



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR data services - update to SPOR TF

24 May 2019





User on-boarding

- **1009** Industry Super Users & **519** Industry Users registered
- **20** organisations (NCAs & Industry) have access to SPOR API

Usage

- Over **3500 CRs** received in **OMS** since 15 December 2017
- **298 RMS CRs** received since June 2017
- eAF using RMS & OMS data
- EV user registration process using OMS data
- IRIS portal using RMS & OMS
- **IRIS portal for PD (latest business process using OMS data)**

SLAs

RMS and OMS compliant with the SLAs (extended SLAs in March - relocation)

OMS data mastering

- Mastering of Manufacturers is ongoing

Priority given to:

- 1) **Operational R&O SLAs** – to ensure no impacts on EV H, eAF, IRIS and business processes
- 2) **Mastering of Manufacturers** – to ensure no impact on CESP deadline in 2019
- 3) **SPOR API and PMS EU IG work-streams** – to ensure stakeholders clarity and allow ample time to prepare for 2021
- 4) Stakeholder engagement e.g. revising TOR and start new groups

- Cannot commence in 2019 due to priorities above
- Option: Industry led group to collect main points & ad hoc webinars

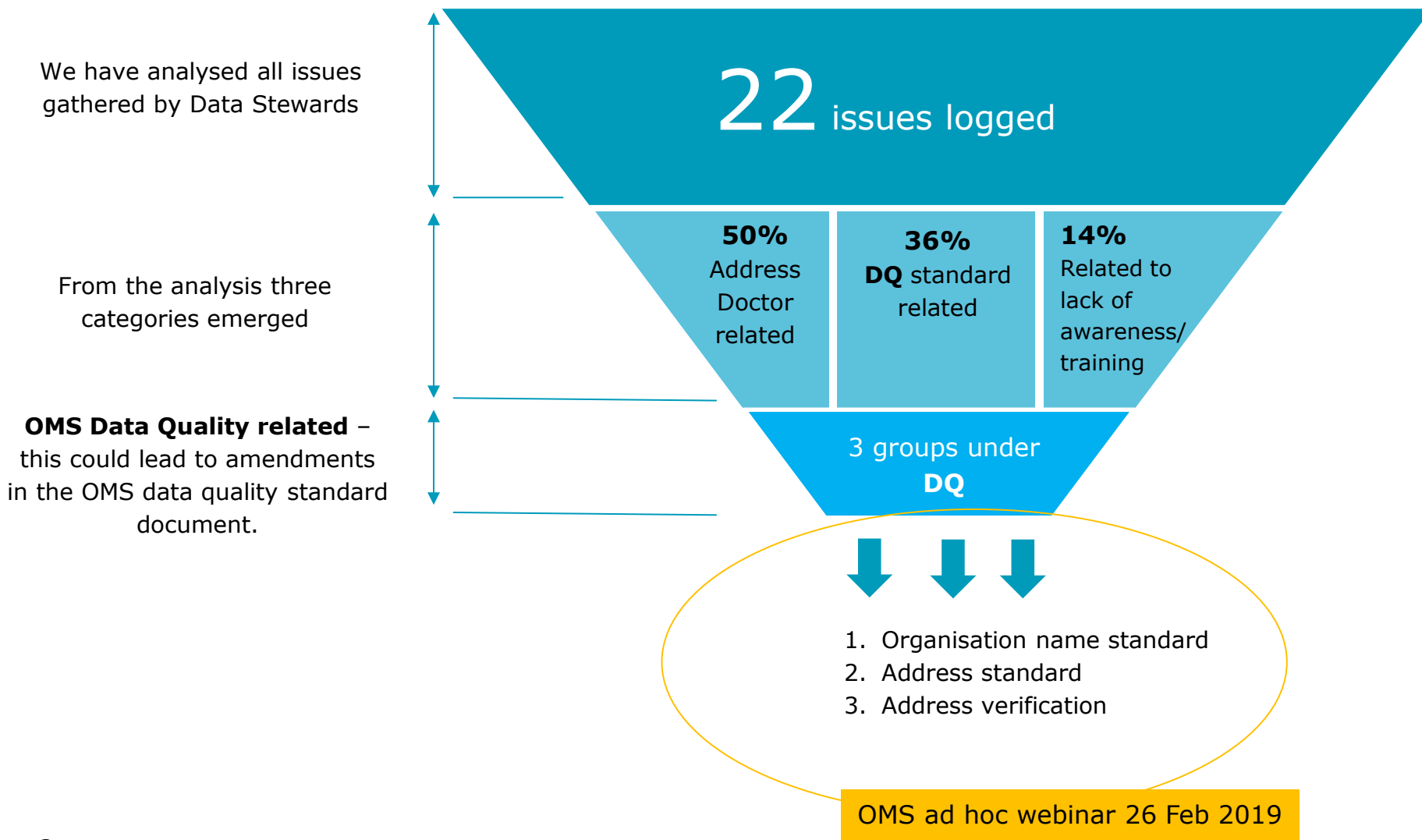
25 February 2019 ad-hoc webinar to **start discussing OMS DQ related issues**



Draft KUG Terms of Reference (ToR)

- Initially planned for Q2 2019

- **Sign off the KUG ToR**
- Call for expression of interest/nominations
- Set up the meetings / work plan
- Initially planned after Q2 2019





- **Format of the webinar**
 - Good starting point, positive comments received from participants
 - Participants indicated that face to face meeting would be beneficial
 - Receiving material and examples well in advance is necessary
- **Issues/examples that were presented**
 - Very useful discussions and feedback from participants, NCA and industry perspective
 - No concrete decisions were taken
 - Outcome of the webinar is documented



- We are in the BCP - engagement activities have not stopped
- SPOR API v.2 + EU IG consultations - excellent stakeholder engagement
 - Draft SPOR API v.2 publication planned in June 2019
 - Publication of EU IG v1 expected in October 2019
- Working with Telematics Secretariat to seek opportunities to bring relevant SPOR updates to Telematics groups
- Upcoming SMS related webinar (timing tbc)
- Updates to SPOR change liaisons around the key project milestones
- Communication campaign to improve the awareness of the OMS data quality standard



Thank you for your attention

Further information

Please send any queries regarding the IDMP/SPOR to:

SPOR-Change-Liaisons@ema.europa.eu

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