IRISS IDMP Topic Group

Frits Stulp, Topic Group Leader

www.iriss-forum.org

IRISS

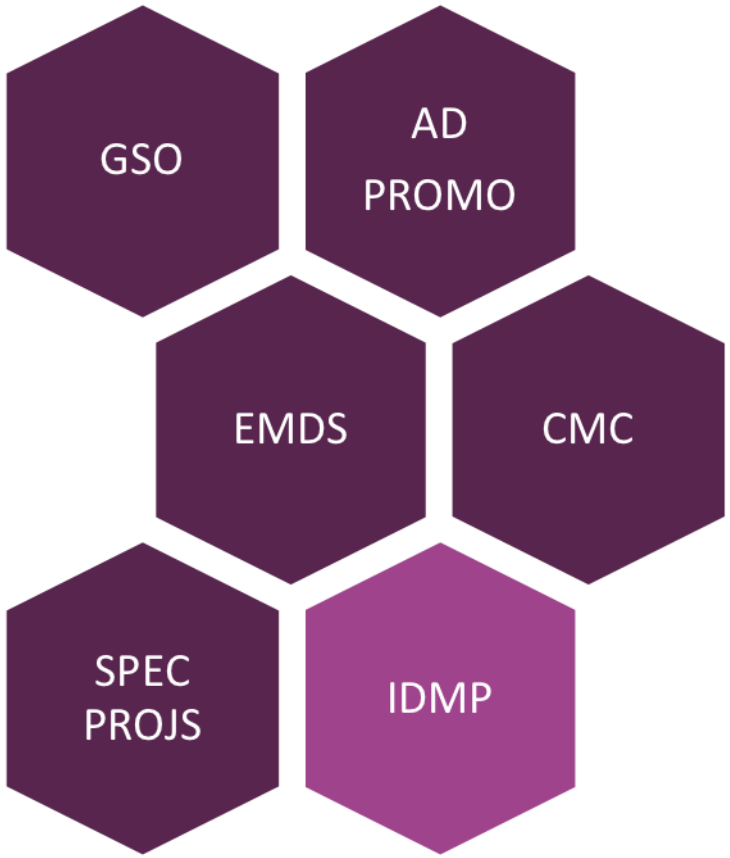
IRISS (Implementation of Regulatory Information Submission Standards) Forum was created to address the need for a single central forum for open, and broad stakeholder discussion of evolving standards, user requirements and practical, global implementation issues of these standards for the mutual benefit of both industry, government agencies and ultimately, public health.

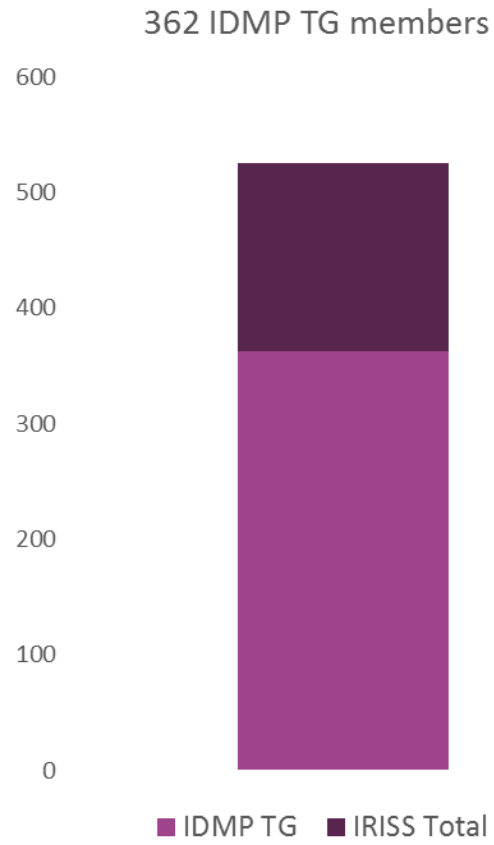
Mission, vision, values

The mission of IRISS is to enable successful implementation and practical usage of paperless regulatory submissions environment which supports current regulatory processes and enables efficient and effective assembly, review, and maintenance of required regulatory information in support of clinical trial applications and marketing applications around the globe.

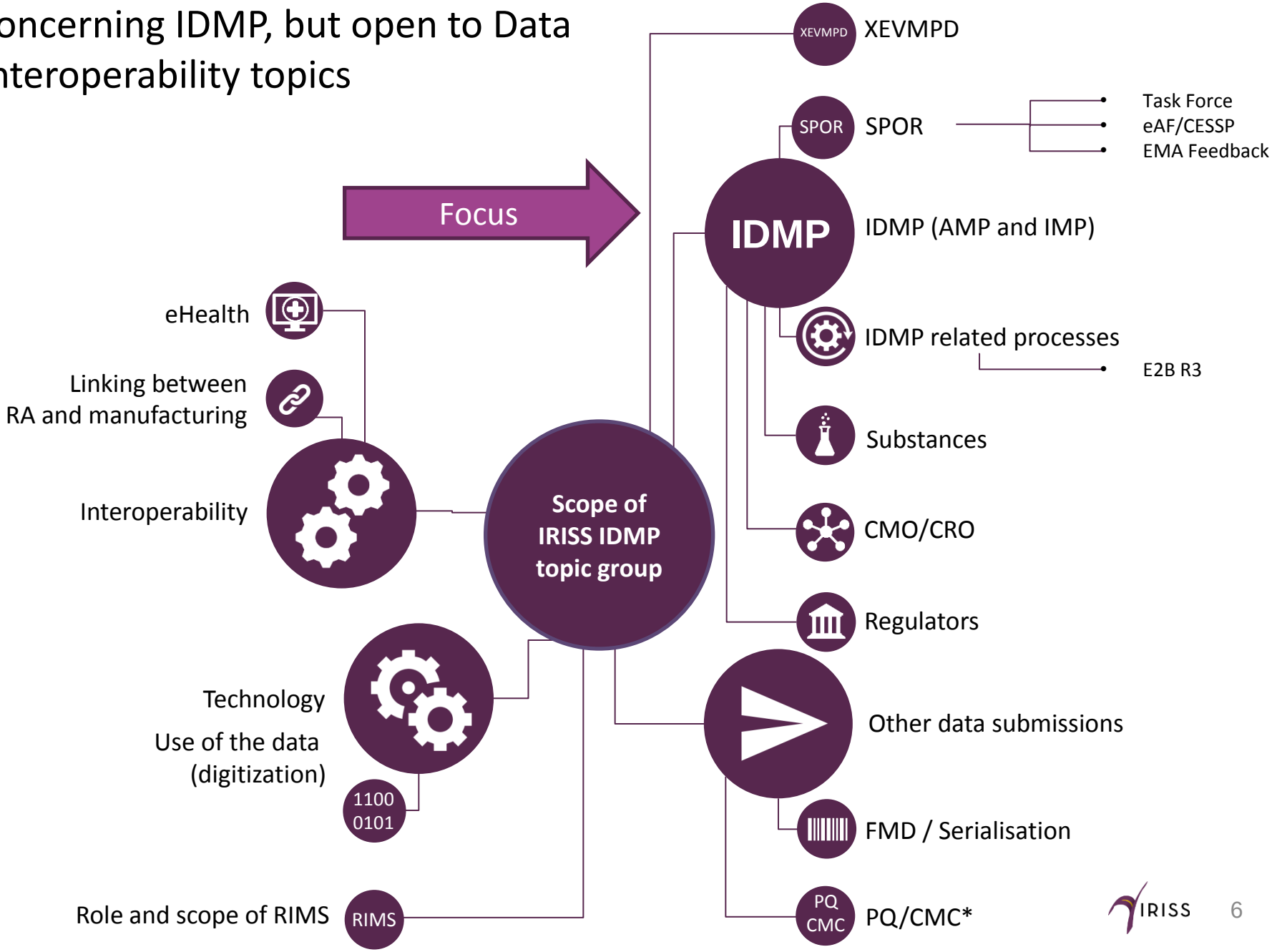
IRISS has been growing at a steady pace since the start in 2012

The IRISS forum consists out of different discussion groups

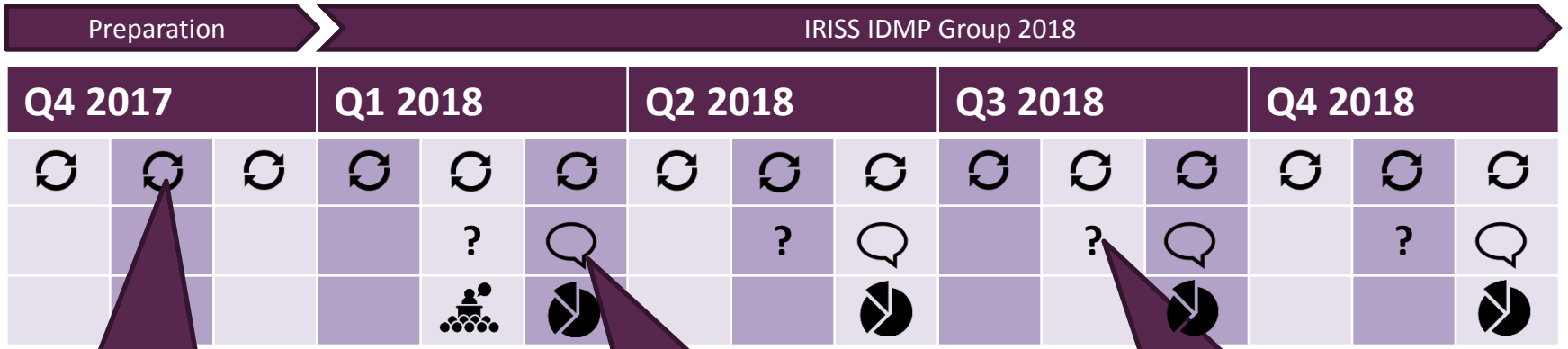




Focus on requlatory developments concerning IDMP, but open to Data Interoperability topics



IRISS IDMP Topic group overview 2018



Monthly industry and regulator updates

- SPOR Taskforce
- ISO
- NCA
- Regional competent authorities
- SPOR Change Liaison
- Others

Quarterly deep-dive in (extra) topic

- IRISS members are encouraged to give input in
- Optional survey of topic of interest

Optional quarterly topic

- Optional extra topic during calls
- E.g.:
  - Vendor presentations
  - Changes in industry
  - Data interoperability
  - Etc.

Monthly IRISS update call

Quarterly extra topic during calls

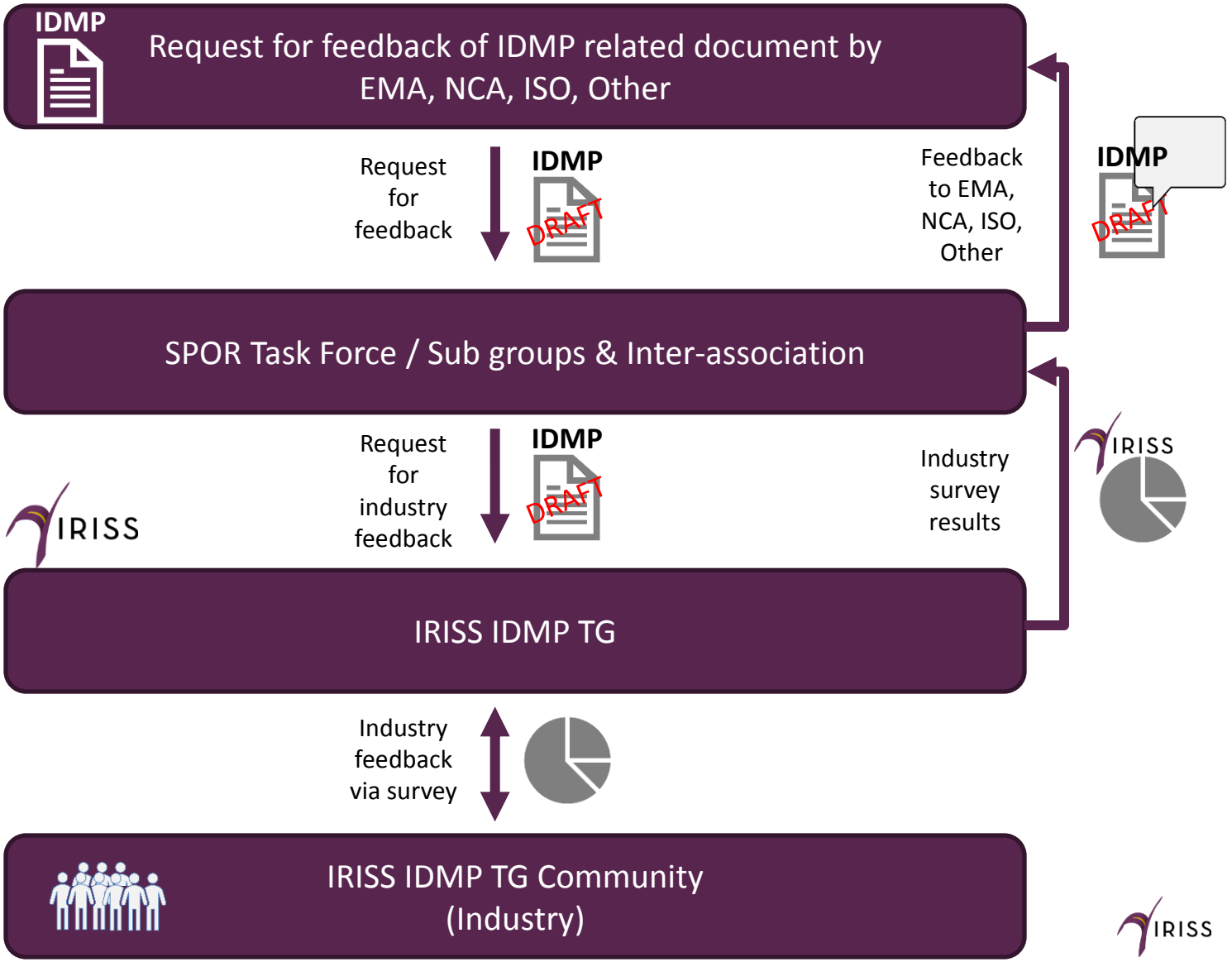
F2F conference

- PMS/SMS guest presentation by Isabel Chicharo
- OMS survey

(Optional) survey of either the deep dive topic or other.

? Optional extra topic e.g. vendor presentation

The IDMP TG can provide industry feedback on IDMP related documents



Questions

Visit IRISS at www.iriss-forum.org

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For contact: Frits Stulp

IRISS IDMP Topic Group Lead / Managing Director of Iperion Life Sciences Consultancy

Frits.Stulp@iperion.nl

+31 652727352