



DEEP-2 STUDY NEWSLETTER ISSUE 31 – JANUARY 2018

**Dear DEEP-2 Investigators and CRAs,
the database will be definitely locked on 31 January 2018.**

Closure of e-CRF database

The Trial Management Team kindly inform you that the **closure of the DEEP-2 e-CRF database** has been scheduled on **31 January 2018**. From that moment on, it will not be possible to insert or modify any data. An official communication has been sent to all Investigators on 23 January 2018.

Therefore, in order to properly close down the e-CRF database and to fulfil the GCP requirements, all Investigators are kindly invited to be compliant with this deadline:

- completing and validating all the **e-CRF sections** that are still empty or in entry process;
- verifying that all **SAEs** have been recorded in the Adverse Event log of the e-CRF;
- solving all the **pending queries** arisen by the CRAs.

DEEP-2 Investigator Meeting

We are happy to announce that ApoPharma has organized the DEEP-2 Investigator Meeting that will be held in Milan (Italy) on 28 February - 1 March 2018.



Please, refer to the [DEEP Website](#) to keep up to date about the [Frequent Asked Questions \(FAQs\)](#) and [Alerts & Recommendations](#) concerning the most relevant aspects of the study.

These sections are regularly updated in order to support You and all the Study Team.

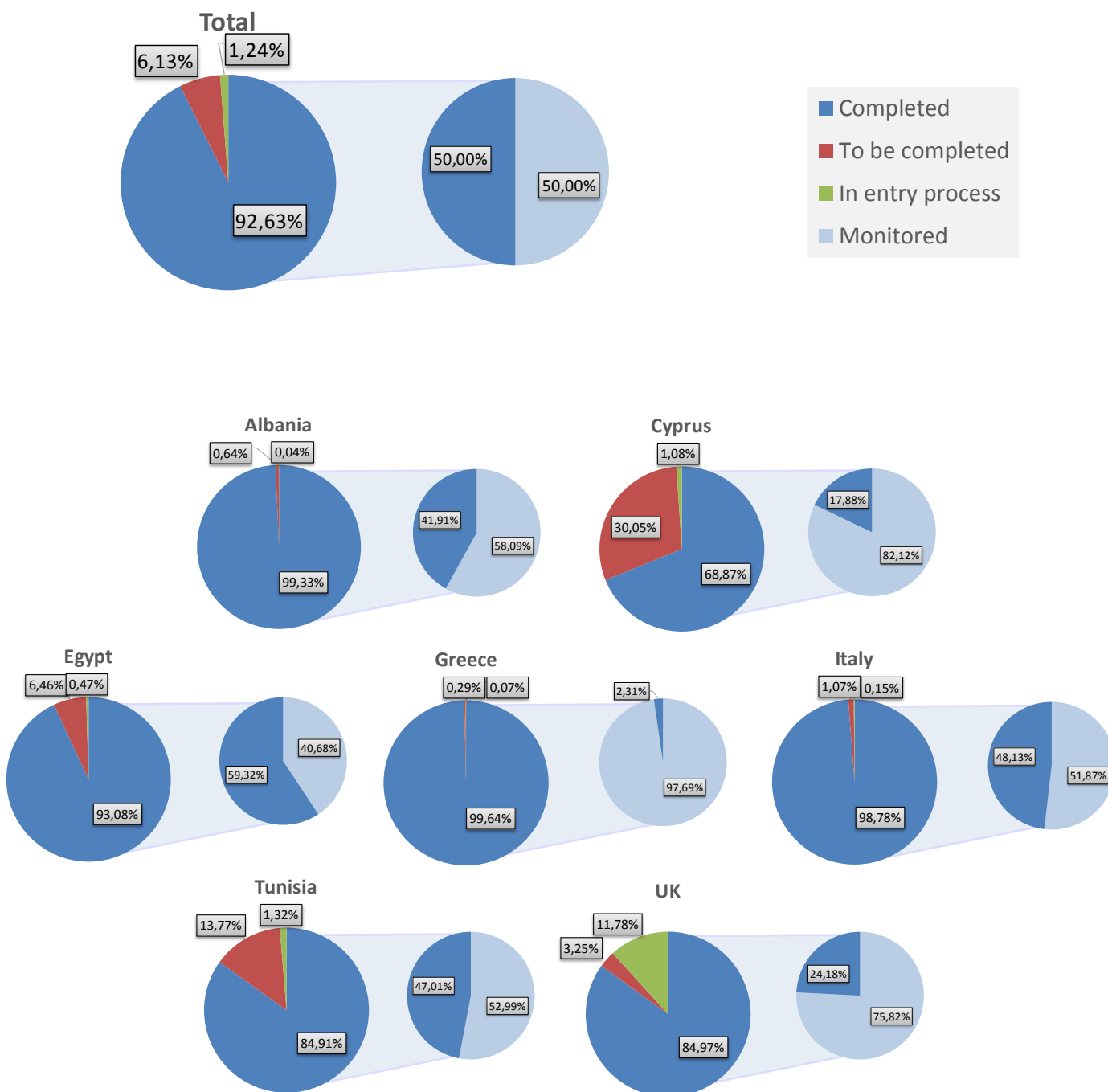
You can also find all revised DEEP-2 FAQs in the “*General Information*” section of the e-CRF.



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e-CRF Form Review Status at different centres

The Trial Management Team wishes to remind Investigators **to correctly complete and validate all data in the e-CRF sections** to allow the CRAs appointed to each study center to perform the check during the monitoring visits.





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Patients' Status



Site ID	PI	Planned	Randomized	Early termination	Completed	SAEs confirmed at COV
ITA/01	Maggio	10	11	0	11	0
EGY/02	El-Beshlawy	130	133	39	94	
GRE/03	Kattamis	12	11	3	8	10
ALB/04	Kreka	20	27	2	25	
CYP/05	Christou	12	8	7	1	
ITA/06	Filosa	14	14	4	10	7
TUN/07	Bejaoui	30	56	2	54	
ITA/08	Putti	9	9	1	8	7
ITA/09	Del Vecchio	12	6	0	6	0
ITA/10	Cuccia	4	3	3	0	0
ITA/11	Bisconte	4	1	0	1	0
ITA/12	Commendatore	6	1	0	1	1
ITA/14	Cosmi	5	5	1	4	3
ITA/15	Origa	7	5	2	3	3
ITA/16	Casini	4	3	0	3	0
ITA/17	Caruso	6	2	0	2	
UK/18	Telfer	20	19	1	18	12
UK/19	Grant	5	4	0	4	0
UK/20	Harewood	5	0	0	0	
EGY/23	Metwally Sherief	40	40	3	37	
EGY/24	Hassab	25	23	9	14	
ALB/31	Zaka	12	12	0	12	
TOTAL		392	393	77	316	43

COVs' Status
Performed on 12/12/2017
To be planned
Performed on 18/10/2017
To be planned
To be planned
Performed on 4-5/12/2017
To be planned
Performed on 6/11/2017
Performed on 23/11/2017
Performed on 11/12/2017
Performed on 18/12/2017
Performed on 1/12/2017
Performed on 16/11/2017
Performed on 29-30/11/2017
Performed on 2/8/2017
To be planned
Performed on 15-16/1/2018
Performed on 11/1/2018
To be planned
To be planned
To be planned



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FAQ

What if I cannot validate a form and the data seems correctly entered?

In case you are not able to validate a form even though all data have been correctly entered, please contact the Data Manager to the email trial.assistant@cvbf.net; you will be helped to validate the form.

Study Contacts

Please find below all DEEP-2 contacts that are glad to support you for any information that you may need:

Trial Leader:

Donato Bonifazi - pmdeep2@cvbf.net

Trial Coordinating Investigator:

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Trial Management Team:

» Clinical Research Coordinator:

Gabriele Morselli - gmorselli@cvbf.net

» Data Manager: **Paola Gandini** - trial.assistant@cvbf.net

» Drug and Technical Operations Managers:

Bianca Tempesta - drugmanagement@deep-project.net

Valeria Pignataro - drugmanagement@cvbf.net

» Administrative Manager:

Marina Montanaro - mmontanaro@cvbf.net

Regulatory Submission Manager and Clinical Trial Archivist:

Elisa Cattani - ecattani@cvbf.net

Pharmacovigilance:

» Safety Contact: **Cristina Manfredi**

pharmacovigilance@deep-project.net

» Qualified Person for Pharmacovigilance:

Mariagrazia Felisi - mariagraziafelisi@cvbf.net

Ferritin Evaluation Centers:

» **Cristina Passarello** - c.passarello@campuscutino.it

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