



MDR Eudamed (IT updates)

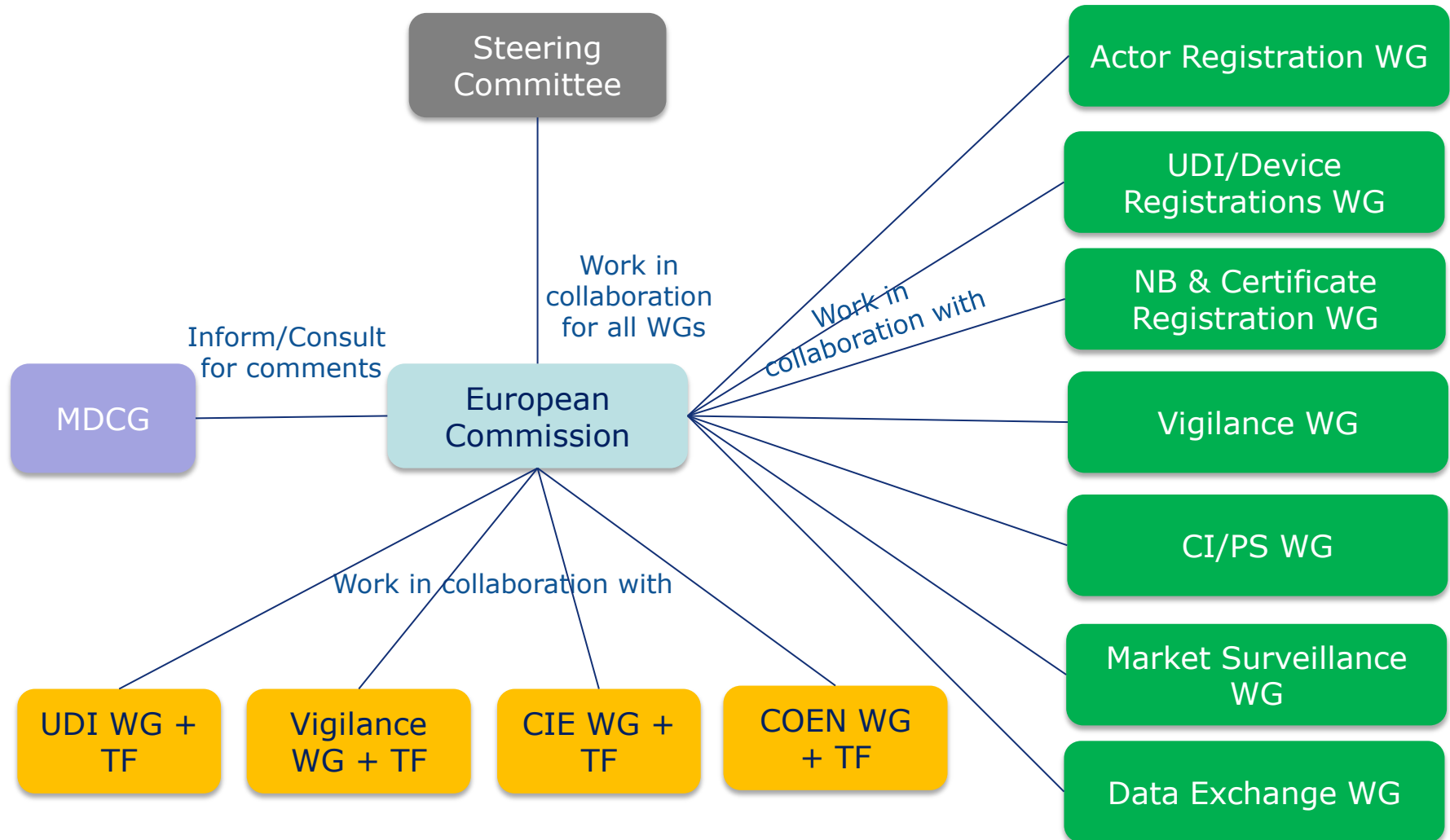
MDCG – 13th December 2019

DG GROW

Working together



Project owner (GROW.D4)
Solution provider (GROW.R3)



Working documents

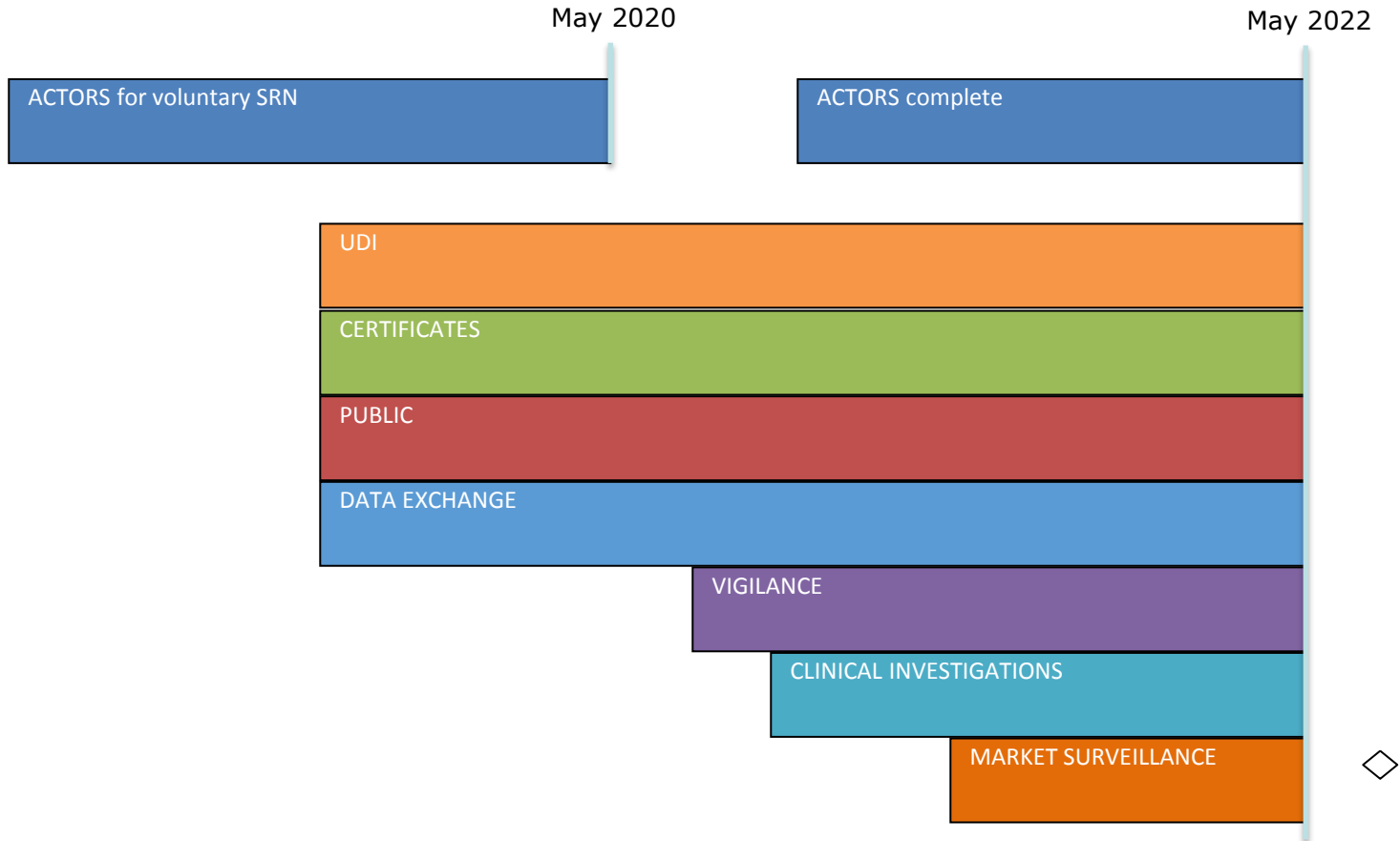
For MDCG and Eudamed WGs' members

- Functional Specifications document with Legal requirements and (Non-Functional specifications)
 - ✓ Version 4.1 published in March 2019
 - ✓ Version 5 to be published including updates for planning following this Implementation plan

Progressively available when ready to be shared in MDR Eudamed WGs CIRCABC space

- Endorsed meeting minutes of all Eudamed WG meetings
- Process overviews and use cases lists (for all modules)
- Data dictionaries (for all modules, not all scope)
- Security matrix/Notifications rules/List of values/Business rules (for all modules, not all scope)
- Demos / Sitemaps/ Mock-ups (for some modules, limited scope)
- Data exchange services definitions, entity models, XML schemas, XML samples, business rules (for some modules, limited scope)

High-level scope & timing



Main milestones

Actors: Release May 2020

- Registration of Economic Operators (MF, AR, IM, PR) (**development done**)
- Update Actor account for Economic Operators (**development done**)
- User Access management for all Actors (**on-going**)
- Email notifications (for Action) (**development done**)
- Bulk XML upload / download for Actor registration (**on-going**)
- M2M Download of Actor data (**development done**)
- Search and view Actors (**development done**)
- Mandates management (**development done**)
- Request for M2M form (**development done**)
- Update Actor accounts for Competent Authorities (**on-going**)
- Deactivate and Reactivate actors (**on-going**)

Actors: Release May 2022

- Update list of subsidiaries by Notified Bodies
- Sponsor Registration and Management
- Confirm periodically Economic operator data accuracy
- Actor Relationships

Main milestones

Actors Public site: Release May 2020

- Search and view Economic Operators, Competent Authorities, and Notified Bodies (**on-going**)

Actors Data Exchange: Release May 2020

- XML Bulk upload / download for Actor registration (**on-going**)
- M2M Download of Actor data (**development done**)

Acceptance testing

- Several playground phases will be open between now and May 2022 to validate the functionality with external stakeholders.
- The final Acceptance testing phase will be open on the 1st half of Q2 of 2022 (indicative planning).
- During the testing phases, all feedback should be sent by email to COM (email address will be provided)

State of play

UDI: Release May 2022

- Registration of a Device (Basic UDI and UDI-DI) (**development done**)
- Registration of a UDI-DI for an existing Basic UDI (**development done**)
- Registration of SPP (**development done**)
- Update Device (Basic UDI and UDI-DI and associated elements) (**development done**)
- Search and view Devices (**development done**)
- Registration of Legacy Devices (**on-going**)
- Search and view of Legacy Devices and SPP (**on-going**)
- Update of SPP (**on-going**)
- Email notifications (for Action) (**development done**)
- M2M upload / download of device information (**on-going**)
- Upload of SSCP (**not started**)
- Link a Legacy Device to a Regulation Device (**not started**)
- Search and View Device Nomenclature (**development done**)
- Authorised Representatives can comment on Devices (**not started**)

State of play

CRF: Release May 2022

- Registration of a Certificate (**on-going**)
- Search and view Certificates (**not started**)
- Update Certificates (**not started**)
- Import Notified Body data from NANDO (**development done**)
- Delete Certificates (**not started**)
- Registration of a CECP and its outcome (**not started**)
- Management of Summary report (**not started**)
- Management of Nominated Expert (**not started**)
- Management of request for withdrawal/suspension of certificate(s) (**not started**)

State of play

PUB: Release May 2022

- Search and view Devices (**on-going**)
- Search and view Certificates (**not started**)
- Search and view Vigilance information (**not started**)

DTX: Release May 2022

- M2M upload / download of device information (**on-going**)
- M2M upload / download of certificates (**not started**)
- M2M upload / download of vigilance data (**not started**)

Q & A

Thank you for your attention