maxer CONSULTING

EMA USER PERSONAS MODEL

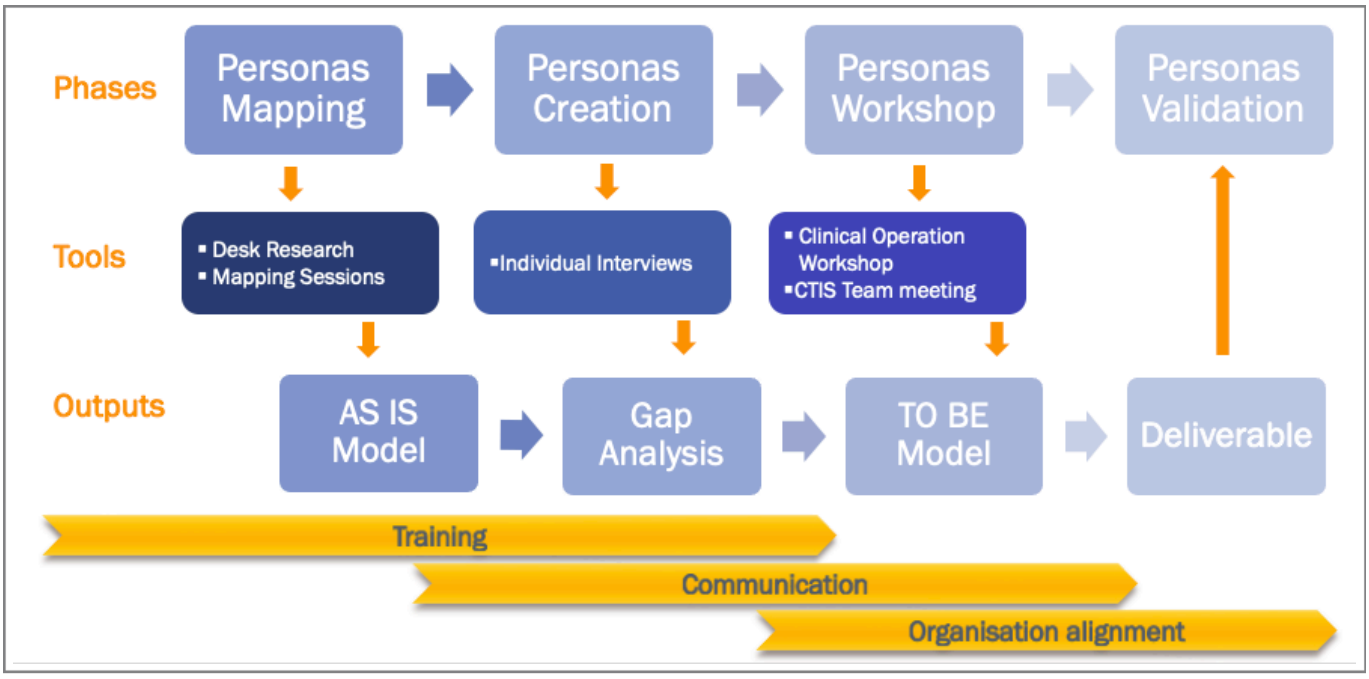
TRAINING PROGRAMME

Implementing the Clinical Trial Information System (CTIS) involves some relevant changes in the management of clinical trials throughout their life cycle. Besides requiring a certain degree of familiarity with the CTIS digital platform, Regulation 536/2014 requires a new approach to submitting the CTA and managing the clinical trial life.

Sponsors need to support individual users working in the CTIS. One of their problems is to define “who will do what” in their organization. Maxer has started from the EMA User Personas model and integrated it with a tailor-made version of the change management approach shaped on the clinical trials management needs.

By applying a four-step roadmap - AS-IS analysis, Gap analysis, TO-BE model definition - TO-BE model implementation - Maxer helps sponsors define their user “Personas,” visual models, filling their gaps where needed, with the final goal of implementing CTIS processes and workflows.

Training, communication, and organization alignment are the underlying processes of the change management approach to CTIS.



USER PERSONAS TRAINING PROGRAMME

After obtaining the EMA CTIS Master Trainer certificate, Maxer has developed a training course, available in English or Italian, dedicated to the following:

1. Key concepts for sponsor organisation models

Outlines the fundamental concepts of the sponsor organization modeling:

- Assisting sponsors in organisation and process preparation for CTIS;
- Clarifying fundamental principles for access to CTIS, user roles, and permissions in different organisational environments.

2. Roles and permissions matrix

Analyses the sponsor organisation models:

- describing clinical trials processes at a high level and how sponsors and their partners (e.g, vendors) may organise for CTIS
- providing the definitions and the analytic mapping of the sponsor roles and permissions:
  - Role: business job function with a collection of permissions:
  - Permission: an approval to do something on data or other system resources.

3. CTIS User Personas

Describes what a persona is and what are the persona's objectives. User personas help the sponsor identify "who typically does what". They also show the possible CTIS user roles each individual may be given to perform their tasks.

4. Organisation models

Describes three organisation models:

- simple, complex 1, and complex 2.
- providing for each model a map and a synopsis of the User access, roles, and permissions.

5. Consolidate CTIS purposes and features

- Underlines that CTIS is designed as a regulatory submission system and does not replace the clinical trial management systems each sponsor has in place. I
- Recaps centralized / de-centralised approaches, user access profiles, and data sharing implications.

6. Maxer Change Management approach

Describing the origins, purposes, and critical topics of change management:

- proposes a detailed user personas change management process flow;
- outlines the steps to undertake for the CTIS change management implementation

7. Considerations before implementing CTIS

Provides a list of recommendations to align the clinical trials organization model with implementing CTIS within an organization.