>> New service

CTIS training

We are providing specific training for pharma and biotech companies in order to guide them through the correct implementation of the new system.

BASIC TRAINING

Introduction of CTIS and user management

- **Introduction to the Clinical Trial Regulation No 536/2014**
  - Purpose of CTR
  - CTIS development/transition period and implementation calendar
  - Differences CT Directive vs CT Regulation
- **CTIS overview**
  - Key benefits
  - Workspaces + interactions with other systems
  - Main common functionalities
  - Publication aspects: transparency and GDPR
- **CTIS User access management**
  - Access/Registration
  - User roles - hierarchy:
    - Default
    - Administrator Roles
    - Business Roles
  - User roles – permissions
  - User management approaches:
    - Organisation Centric
    - Trial Centric
- **Conclusions / Recommendations**

COMPLETE TRAINING

CTIS overview and practical case for Clinical Trial Application submission

- **Submission of an initial Clinical Trial Application in CTIS**
  - Content and structure of an initial CTA
    - Form section
    - Part I
    - Part II
- **Creation, submission and withdrawal of a CTA**
- **Search, view and download information on clinical trials and clinical trial applications**
- **Update of an initial CTA**
  - Substantial modifications
  - Addition of a new Member State Concerned
  - Requests for Information (RFI)
  - Non-substantial modifications
  - Notifications required during the life-cycle of a clinical trial
    - Trial and recruitment periods
    - Other notifications
- **Submission of trial results and layperson summary**
- **Transparency – publication of clinical trial information**
  - General principles
  - Deferral rules: definition and management in CTIS
- **Work-planning and management tools**
  - Notices and alerts
  - RFIs
  - Timetable

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