



European Medicines
Verification Organisation



FMD WORKSHOPS 2020

 04/12/2019

EMVO AGENDA



12/11/2019

FMD WORKSHOPS 2020

PRACTICAL ARRANGEMENTS FOR FMD 2020

- The Hotels for the workshops are now booked:
 - 12th February 2020, Thon Hotel Brussels City Centre
 - 13th May 2020, Thon Bristol Stephanie
 - 16th September 2020, Thon Hotel Brussels City Centre
 - 16th December 2020 (tbc), Thon Bristol Stephanie
- Similar to the current format, we will be in 'Theatre' format with projectors and a front screen, a stage with a 'top table' including the chair(s) of each workshop.

PRACTICAL ARRANGEMENTS: AGENDA AND FOLLOW-UP

- We will attempt to circulate the Agenda for each workshop in draft form 4 weeks ahead of each workshop. This will include (broad) topics and suggested speakers.
- This will be shared with NMVOs for their comments and adapted accordingly.
- Presenters will be asked in good time; with back-ups arranged.
- A follow-up document, similar to that created for PM Community meetings, will be shared after each workshop – alongside the slides which have been presented.
- This can form the basis for the next workshop, so that there is a real link between each session.

PLANNED INVITEES (1)

- As presented at the last FMD meeting, we will expand the invitations and include:
 - **c.150 in total:**
 - Current participants
 - We have received the list of current invitees from EFPIA and these will form the basis of the invitees for 2020.
 - End Users
 - End User IT providers
 - National level representatives
 - Additional OBPs
 - National Competent Authorities
 - The European Commission

INVITING ADDITIONAL PARTICIPANTS

- Inviting additional participants will allow different/fresh perspectives on the system, increased knowledge sharing and awareness.
- NCAs
 - With the express consent of each NMVO.
- End-Users
 - EMVO has no direct relationship with End-Users, and therefore any form of contact with them must be done with the assistance of NMVOs.
 - As there are c. 200,000 End-Users, accurate representatives would ideally be found – national representatives/individual representatives?
- Expert speakers – depending on the topic
 - E.g. Legal questions
 - E.g. Brexit

INVITATIONS TO THE WORKSHOPS

- EMVO will issue the first invitations to the February workshop in due course. We will send out reminders in the weeks preceding the event.
- The same pattern will be followed for subsequent workshops.
- We will send out invitations by email and we have an event management tool to monitor responses.
- In the invitations we will include a 1-page summary of foreseen topics and, in the first invite, information that EMVO will organise the sessions in 2020.
- Therefore, the topics for the February session need to be announced in advance.

TOPICS FOR DISCUSSION IN THE NEXT WORKSHOPS (1)

- Operations updates – alongside providing information to the OBPs present, it is possible to collect their feedback by presenting in advance and in detail forthcoming releases.
 - EMVO releases
 - NMVS releases
- Stabilisation periods
 - As stabilisation periods are now coming to an end in some countries (e.g. Slovenia), further discussion can be had – particularly if there is the participation of NCAs.
- (Hospital) Aggregation
- Alert management
 - Alignment of alert error codes
 - Alert Management System

TOPICS FOR DISCUSSION AT THE NEXT WORKSHOPS (2)

- Other potential topics of discussion:
- Alerts
- Brexit
- Change Management
- Inter-Market Transactions
- End User connections
- As detailed in the organizational slides, these topics must be decided in advance to contact the relevant speakers and prepare the content in good time.

OBP FEEDBACK

- Prior to the last session, we took feedback from some NMVOs. We now have some OBP feedback to share:
- **Release roadmap:**
 - OBP participants would like to hear more information on future releases of the EMVS. This is not to influence the roadmap, but to hear more, further in advance.
- **Information gathering:**
 - Use the workshops as a consultative forum, where EMVO can gather OBPs thinking on certain topics of discussion.
- **NMVO/OBP exchange:**
 - Future FMD workshops should/must provide the opportunity to exchange opinions between NMVOs and OBPs, who can have different perspectives on the topics of discussion. E.g. alert investigation processes and timelines.
- **Introduction of 'new' topics:**
 - The workshops allow the discussions of upcoming topics such as alert harmonisation and hospital aggregation. The 2020 workshops can be a 'transition' to the 2021 format and look ahead to future EMVS issues.