

Management Board

17 June 2020

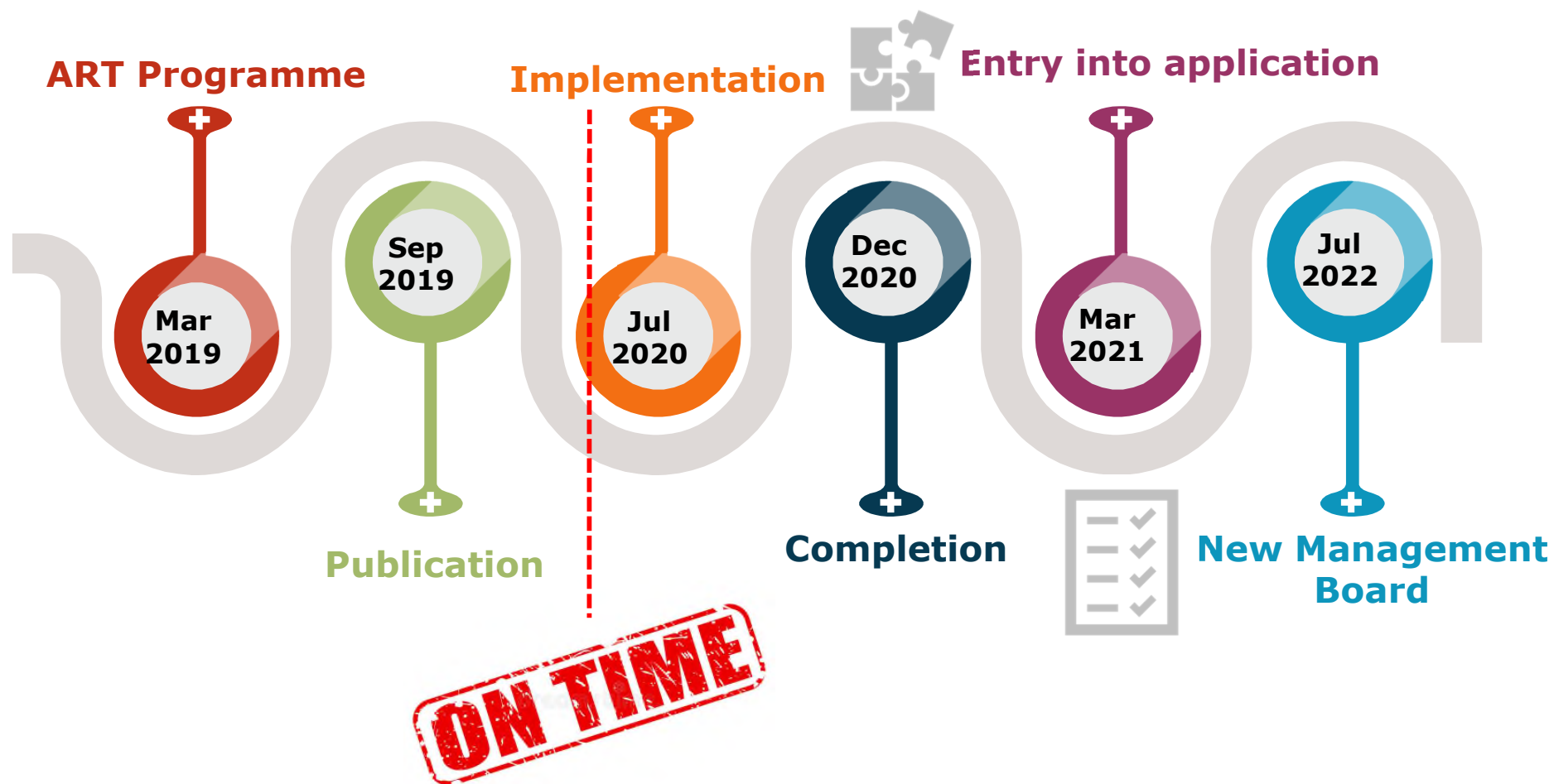
Update on the Implementation of Transparency Regulation

Claudia Paoletti

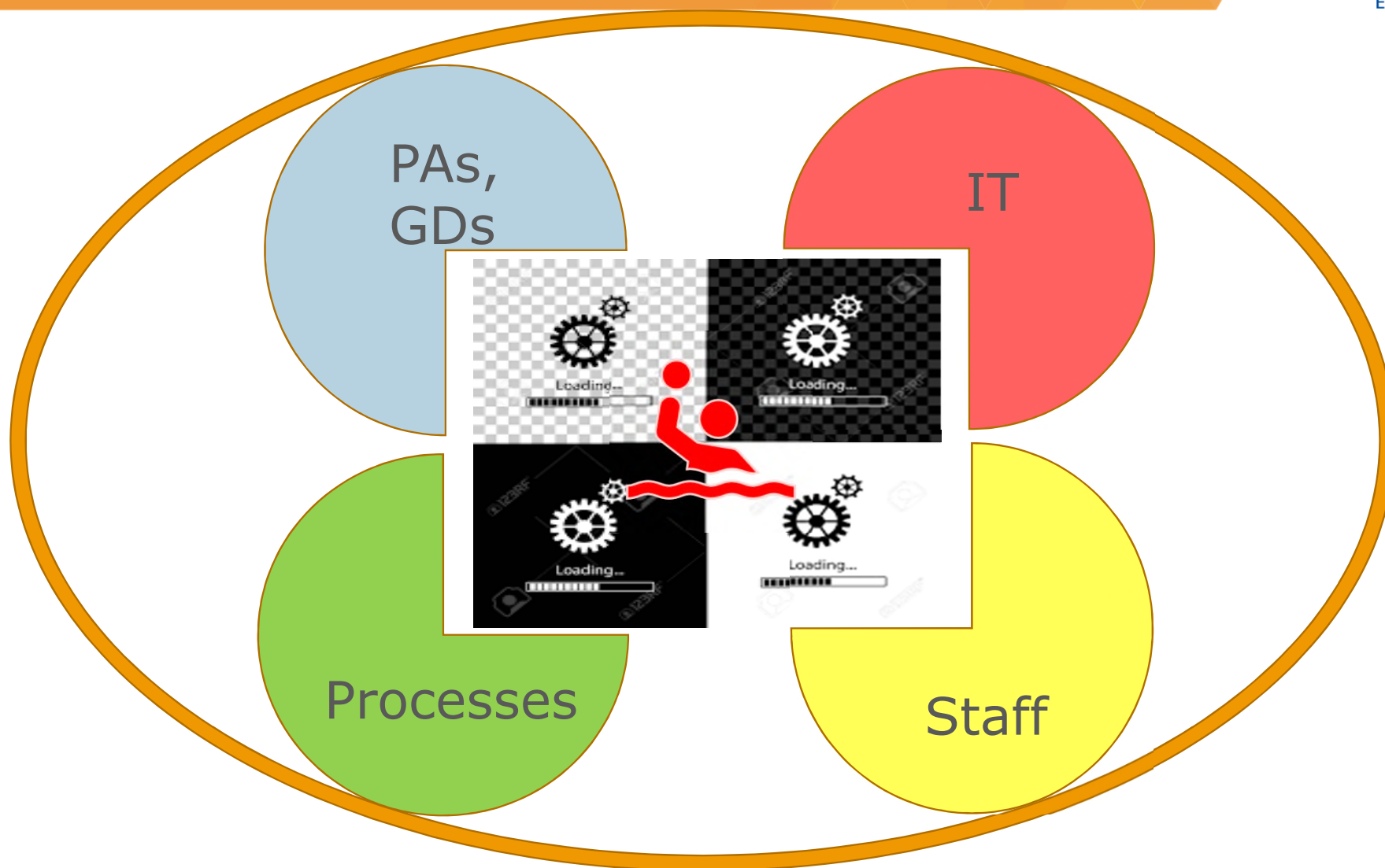
Programme Manager

Trusted science for safe food

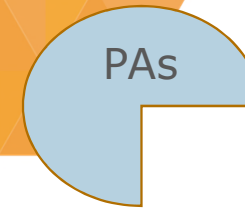
Progressing according to plan



Elements of ongoing work



Practical Arrangements



1. Transparency and Confidentiality Assessment

Under consultation with SANTE

2. PPPs (Confidentiality Assessment by MS)

➤ Under consultation with SANTE
➤ Consultation with MS in July

3. Pre-submission advice, NoS, Public Consultation

Under consultation with SANTE

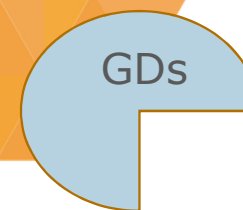
Introduction, update to:

- ✓ Sounding Board (March, July, September)
- ✓ Advisory Group (June, September)

✓ Presentation to Stakeholders (November)

✓ Adoption and publication in December

Guidance Documents



➤ To be updated:

10 administrative GDs

+

16 scientific GDs

- All changes to GDs aligned with DG SANTE
- Work on GDs updating is ongoing, aligned with drafted Practical Arrangements
- To be shared with DG SANTE for comments

Finalization/Adoption:
Fall 2020

Processes (by end 2020)

Processes

New due to TR:

- Confidentiality assessment;
- Proactive dissemination;
- Verification studies;
- Pre-mandate activities:
 - Pre-submission advice
 - Advice for renewal
 - NoS database

Changed due to TR:

- Dossier validation (+ NoS, GLP)
- Public consultation

Leaned / harmonised:

- Risk assessment
- Scientific service support
- Scientific administrative support
- Shared Service Office (SSO)

Sourcing:

Partnership model/Sourcing framework: work in progress

Technology building blocks and structure

SALESFORCE 1,6 M Eur:

- ✓ Notification of studies
 - ✓ Pre-submission advice
 - ✓ Public access to documents
 - ✓ Public Consultation
- 49% Complete**

FSCAP – 0,8 M Eur:

- ✓ Dossier eSubmission (except pesticides)
- 33% Complete**

IUCLID - 1,3 M Eur:

- ✓ Pesticides PPP & MRL eSubmission
- 40% Complete**

APPIAN 1,3 M Eur:

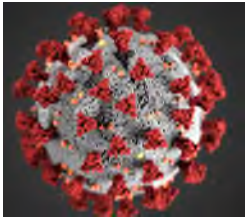
- ✓ Risk assessment workflow
 - ✓ Confidentiality assessment
- 23% Complete**

MICROSOFT AZURE 1,6 M Eur:

- ✓ Secure storage and controlled access
 - ✓ Dissemination
 - ✓ Proactive disclosure
- 18% Complete**

Percentages of completion refer to the percentage of user requirements that have been built. Completion of the build phase in September will be followed by user acceptance testing in Q3.

Interim solution for staff allocation



Organisational Design Project
postponed to the end 2021



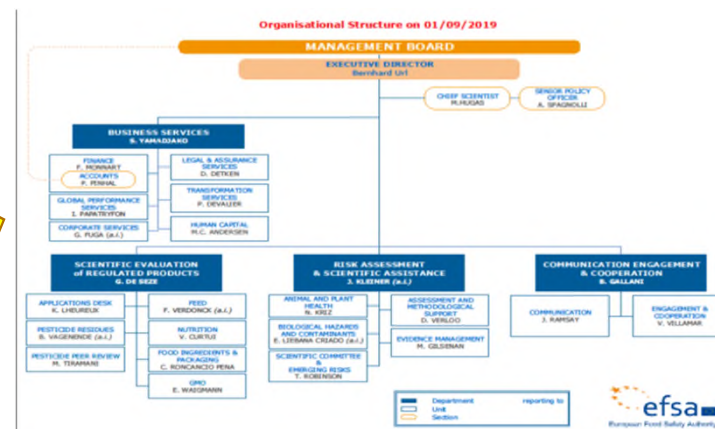
End to End science to-be processes (including mandatory TR activities)



EFSA Current organisational structure



Interim
solution



Challenges

Complexity of changes:

- ✓ new processes
- ✓ new tools

- ✓ Tight schedule
- ✓ COVID-19 emergency

Alignment with MSs

Solutions



- ✓ Close monitoring of progresses and issues
- ✓ Training on new processes and tools

- ✓ Extensive consultancy
- ✓ Re-prioritisation

Structured cooperation



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