

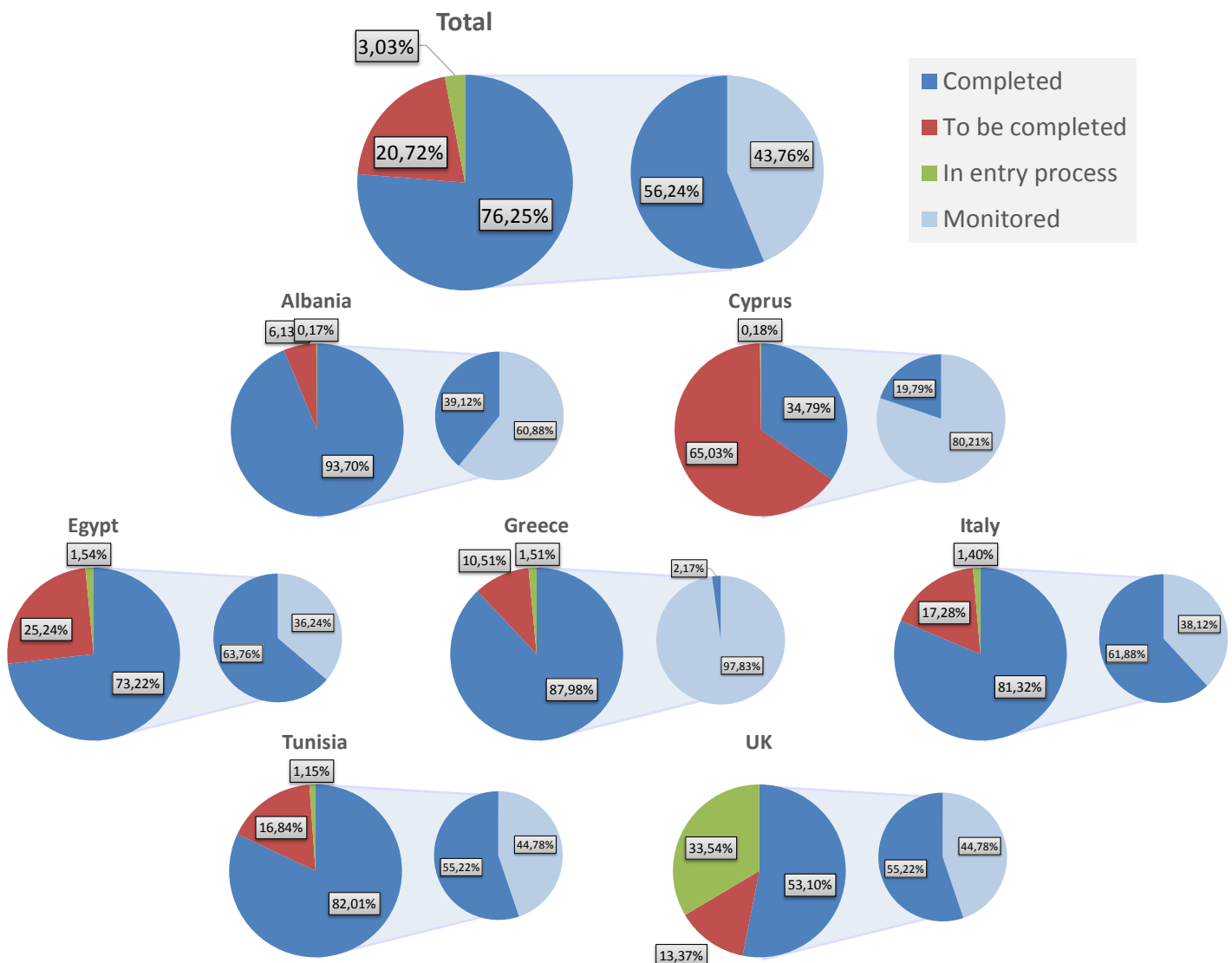


DEEP-2 STUDY NEWSLETTER ISSUE 26 - MARCH/APRIL 2017

Dear DEEP-2 Investigators,
**in this newsletter we would like to direct your main efforts on a careful
IMPs' accountability and disposal planning.**

e-CRF Form Review Status at different centres

The Trial Management Team wishes to remind Investigators to complete and validate e-CRF within 7 days from each patient visit. Moreover, as requested by the Monitoring Plan, all CRAs, appointed to each study center, are kindly invited to continue performing a strict monitoring activity at the sites.



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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Frequently Asked Questions (FAQs)

Once the dated and signed “Minutes of IMPs’ forwarding for destruction” has been sent to the Drug Manager, is the disposal process ended?

No, the Hospital pharmacy has to issue a **certificate of destruction** to be sent to the Drug Manager (at: drugmanagement@deep-project.net).

Can the Pharmacy destroy the unused bottles without a prior CRA’s accountability verification?

No. As stated in the **SD.046 “Standard Operating Procedure on Disposal of IMPs in DEEP-1 and DEEP-2 studies”** all the unused/used/partially used bottles have to be verified by CRA. Only after CRA’s accountability verification they can be destroyed.

Study Conduct

At this point of the study conduction, most of the experimental centers have completed the DEEP-2 clinical trial. For this reason, the attention needs to be conveyed on

» **Filling the e-CRF:**

1. **Record** all the collected study data in each patient’s schedule
2. **Solve** all the pending queries arisen from the CRAs. Please be noted that the updated e-CRF is an essential tool for the CRA during the IMPs’ accountability.

» **Drug Accountability:** Please pay attention to the correct fulfillment of the Drug Dispensing and Accountability logs of DFP and DFX.

» **IMP Disposal Procedure:** It is composed of three key steps:

1. Filling in the “Destruction Authorization Request” form of the unused/used/partially used bottles of Deferiprone and boxes of DFX after accountability verification performed by the CRA during the MOV;
2. Sending the completed request to the Drug Manager (at: drugmanagement@deep-project.net) to receive the green light for the disposal;
3. Sending the dated and signed “**Minutes of IMPs’ forwarding for destruction**”, once the IMPs are delivered to the company in charge for the disposal.

In this newsletter, we will focus on the correct fulfillment of the “Destruction Authorization Request”. Following is reported a guideline about its compilation.



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In the first table on the top of the form

CONTROLLED IMPs' DESTRUCTION AUTHORIZATION REQUEST		
<i>Date:</i>	<i>Centre Id:</i>	<i>Destruction Request N.:</i>
<i>Principal Investigator (name, surname):</i>		
<i>Telephone:</i>	<i>Email:</i>	

- **The center ID:** It is the ID of the center
- **Destruction Request No.:** It is a progressive number of the disposal procedure performed at the site. For example, it will be 01 in case it is your first disposal.
- **Principal Investigator (PI):** name, surname
- **Telephone:** telephone number of the PI
- **Email:** Email address of the PI

In the second table (starting from right):

Batch [N°]	Expiry Date	IMP [Name and Dosage]	N°Bottles (Deferiprone) or N°Tablets (Deferasirox)	Quantity [ml (Deferiprone) or mg (Deferasirox)]	Reasons for destruction	Patient Code

- **Patient Code:** It is the Patient ID
- **Reasons for destruction:** If the IMPs are expired, you can write: **"Expired IMPs- VERIFIED BY CRA"**. In case the IMPs have not been dispensed to any patient, please write **"Unused Medication-VERIFIED BY CRA"**. If the IMPs have previously been dispensed to the patients, you can write "Returned IMPs-VERIFIED BY CRA"
- **Quantity (ml/mg):** It is the total amount of all the residual volume (ml or mg) of the IMP with the same Batch Number
- **No. Bottles (on the Destruction Authorization Request of the DFP):** It is the number of verified bottles with the same Batch Number
- or
- **No. Tablets (on the Destruction Authorization Request of the DFX):** It is the number of verified tablets with the same Batch Number
- **IMP (name and dosage):** In case of DFP, you have to write "Deferiprone 80 mg/ml". In case of DFX, you can write "Deferasirox 125 mg" or "Deferasirox 250 mg" or "Deferasirox 500 mg" on the basis of the dosage of the specific Batch Number
- **Expiry Date:** date of expiration of the related Batch Number
- **Batch Number:** as reported on the labels

			TOT.

- **TOT.** (at the end of the table): Report the total amount of the bottles/tablets and their quantities expressed in mg/ml to be disposed

At the bottom of the form

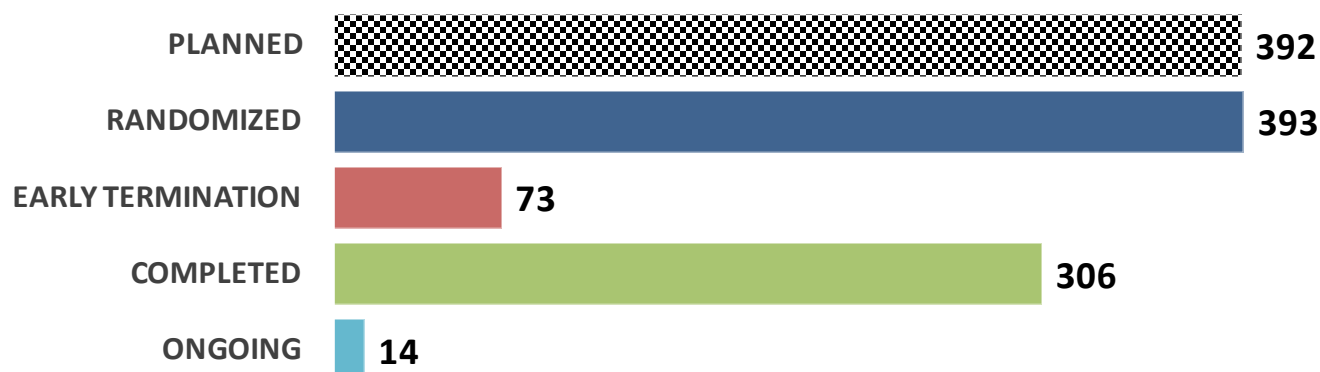
In case of Deferiprone please indicate each "Treatment n.":

Please be noted that in case of Deferiprone you have to fill in the above section reporting **all the Treatment Numbers** of the bottles to be destroyed.



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Patients' Status DA AGGIORNARE



Site ID	PI	Planned	Randomized	Early termination	Completed	Ongoing
ITA/01	Maggio	10	11	0	6	5
EGY/02	El-Beshlawy	130	133	39	94	0
GRE/03	Kattamis	12	11	2	8	1
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	73	306	14



**DEFERIPRONE
EVALUATION IN
PAEDIATRICS**



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Study Contacts

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

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Trial Management Team:

- » Clinical Research Coordinator: **Gabriele Morselli** - gmorselli@cvbf.net
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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

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MRI Centre:

- » Resonance Health LTD - Help Desk - support@ferriscan.com

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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