EU Portal and Database Update

TOPRA  4 October 2017

Presented by Noémie Manent on 4 October 2017
Committees and Inspections Department
<table>
<thead>
<tr>
<th>1</th>
<th>EU Portal and Database Update</th>
</tr>
</thead>
</table>

Table of content

- EMA Portal and Database status update
- The detailed functionalities for Sponsors
- Conclusions
EU Portal and Database Update
Collaborative working

The EMA is working collaboratively to develop systems to implement the regulation.
Eu Portal and Database Update – key milestones

- System Release 0.6 – UAT dates: 6 Nov – 27 Nov 2017
- System Release 0.7 – UAT Dates: end of Q1 2018
- The audit of the EU portal and database: Q2 2018

The purpose of the audit is to confirm that the EU Portal and Database have achieved full functionality and the system meets the functional specifications which are defined in the document “Functional Specifications of the EU Portal and EU Database to be audited” (EMA/42176/2014 Rev.1, Corr.).

- System Release 0.8 – UAT dates: beg of Q3 2018
- EMA MB to endorse the results of the audit
- EU portal and database Launch: 2019 (actual date to be 6 months after the notice referred to in Article 82(3) of the CT regulation No. 536/2014 is published)
Detailed Functionalities
EU portal and database - System interfaces

Business Processes

User Interfaces

CT System

Data Warehouse (DWH)

Document Management (DMS)

CT DB

Public DB

Sponsors

EMA

User Registration & Security (IAM)

Master Data Management (RMS/OMS)

WHO

EU Portal and Database Update

EU Portal and Database Update
Submit application (CTA dossier) / Address request for information

Update of Clinical Trial information (re non substantial modifications)

Submit notifications:
- Start of trial
- First visit first subject
- End of recruitment
- End of trial (in each MS, All MS, Global)
- Temporary halt & restart
- Serious Breach, Unexpected event, urgent safety measure
- Inspection from third country inspectorate

Submission of clinical study result (summary and lay person summary)

Notification of willingness to be RMS (part I) / Decision on RMS

Submission of requests for information

Notification of the final validation (initial, additional MS or Substantial Modification)

Submission final conclusion to Part I and Part II

Final single decision notification

Submission Inspection Information

Communication disagreement to part 1 assessment

Communication on implementation of corrective measures

Search and view CT information

System Maintenance

General public

EMA

Commission

Applicant of a MA

Submission of CSR

Submission of Union Control Reports

Sponsors

Member States
User management
A structured top-down approach to maintain the integrity of the system

**High-level administrators**
- (Sponsors, Member States, EU Commission, MAHs)
- Approves

**Medium-level administrators**
- (Sponsor Clinical trial and MS national organisation administrators)
- Approves

**Regular users**

---

Assign new role/CT access
Amend role/CT access
Revoke role/CT access
Approve/reject user requests for a role (only applicable to sponsor users)

Role allocated to perform activities in the system
### Administration of users

**User ID**: Perseas Unisystems  
**Email**: perseas.unis@email.com

**Search filters Status**: requested

<table>
<thead>
<tr>
<th>User Id</th>
<th>Email</th>
<th>Employer</th>
<th>Organisation name</th>
<th>Organisation ID</th>
<th>Role</th>
<th>Scope</th>
<th>EUCT Number</th>
<th>Creation Date</th>
<th>Assessment Date</th>
<th>Status</th>
<th>Authorised from</th>
<th>Authorised to</th>
<th>Actions</th>
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</table>
Assign role(s)

User Id

Organisation name
Pfizer Hellas S.A

Organisation ID
ORG-100004098

Role

Scope

EUCT Number

Authorised from
28/09/2017

Authorised to

add

Assign
Cancel

<table>
<thead>
<tr>
<th>Employer</th>
<th>Organisation name</th>
<th>Organisation ID</th>
<th>Role</th>
<th>Scope</th>
<th>EUCT Number</th>
<th>Creation date</th>
<th>Assessment date</th>
<th>Status</th>
<th>Authorised from</th>
<th>Authorised to</th>
<th>Action</th>
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</thead>
<tbody>
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<td>Pfizer Hellas S.A</td>
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<td>CT</td>
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<td>2017-588000-11-00</td>
<td>27/09/2017</td>
<td></td>
<td>requested</td>
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</tbody>
</table>
Creation of clinical trial applications, responding to RFI, submit trial notification (e.g. trial start) and viewing the clinical trials
<table>
<thead>
<tr>
<th>EU CT number</th>
<th>Trial name</th>
<th>Lead sponsor</th>
<th>Member States Concerned</th>
<th>Submission date</th>
<th>Decision date</th>
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<tbody>
<tr>
<td>2017-520300-36-00</td>
<td>Sanity_Test_01_ha</td>
<td>Pfizer Hellas S.A</td>
<td>AT (Ended)</td>
<td>19/09/2017</td>
<td>19/09/2017</td>
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<td>2017-524280-83-00</td>
<td>UAT</td>
<td>National Agency for Medicines and Health Products Safety</td>
<td>FI (Ended) GR (Ended)</td>
<td>21/09/2017</td>
<td>21/09/2017</td>
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<tr>
<td>2017-537554-26-00</td>
<td>UAT phase 2</td>
<td>National Agency for Medicines and Health Products Safety</td>
<td>FI (Ended) GR (Ended)</td>
<td>22/09/2017</td>
<td>25/09/2017</td>
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<td>2017-516271-86-00</td>
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<td>2017-534183-66-00</td>
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<td>2017-551302-71-00</td>
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</table>
A 52-week, multicenter, randomized, double-blind study of Protoneumab (15 mg) to demonstrate efficacy as assessed by affected area and...
A 52-week, multicenter, randomized, double-blind study of Protoneumab (15 mg) to demonstrate efficacy as assessed by Severity Index on the affected area.

### Trial specific information (Part I)

#### Trial details

- **Trial identifiers**
- **Trial information**
- **Protocol information**
- **Scientific advice and Paediatric Investigation Plan (PIP)**
- **Associated clinical trials**
- **References**
- **Clock stop**

### Sponsors

<table>
<thead>
<tr>
<th>Name</th>
<th>Type</th>
<th>Country</th>
<th>Status</th>
<th>Legal representative</th>
<th>Scientific contact point</th>
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<tbody>
<tr>
<td>Pfizer Hellas S.A</td>
<td>Other</td>
<td>Greece</td>
<td>Non-commercial</td>
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### Products

<table>
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<th>EUMP number</th>
<th>Marketing authorisation number</th>
<th>Product authorisation status</th>
<th>Product name</th>
<th>Pharmaceutical form</th>
<th>Strength</th>
<th>Sponsors product code</th>
<th>Active substance</th>
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<tr>
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<td>ATC Name</td>
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<td></td>
<td></td>
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</table>
## Member States Concerned

<table>
<thead>
<tr>
<th>Member States Concerned</th>
<th>Reporting Member State</th>
<th>First submissions date</th>
<th>Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td></td>
<td></td>
<td>50</td>
</tr>
<tr>
<td>France</td>
<td></td>
<td></td>
<td>50</td>
</tr>
</tbody>
</table>

**Countries outside the European Economic Area**

**Rest of the world subjects**

0

**Estimated total population for the trial**

- **EEA subjects**: 100
- **Rest of the world subjects**: 0
- **Total subjects**: 100
A 52-week, multicenter, randomized, double-blind study of Protoneumab (15 mg) to demonstrate efficacy as assessed by Severity Index on the affected area. 2017-526241-23-00

Initial ID: 120  Draft

**Actions by the user**

**Lock/unlock**

### Country specific details (Part II - BE)

#### Trial sites

<table>
<thead>
<tr>
<th>Organisation ID</th>
<th>Organisation name</th>
<th>Site location</th>
<th>Site street address</th>
<th>Site city</th>
<th>Site post code</th>
<th>Site country</th>
<th>Site</th>
<th>First Names</th>
<th>Last Name</th>
<th>Department</th>
<th>Title</th>
<th>Email</th>
<th>Telephone number</th>
</tr>
</thead>
</table>

#### Documents

- All documents
- Proof of payment of fee
- Proof of insurance cover or indemnification
- Financial and other arrangements
- Suitability of the facilities
- Subject information
- Suitability of the investigator

**Left inside navigation**

**Right inside navigation**
### Deferral of clinical trial information

The trial does not include paediatric subjects. If the trial is changed to be listed in a PIP or to include paediatric subjects, then notifications associated with this trial will be published at the date of decision on the trial.

#### Trial category

- **Category 1**

#### Justification of trial category

- this is a phase 1 first in human

<table>
<thead>
<tr>
<th>Data/Document type</th>
<th>Publication date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main characteristics</strong></td>
<td><em>Date of decision</em>&lt;br&gt;Publication of final summary of results</td>
</tr>
<tr>
<td><strong>Notifications</strong></td>
<td><em>At designated time</em>&lt;br&gt;Publication of final summary of results</td>
</tr>
<tr>
<td><strong>Subject information sheet</strong></td>
<td><em>Date of decision</em>&lt;br&gt;_________ years and _________ months after the end of trial</td>
</tr>
<tr>
<td><strong>Protocol</strong></td>
<td><em>Date of decision</em>&lt;br&gt;_________ years and _________ months after the end of trial</td>
</tr>
<tr>
<td><strong>IMPD SendE sections and Investigator brochure</strong></td>
<td><em>Date of decision</em>&lt;br&gt;_________ years and _________ months after the end of trial</td>
</tr>
<tr>
<td><strong>Responses to RFI</strong></td>
<td><em>Date of decision</em>&lt;br&gt;_________ years and _________ months after the end of trial</td>
</tr>
<tr>
<td><strong>Clinical trial results summary for an intermediate data analysis</strong></td>
<td><em>12 months after interim data analysis date</em>&lt;br&gt;As soon as results are submitted</td>
</tr>
</tbody>
</table>
The trial does not include paediatric subjects. If the trial is changed to be listed in a PIP or to include paediatric subjects, then Notifications associated with this trial will be published at the date of decision on the trial.

<table>
<thead>
<tr>
<th>Trial category</th>
<th>Justification of trial category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 2</td>
<td>this is a phase 2 with a dose escalation armence</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data/Document type</th>
<th>Publication date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject information sheet</td>
<td>○ Date of decision [ ] years and [ ] months after the end of trial</td>
</tr>
<tr>
<td>Protocol</td>
<td>○ Date of decision [ ] years and [ ] months after the end of trial</td>
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</tr>
<tr>
<td>Responses to RFI</td>
<td>○ Date of decision [ ] years and [ ] months after the end of trial</td>
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</table>
Verification of the completion of the dossier before submission

There are no attached documents.

Redacted cover letter:

<table>
<thead>
<tr>
<th>Document title</th>
<th>File type</th>
<th>Document type</th>
<th>Language</th>
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<td>Redacted Cover Letter</td>
<td>English</td>
<td>19/09/2017</td>
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<td>27/08/2017</td>
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</table>
Confirmation message once the user has clicked "submit"
### Validation

<table>
<thead>
<tr>
<th>Conclusion</th>
<th>Dossier completeness</th>
<th>Validation date</th>
<th>Scope</th>
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<tr>
<td>Valid</td>
<td>Complete</td>
<td>19/09/2017</td>
<td>In scope</td>
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### Assessment Part I

<table>
<thead>
<tr>
<th>Conclusion</th>
<th>Disagreements</th>
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</table>

### Assessment Part II

<table>
<thead>
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<th>Conclusion</th>
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</thead>
</table>

### Decision

<table>
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<th>MSC</th>
<th>Date</th>
<th>Decision</th>
<th>Part II conclusion</th>
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<td>EUCT number</td>
<td>Evaluation process</td>
<td>Due date</td>
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<tr>
<td>47</td>
<td>2017-537554-26-09</td>
<td>Assess Part II</td>
<td>12/10/2017</td>
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</table>

**Evaluation**

**Validation**

**Conclusion**

- Valid
- Dossier completeness: Complete

**Assessment Part I**

**Conclusion**

- Part I conclusion: Acceptable
- Conclusion date: 25/09/2017

**RFI**

- ID: 42 Responded: 25/09/2017
- ID: 44 Responded: 25/09/2017
- ID: 43 Responded: 25/09/2017
The Public View
Clinical trial search

Basic Criteria

Contain all of these terms:

Contain any of these terms:

Does not contain any of these terms:

Show Advanced Criteria

Search Reset
### Advanced Search Criteria

- **Basic Criteria**
  - Contain all of these terms:
  - Contain any of these terms:
  - Does not contain any of these terms:

- **Hide Advanced Criteria**

#### Advanced Criteria

- **Country**
- **Age group**
- **Therapeutic area**
- **Trial phase**
- **Sponsor type**
- **Gender**
- **Events**
  - Study results
  - Clinical study report
  - Low intervention trial
  - Serious breach
  - Unexpected event
  - Urgent safety measure
  - Inspection
  - Trial region

---

**Advanced search**
9 results found

Modify my search

Sort by: Decision date ASC Sort

Download results Subscribe to search

- **2017-574752-42-00 - On-going, recruiting - George 19/9**

  Overall start date of the trial (in the EU): 19/09/2017 | Overall end date of the trial (in the EU): 20/09/2017 | Conditions: Test | Countries where the trial is taking place (EU country code): Finland:Ended, Austria:Ended | Decision date: Finland:19/09/2017 | Product: Ambisome 50 mg infuusiokuva-aine iluosta varten

- **2017-520300-36-00 - On-going, recruitment ended - Sanity_Test_01_ha**

  Overall start date of the trial (in the EU): 20/09/2017 | Overall end date of the trial (in the EU): 20/09/2017 | Conditions: Sanity_Test_01_ha | Countries where the trial is taking place (EU country code): Austria:Ended | Decision date: Austria:19/09/2017 | Product: Ambisome 50 mg infuusiokuva-aine iluosta varten

- **2017-553215-05-00 - On-going, recruiting - new test trial**
View Clinical Trial

Notifications demo trial three
EUCT number: 2017-560255-05-00

Current information on the trial

Trial specific information (Part I) English

- Trial details
- Sponsors
- Products
- Documents

Country specific details (Part II)

- Finland - Authorised
- Austria - Authorised
Training
CT Programme: Training principles and approach

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

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

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

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

**Targeted at:**
- **All stakeholders**
- **Large commercial sponsors**
- **SME’s**
- **Non-commercial sponsors**
- **Member States**
  - Large commercial sponsors
  - SME’s
  - Non-commercial sponsors

Primary focus of training

32 EU Portal and Database Update
Off site and on-site UAT approach
Key Objectives

- MS & sponsor orgs represented in UAT with on-site testing and off-line testing (37 testers/UAT6)
- **Interactive and E2E scenarios** Sponsors - MSC
- Additional features tested

**Testing date:** 6 Nov – 27 Nov 2017 with collection of feedback on an on-going basis

UAT 6 bugs to be with our developer **before** 22-Dec-2017
<table>
<thead>
<tr>
<th>Event</th>
<th>Date/Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>UAT 6 Webinar Details Communication</td>
<td>w/c 18-Sep-2017</td>
</tr>
<tr>
<td>UAT 6 Provisional Webinar Dates</td>
<td>w/c 16-Oct-2017</td>
</tr>
<tr>
<td>UAT 6 On-site Execution (and Support)</td>
<td>06-Nov-2017 to 10-Nov-2017</td>
</tr>
<tr>
<td>UAT 6 Off-site Execution</td>
<td>06-Nov-2017 to 27-Nov-2017</td>
</tr>
<tr>
<td>EMA Management Board Meeting</td>
<td>13-Dec-2017 to 14-Dec-2017</td>
</tr>
<tr>
<td>UAT 6 Completion Report Preparation</td>
<td>w/c 11-Dec-2017</td>
</tr>
</tbody>
</table>
Conclusions
Conclusions:

- **Harmonisation**: One single submission for authorisation of a clinical trial to and for public registration (primary register of clinical trials);
- **Member state collaboration**: Facilitate cooperation among MSCs
- **One single decision** per Member State;
- **IT maintenance**: EMA to maintain and update the IT platforms;
- **Public data** and information about medicines, their development and authorisation
  - To generate trust – information is available
  - To build confidence – I understand what is happening
  - To empower – knowledge enables decision-making
Clinical Trial Regulation

The way clinical trials are conducted in the European Union (EU) will undergo a major change when the Clinical Trial Regulation comes into application in 2019. The Regulation harmonises the assessment and supervision processes for clinical trials throughout the EU, via an EU portal and database. The European Medicines Agency (EMA) will set up and maintain the portal and database, in collaboration with the Member States and the European Commission.

The goal of Clinical Trial Regulation EU No. 536/2014 is to create an environment that is favourable to conducting clinical trials in the EU, with the highest standards of safety for participants and increased transparency of trial information. The Regulation will require:

- consistent rules for conducting clinical trials throughout the EU;
- information on the authorisation, conduct and results of each clinical trial carried out in the EU to be publicly available.

This will increase the efficiency of all trials in Europe with the greatest benefit for those conducted in multiple Member States. It aims to foster innovation and research, while helping avoid unnecessary duplication of clinical trials or repetition of unsuccessful trials.

When the Regulation becomes applicable, it will replace the existing EU Clinical Trial Directive (EC) No. 2001/20/EC and national legislation that was put in place to implement the Directive. It will also apply to trials authorised under the previous legislation if they are still ongoing three years after the Regulation has come into operation.

The authorisation and oversight of clinical trials remains the responsibility of Member States, with EMA managing the database and supervising content publication on the public website.

Key benefits of the Regulation

- Harmonised electronic submission and assessment process for clinical trials conducted in multiple Member States
- Improved collaboration, information-sharing and decision-making between and within Member States
- Increased transparency of information on clinical trials

Any questions?

Further information

Noemie.manent@ema.europa.eu

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