

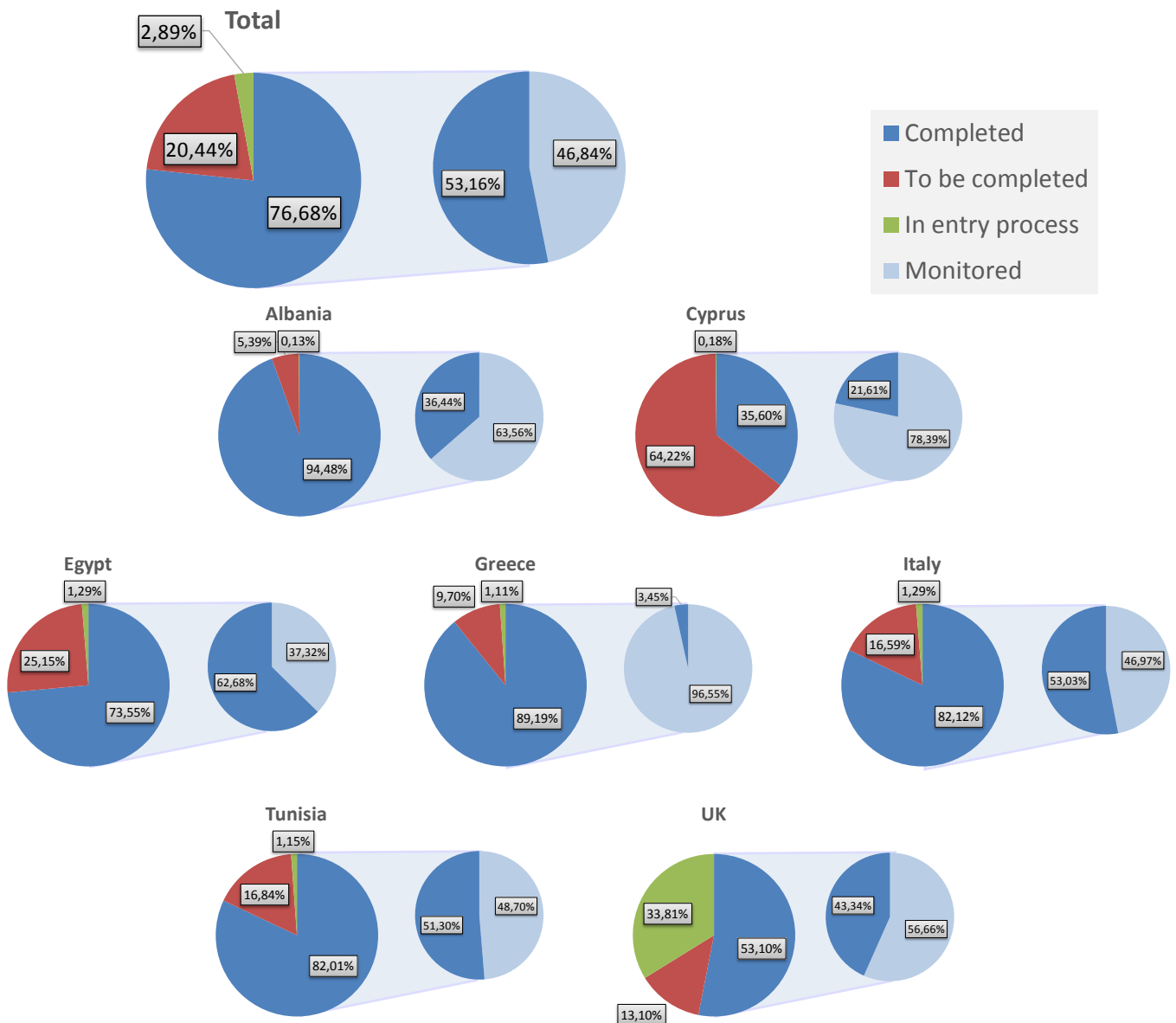


DEEP-2 STUDY NEWSLETTER ISSUE 27 - MAY 2017

Dear DEEP-2 Investigators,
in this newsletter we would like to focus on the importance of e-CRF compilation and to inform you of adding new tab in the PK e-CRF section.

e-CRF Form Review Status at different centres

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



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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Study Conduct

The TMT kindly informs you that a **new feature** has been added in the **Pharmacokinetics (PK) e-CRF section** at V15.

Specifically, a “*not applicable*” option has been added to the PK section at V15 for those patients for which the PK withdrawal at V15 is not required and have the status on e-CRF as “*not entered*”.

Therefore, to complete the PK section, it is kindly required to follow the instructions hereinafter:

- » selecting this new option, clicking on “*not applicable*”;
- » entering the reason why the form is not applicable (as in the screenshots below) into the window that will appear;

V15 : Month 12

Pharmacokinetics

Examination

Laboratory

Hepatitis serology

Urinalysis

12 - Lead ECG

Pubertal staging - Tanner scale

Transfusion regimen - Neutrophil count

Liver MRI - Cardiac MRI T2

Ocular and audiometric examination

Concomitant medication

Not Entered

Not Entered

Not applicable

Not applicable

PK withdrawal has not been performed

Cancel Validate

Not Entered

Not Entered

- » once the information inserted in the window is validated, the status of the form becomes “*not applicable*”.

V15 : Month 12

Pharmacokinetics

Examination

Laboratory

Not Entered

Not applicable

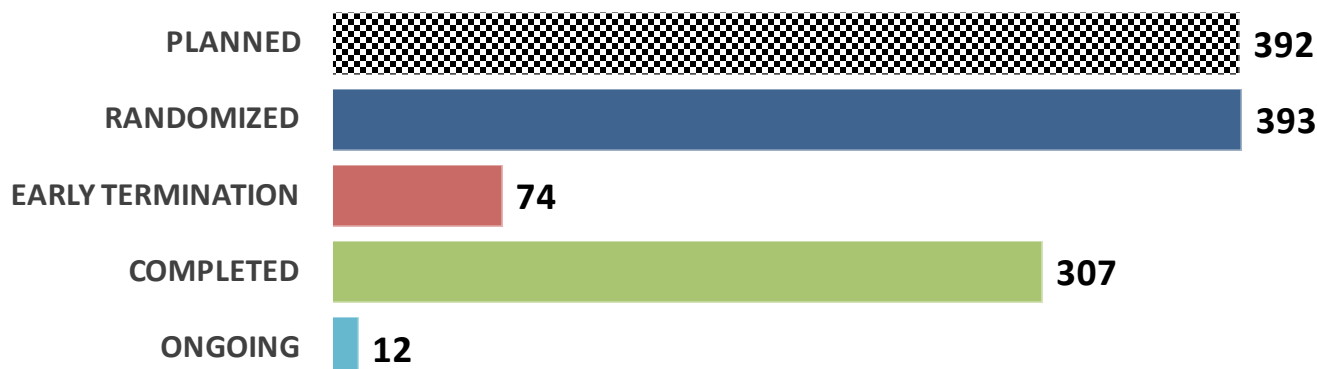
Not Entered

Not Entered



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Patients' Status



Site ID	PI	Planned	Randomized	Early termination	Completed	Ongoing
ITA/01	Maggio	10	11	0	7	4
EGY/02	El-Beshlawy	130	133	39	94	0
GRE/03	Kattamis	12	11	3	8	0
ALB/04	Kreka	20	27	2	23	2
CYP/05	Christou	12	8	7	0	1
ITA/06	Filosa	14	14	4	10	0
TUN/07	Bejaoui	30	56	2	54	0
ITA/08	Putti	9	9	1	8	0
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	0
ITA/14	Cosmi	5	5	1	4	0
ITA/15	Origa	7	5	2	3	0
ITA/16	Casini	4	3	0	3	0
ITA/17	Caruso	6	2	0	2	0
UK/18	Telfer	20	19	1	14	4
UK/19	Hemmaway	5	4	0	4	0
UK/20	Harewood	5	0	0	0	0
EGY/23	Metwally Sherief	40	40	3	37	0
EGY/24	Hassab	25	23	6	17	0
ALB/31	Zaka	12	12	0	11	1
TOTAL		392	393	74	307	12



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Frequently Asked Questions (FAQs)

When do I have to fill in the renal function in e-CRF?

Renal function (assessed as serum creatinine and creatinine clearance) must be determined:

- at each scheduled study visit (V4 to V15) for each patient;
- weekly during the first month after initiation;
- weekly after therapy's modification. For example if at visit X (e.g. V5) you modify the therapy, you have to monitor the renal function weekly and fill it in the e-CRF at the next visit (in this case at V6).

When do I have to fill in the Healthcare Resources form in the e-CRF?

This form has to be completed only in case of use of resources (visits, tests or procedures) outside the study protocol. This means that every time your patient needs any additional clinical intervention, not already planned according to the study, you have to report it in this 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:

Aurelio Maggio - md.amaggio@gmail.com

Trial Management Team:

- » Clinical Research Coordinator: **Gabriele Morselli** - gmorselli@cvbf.net
- » Clinical Research Specialist: **Giuseppe Lassandro** - giuseppelassandro@deep-project.net
- » Data Manager: **Paola Gandini** - trial.assistant@cvbf.net
- » Drug and Technical Operations Manager: **Bianca Tempesta** - btempesta@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
- » Medical Monitor: **Maria Marsella** - mariamarsella@deep-project.net

Ferritin Evaluation Centers:

- » **Cristina Passarello** - c.passarello@campuscutino.it
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MRI Centre:

- » Resonance Health LTD - Help Desk - support@ferriscan.com
Postal Address: PO Box 1135 Nedlands, Western Australia, 6909 Australia
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Ph.: +61 08 9285 300

**We would inform you that the new fax number for DEEP-2 pharmacovigilance is:
+39 080 9909321**