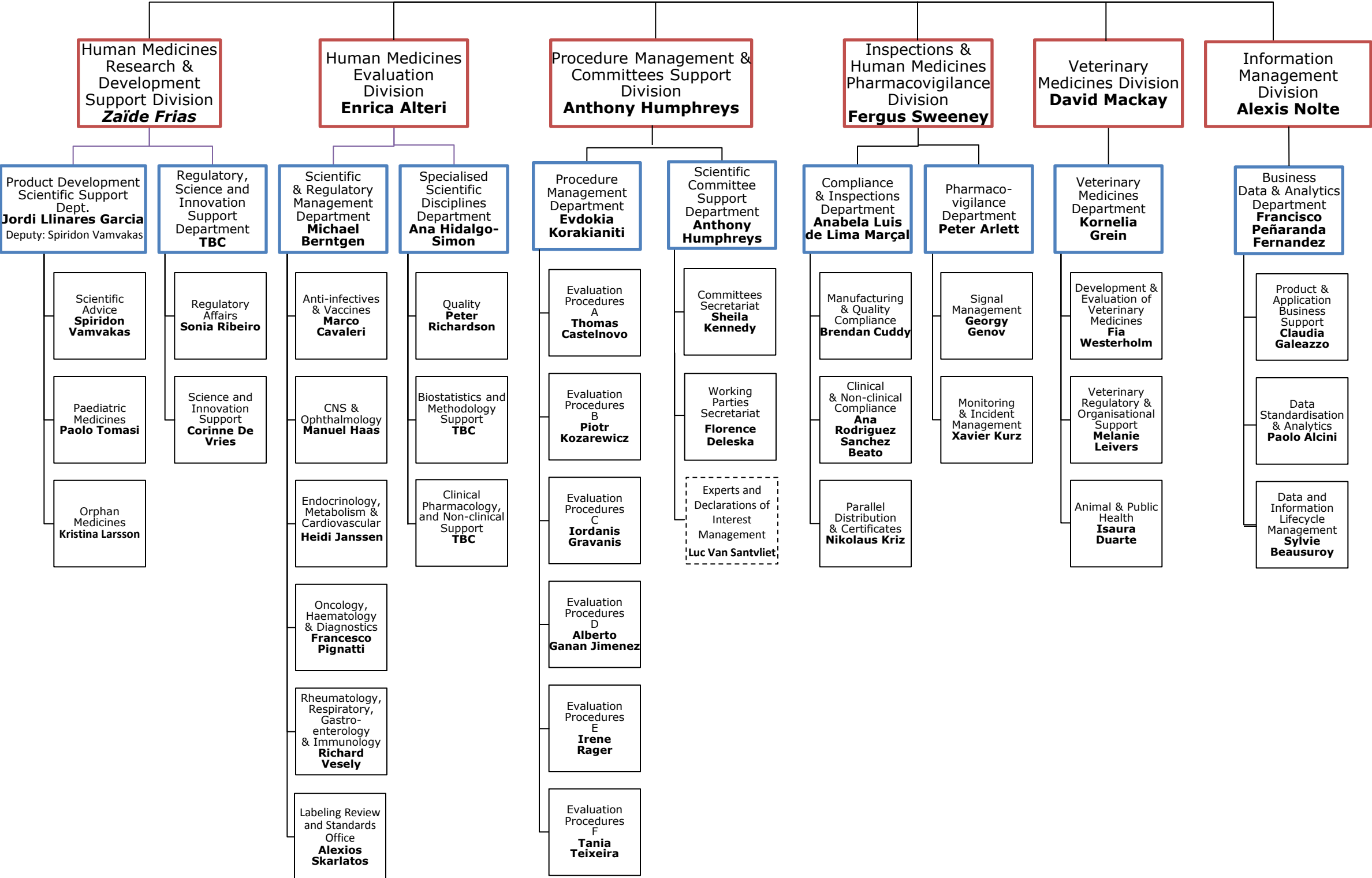
Joint Workshops

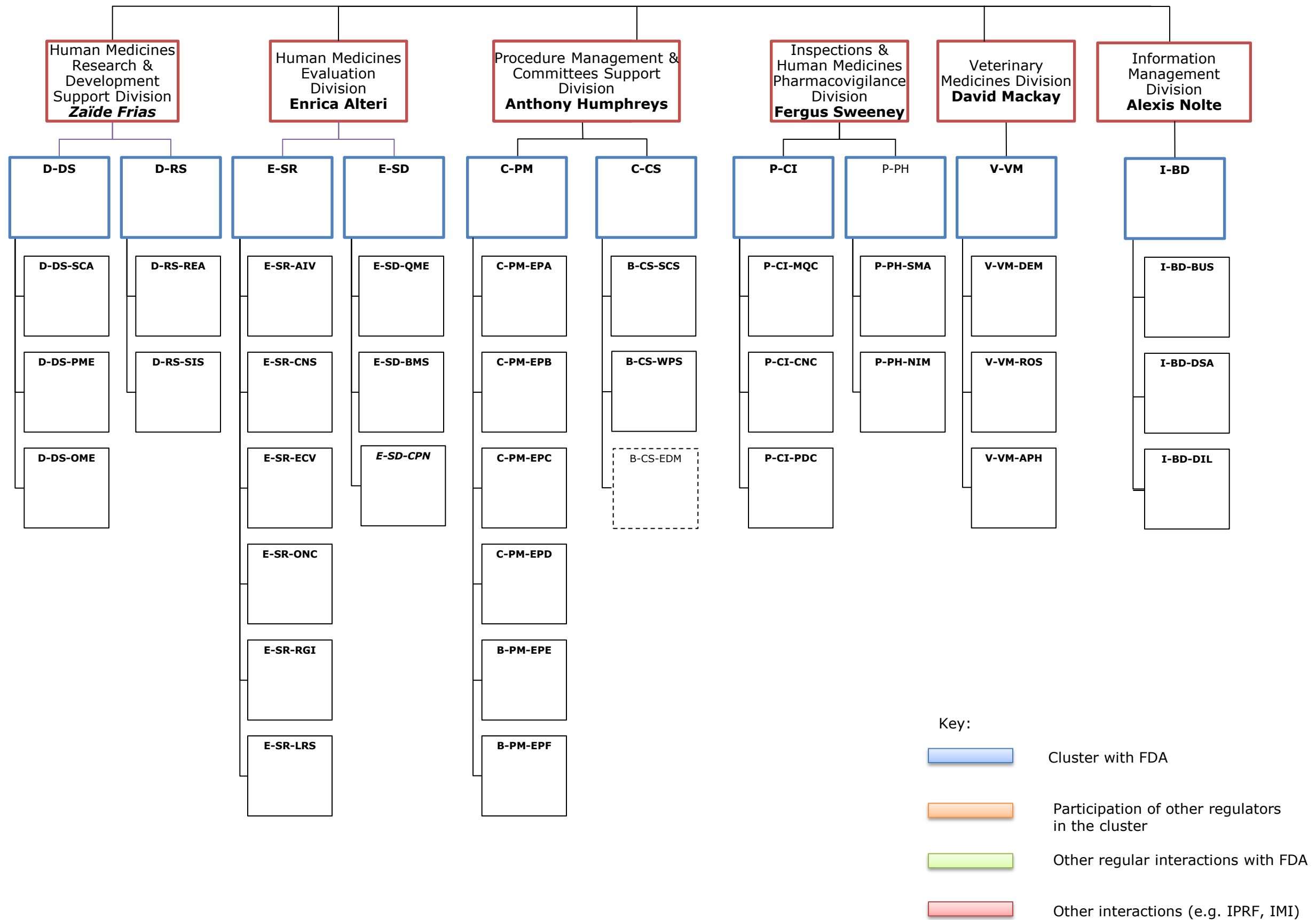
- Orphan Workshops
- CNS Workshops

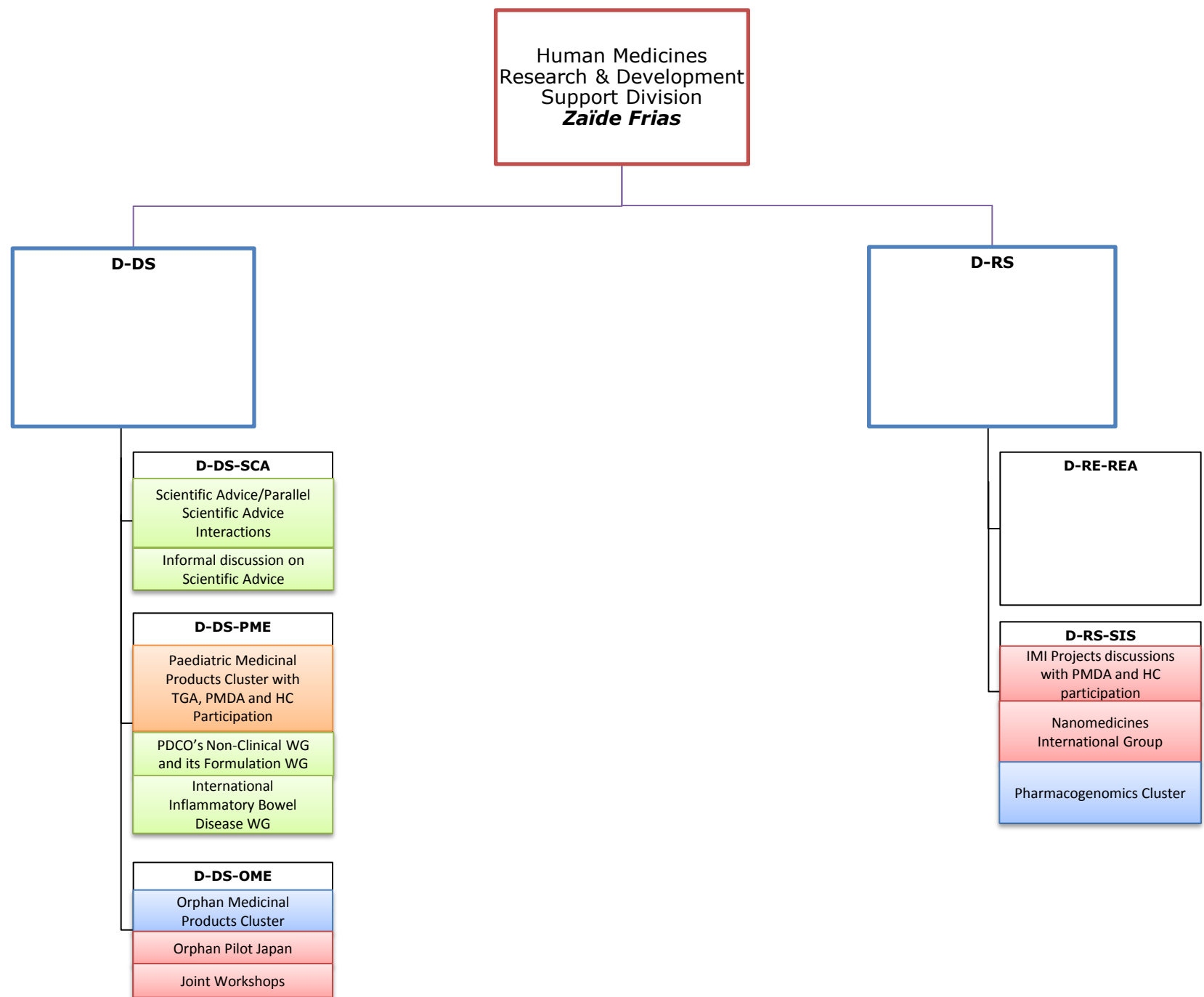
Other Regular Interactions with FDA:

- 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

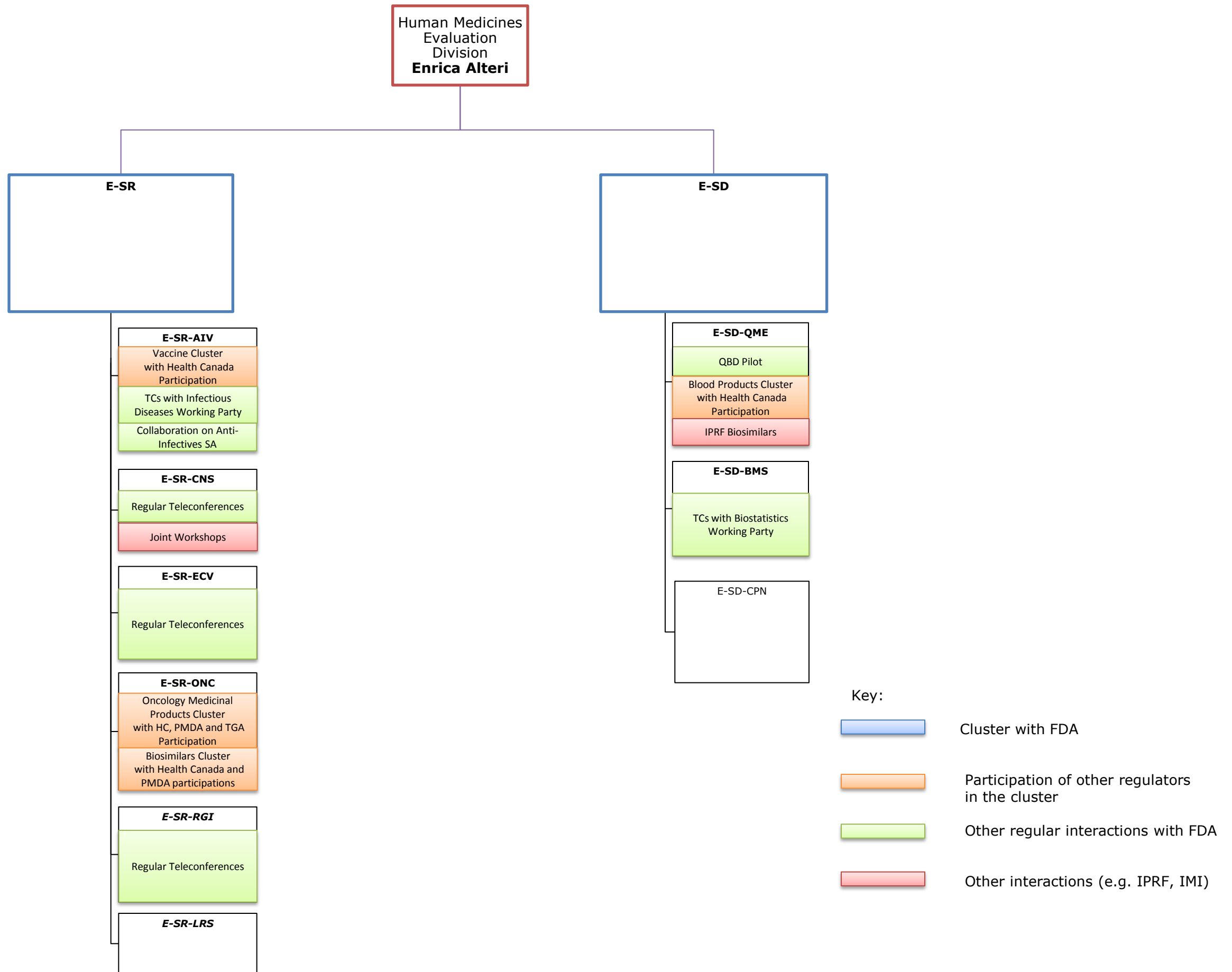
¹ Multilateral interactions are included only when the primary interaction was with FDA. Interactions with WHO and ICH are excluded as well as the involvement in ad hoc workshops and product related and communication interactions.

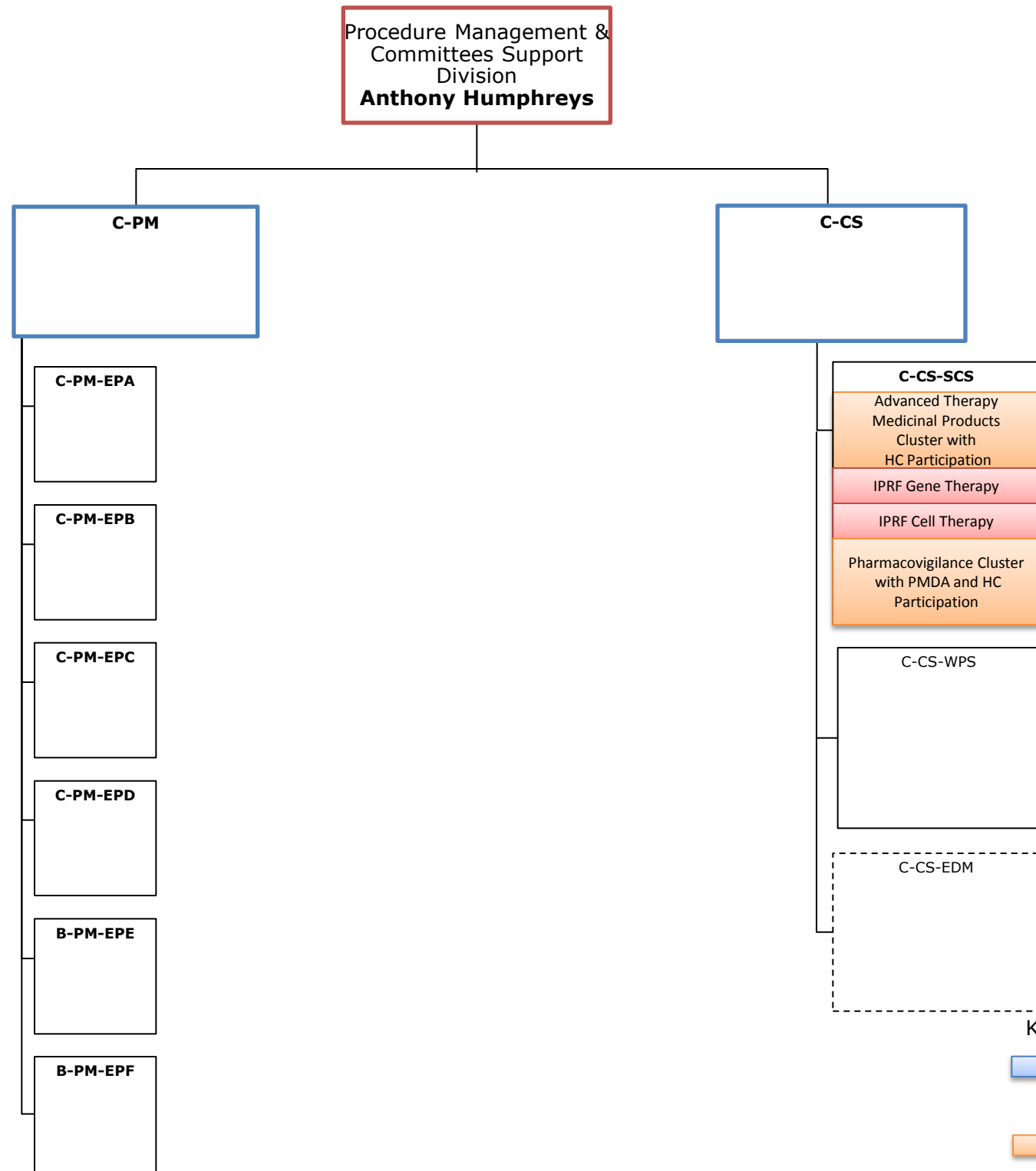




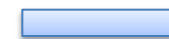


- Key:
- Cluster with FDA
 - Participation of other regulators in the cluster
 - Other regular interactions with FDA
 - Other interactions (e.g. IPRF, IMI)





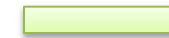
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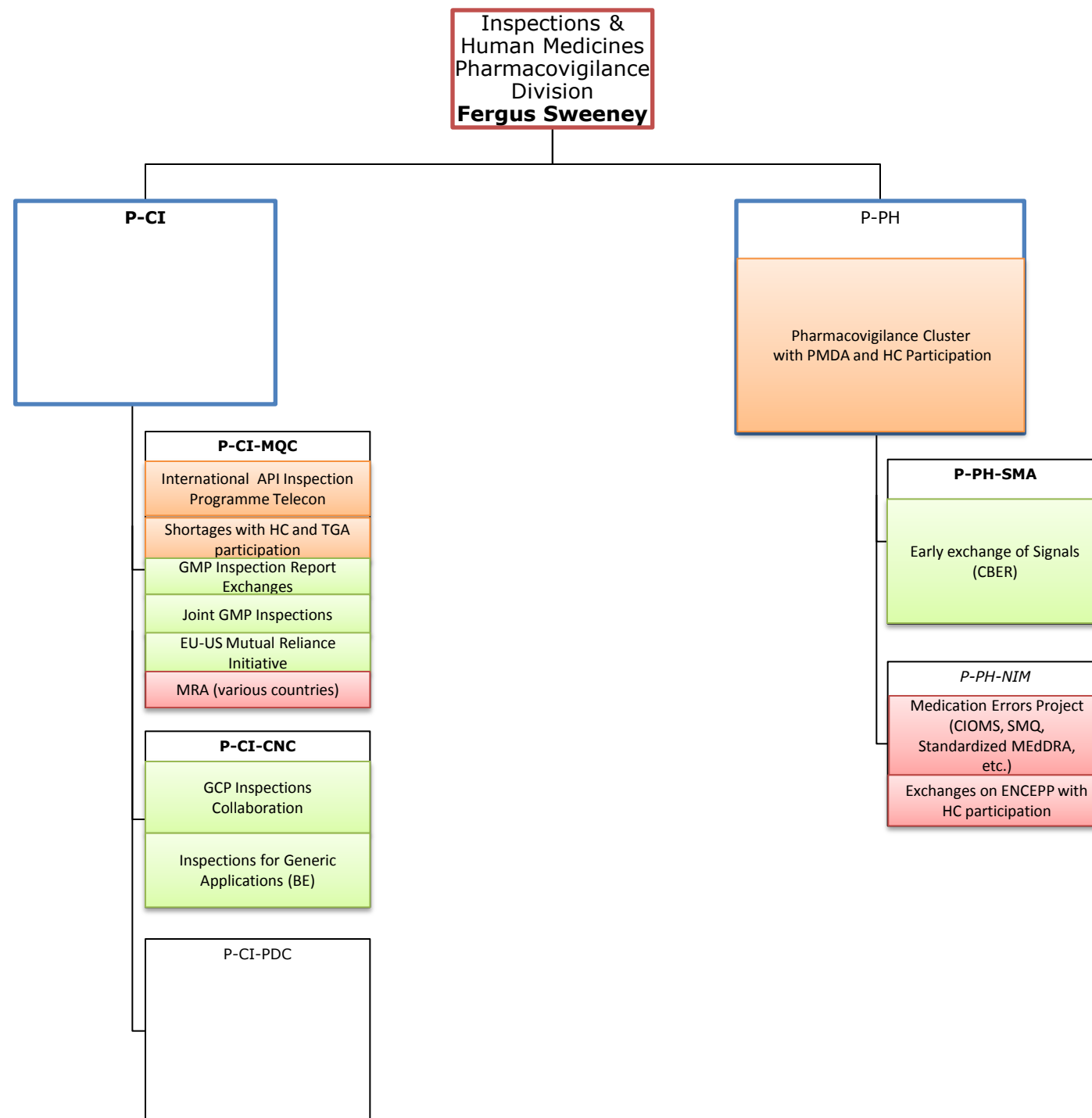
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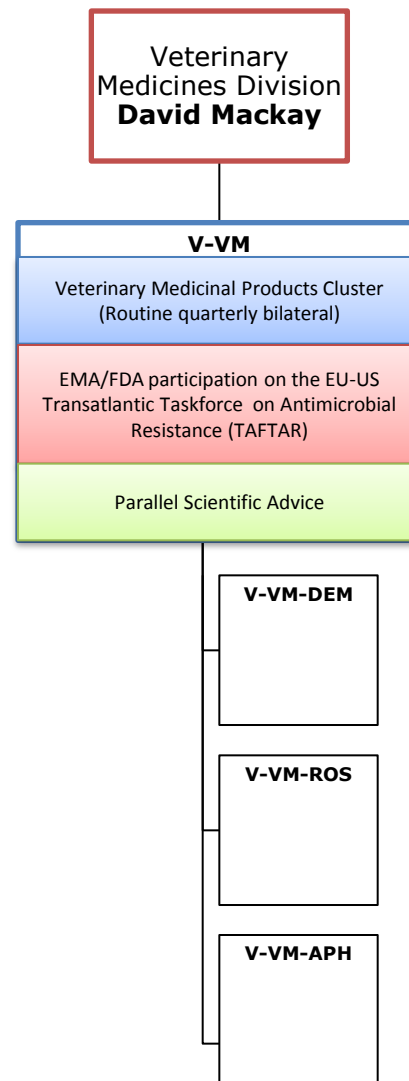
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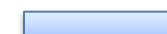
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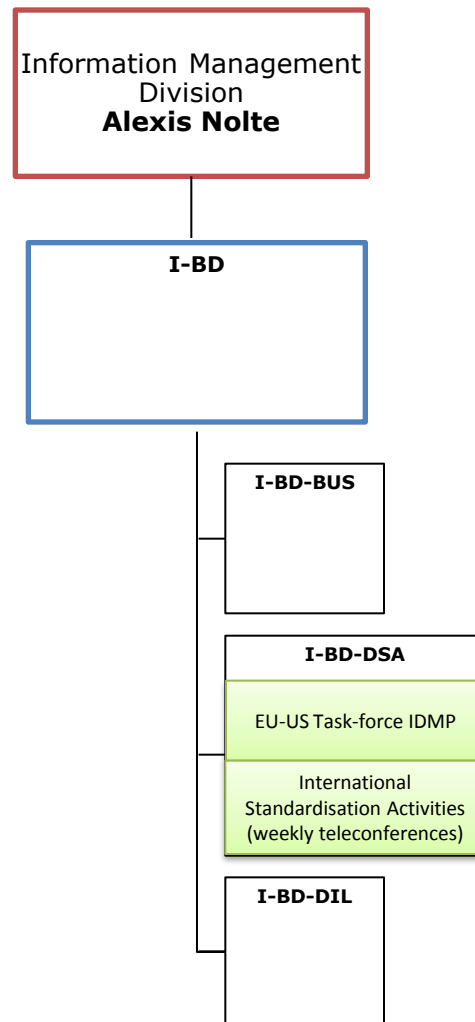
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Cluster:

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)

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