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SCIENCE MEDICINES HEALTH

Future Training Programme

SME info day: The new clinical trial regulation, 20 March 2017

Presented by:
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Training purpose

- Training plays a critical role in providing stakeholders with the skills, capabilities and knowledge needed to implement the changes required for a successful transformation and adoption of the new ways of working.
- A programme training strategy has been developed for the Clinical Trial programme which provides an overview of how training needs have been analysed and how training will be designed, developed, delivered and evaluated.
- Training will be delivered in line with a training framework:

Training framework

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The training framework sets out the steps through which training requirements are defined and material is designed, delivered and evaluated.

Analyse

- **Analyse the gaps** between the skills, knowledge, capability and behaviours of system users today and requirements of them in the future state.
- **Assess existing infrastructure** to support training efforts

Design & Develop

- **Build** tailored, focused and user-friendly training **content** to bridge the identified skills, knowledge, capability and behaviour gaps
- **Prepare** for training deployment

Deliver

- Deliver e**ffective** training
- Enable all impacted users to **adopt new ways of working**.
- Establish a **Super User network** for ongoing support post Go Live

Evaluate

- **Measure** training **effectiveness**
- Identify **additional training needs** and areas for improvement to factor in the next training roll-outs

Training framework

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Analyse

Outputs

- Training needs assessment
- Training channel assessment
- Detailed plan for Design & Develop stage
- High level plan for Deliver and Evaluate stages

Design & Develop

Outputs

- Training templates
- Training material
- Detailed plan for Deliver and Evaluate stages

Deliver

Outputs

- Trained end users

Evaluate

Outputs

- Updated training material where required
- Lessons learned for training material development for future programmes

Guiding principles

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The following guiding principles underpin the Clinical Trial Programme training.

1. Not mandatory for users to complete training prior to accessing the system
2. Training material should be developed and disseminated in a way to enable sponsor users to submit a Clinical Trial Application within 1 working day
3. Existing EMA capabilities and facilities including current query management systems to be utilised where possible
4. Training material templates should where possible be consistent with other Agency programmes to ensure that external stakeholder receive a consistent training experience
5. Training to be supplemented with robust, ongoing online support and query management
6. Opportunities and budget for Face – to – Face training is limited and therefore should be targeted at key processes.

Targeted Audience

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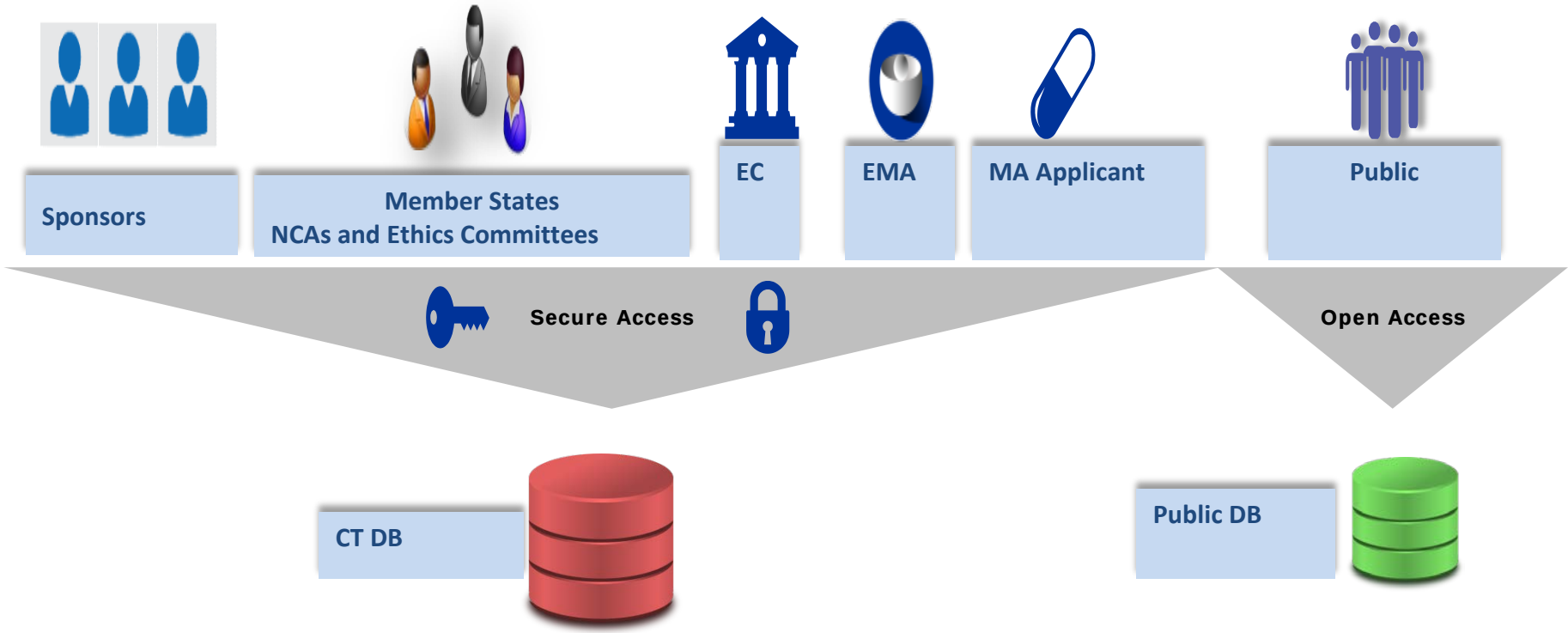

Training Needs Assessment- Outcome

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- Understand the impact of the CT regulation implementation on the different stakeholders groups
- Conducted a survey to identify training requirements
- Overview of the training modules identified

Training content			Audience to be targeted
Module Ref	Module Title	Module Description	
CTTM01	**Introduction to the Clinical Trial Regulation**	• Overview of the Regulation • Explanation of key changes from the Directive 2001/20/EC • Overview of the transition period	• Member States • Sponsors • EMA • Public
CTTM02	**Introducing the EU Portal and Database for Public Users**	• Overview of the functionality available to Public Users • Guides on how to search and download data and the pre-defined reports on Clinical Trial information	• Public
CTTM03	**Introducing the EU Portal and Database for Registered Users**	• Overview of the core functionality available to Registered Users • Overview of the different roles which can be assigned to Users and the functionality that each of these roles provides	• Member States • Sponsors • EMA
CTTM04	**Managing Registered Users**	• Guides on how to assign a role/clinical trial access to a registered user affiliated to an organisation • Guides on how to amend/revoke the roles/CT access assigned to a user	• Administrators

Training Needs Assessment- Outcome

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Training content			Audience to be targeted
Module Ref	Module Title	Module Description	
CTTM05	**Creating and submitting a Clinical Trial Application**	• Overview on how to prepare and submit a Clinical Trial Application • Introduction to the Assessment process and associated timelines	• Sponsors
CTTM06	**Managing a Clinical Trial through the EU Portal and Database**	• Overview of the Sponsors reporting responsibilities throughout the Clinical Trial lifecycle (Request for information, notifications, withdrawals etc.) • Overview of the functionality available to Sponsors to manage a Clinical Trial through the EU Portal and Database	• Sponsors • MAH
CTTM07	**Assessing a Clinical Trial Application**	• Overview of the stages and associated timelines for assessing a Clinical Trial Application • Overview of the functionality available to Member States to assess a Clinical Trial Application	• Member States
CTTM08	**Supervising a Clinical Trial through the EU Portal and Database**	• Overview of how Clinical Trials are supervised including initiation of corrective measures (revoke , suspend or modify the trial) and the available functionality	• Member States
CTTM09	**Supervising- Creating Inspection Records in the EU Portal and Database**	• Overview of how to exchange inspection plans and prepare and submit inspection reports and the available functionality	• MS Inspectors

Training Needs Assessment- Outcome

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Training content			Audience to be targeted
Module Ref	Module Title	Module Description	
CTTM10	**Managing publishing**	• Remove data that contains commercially confidentially confidential information or personal data from public view • Publish CT data when there is an overriding public interest • Leave a public comment on a clinical trial	• EMA Administrators
CTTM11	**Managing Union controls**	• Overview on how to create and submit a union control plan report as well as the submission of Union controls and the functionality available in the system to facilitate this	• European Commission

Training channel assessment- Outcome

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- To understand the potential means by which training material can be disseminated

Channel	Summary of scope
• **User Manual**	• Full and comprehensive system guide – addresses happy and all alternate paths • MS Word or pdf document
• **Overview video** • **Step by step process video**	• Addresses discrete functionality or topic • Level of detail varies by video type • Presented in an online MS PowerPoint presentation with voice over • Videos in similar format to UAT videos, produced using the "Snag It" tool
• **Quick guide**	• Process overview • 1-2 page A4 MS Word or pdf document including screenshots of key steps. • Typically only covers the happy path
• **In-system help**	• Short "pop up" explanation of fundamental items • Templates to provide guidance on when tool tips should be provided in the system including length and purpose • Content to be derived from user manual
• **Online presentation**	• Detailed walk-through of functionality • Addresses happy path, and commonly-used alternate paths • MS PowerPoint presentation with no voice over/ video
• **Webinar** • **Face-to-face training**	• Interactive delivery of the material within online PowerPoint presentation • Split by stakeholder group i.e. Sponsors/ Member States

Training approach

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Online training

Details

- Enable submission of dossier in 1 day
- Online material:
  - demo videos,
  - test environment,
  - user manuals,
  - guidance documents
  - in-system information

Targeted at:

- **All stakeholders**

Primary focus of training

Face - to - face

Details

- Tailored training of **Lead trainers**
- Provided by training concessionaire
- 2-3 days for commercial sponsors
- 1 day for SME's & non-commercial sponsors

Targeted at:

- Member States
- Large commercial sponsors
- SME's
- Non-commercial sponsors

Training colleagues

Details

- **Lead trainers** use knowledge and online material to train colleagues
- Online material (refer to the Online training section)

Targeted at:

- Member States
- Large commercial sponsors
- SME's
- Non-commercial sponsors

On-going support

Details

- The EMA provides on- going support through Webinars, Query management, etc.

Targeted at:

- All stakeholders

EUPD maximum project timelines: Training Plan

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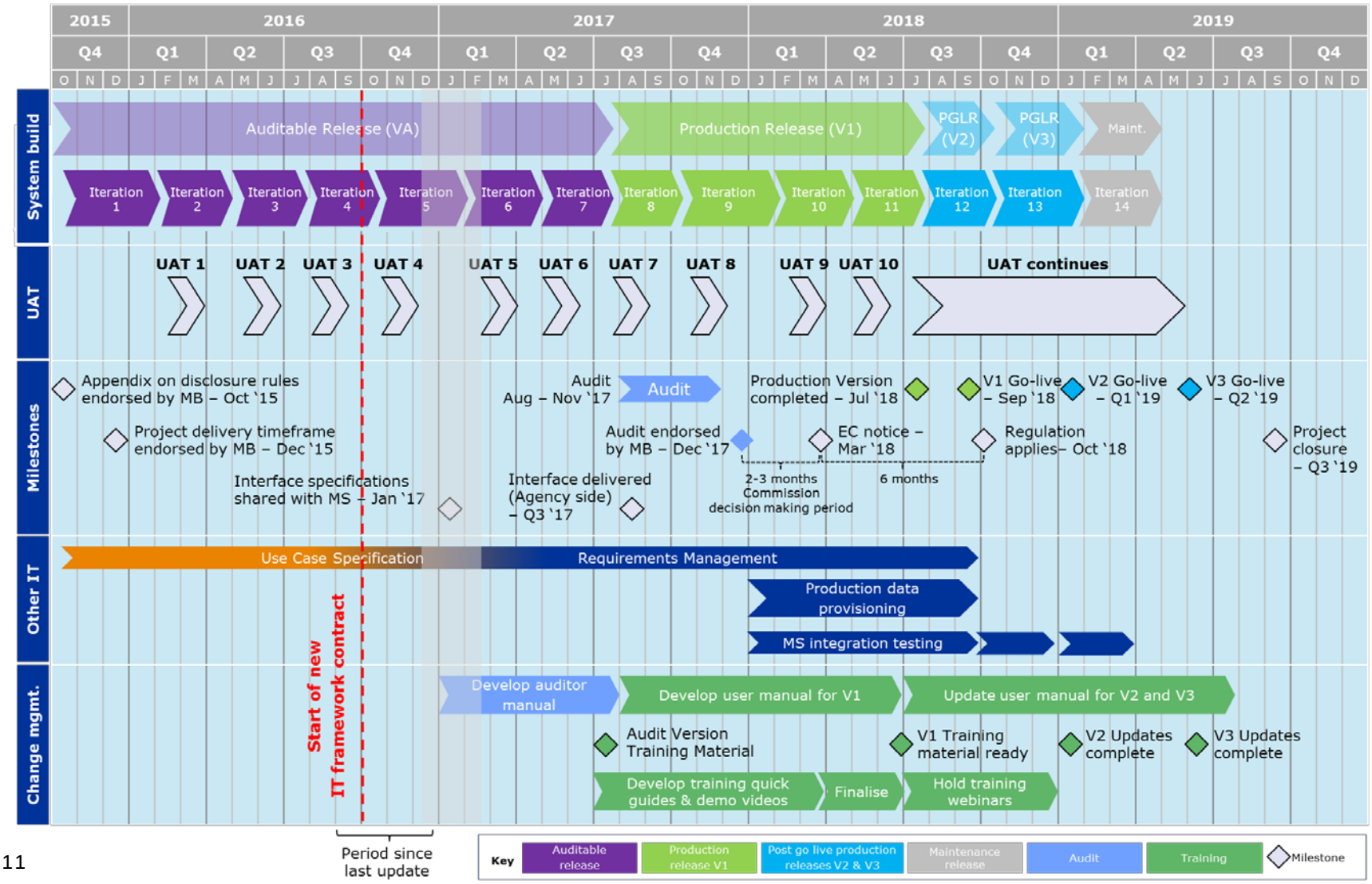
EU Portal and Database - Maximum project timeline

as per the delivery time frame endorsed at Dec '15 Management Board



Thank you for your attention

Further information

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