

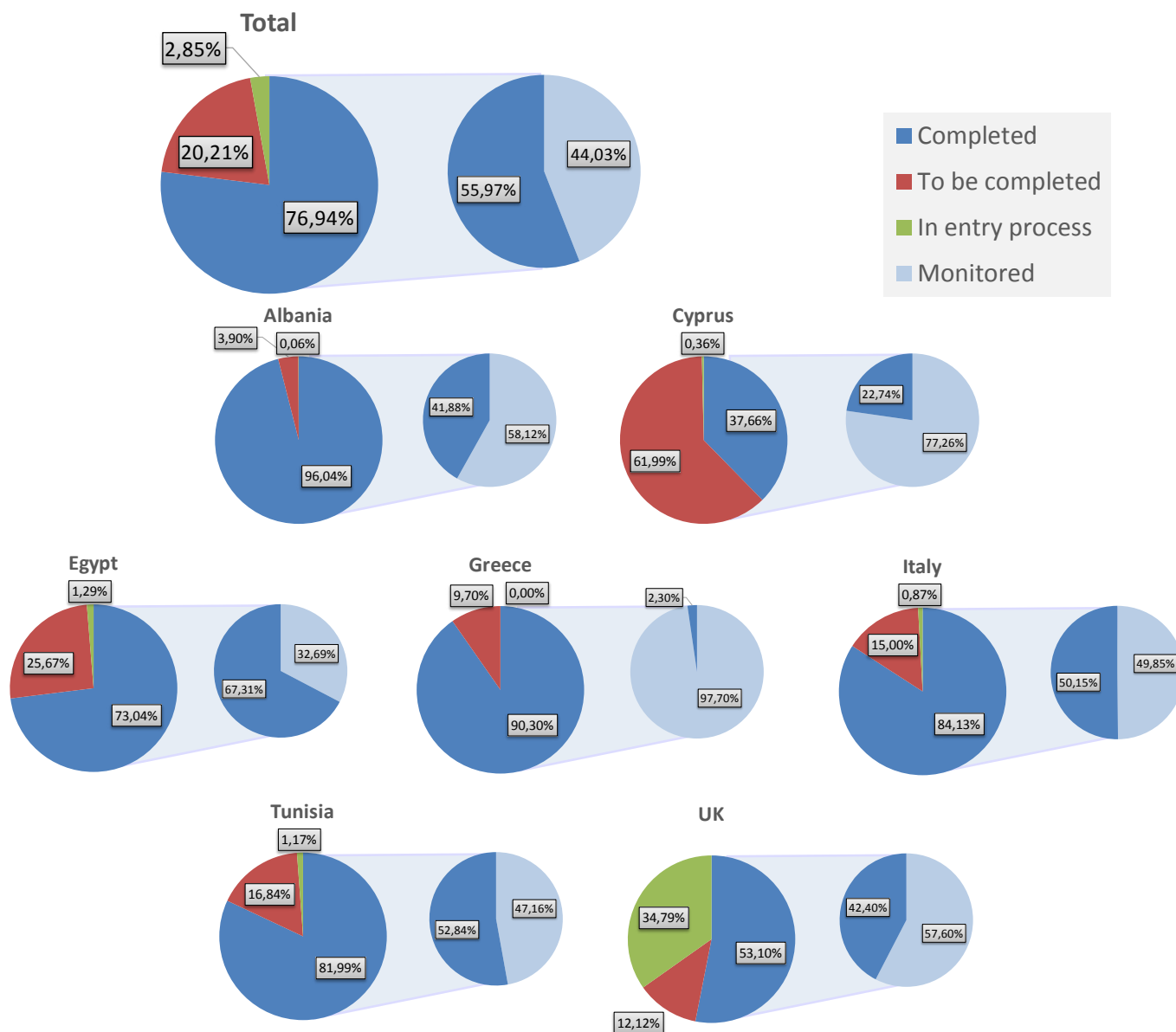


## DEEP-2 STUDY NEWSLETTER ISSUE 28 - JUNE/JULY 2017

**Dear DEEP-2 Investigators,**  
**in this newsletter we would like to focus the attention on the execution of the IMPs' disposal procedures.**

### 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.



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.

## DEEP-2 STUDY NEWSLETTER ISSUE 28 - JUNE/JULY 2017

### Study Conduct

As concerns the IMPs' disposal procedures, we would like to highlight the importance of:

- » the correct filling of the **Drug Dispensing and Accountability log** made by the PI, which is a precious tool for the writing of the Controlled IMPs' Destruction Authorization Request,
- » the monitoring by the CRA of all data available on the different paper and digital forms, granting the correspondence between the data in the **Drug Dispensing and Accountability log** and those in the e-CRF,
- » the accountability of the IMPs made step by step by both, PI and CRA, that will help you in an easier compilation of the **Controlled IMPs' Destruction Authorization Request**.

The table below resumes the status of the disposal process in each clinical center related to Deferiprone and Deferasirox.

The legend describes:

- » in **green** the centers that successfully ended the disposal of all those IMPs available in place,
- » in **yellow** the centers in which the disposal process is on going, as in case of:
  1. partial disposal of the IMPs at the center,
  2. IMPs already withdrawn from the center to be disposed by the Sponsor.
- » in **red** the centers that have not performed the disposal yet.

SITE ID	DEFERIPRONE STATUS	DEFERASIROX STATUS
ITA/01		
EGY/02		
GRE/03		
ALB/04		
CYP/05		
ITA/06		
TUN/07		
ITA/08		
ITA/09		
ITA/10		N/A
ITA/11		N/A
ITA/12		N/A
ITA/13		N/A
ITA/14		
ITA/15		

SITE ID	DEFERIPRONE STATUS	DEFERASIROX STATUS
ITA/16		
ITA/17		
UK/18		
UK/19		
UK/20		N/A
EGY/23		
EGY/24		
ALB/31		

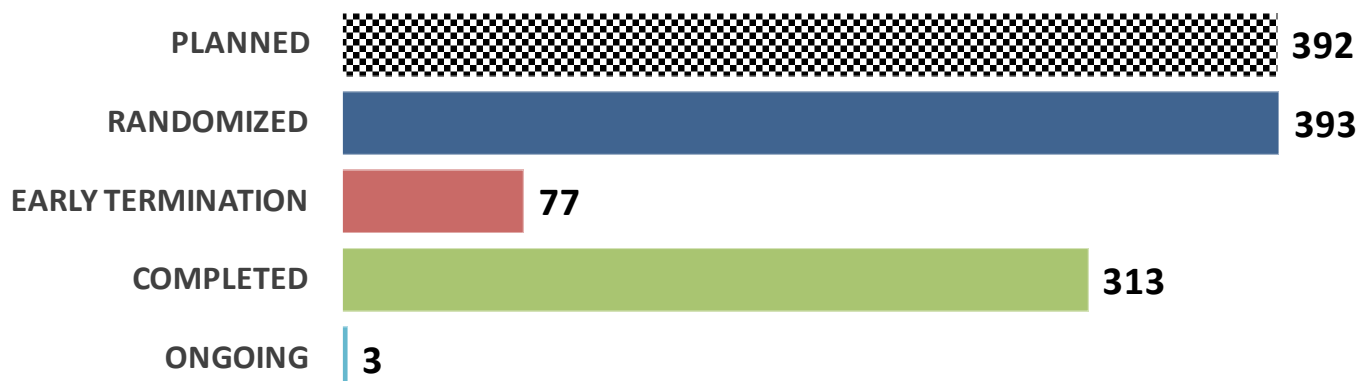
As you can see, the 77% of the centers has not already begun the disposal of the DFX and the 48% has not begun the disposal of the DFP yet.

Your efforts will be precious to turn the **red** or **yellow** lights in **green** lights and lighten your centers up of the IMPs.



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### Patients' Status



Site ID	PI	Planned	Randomized	Early termination	Completed	Ongoing
ITA/01	Maggio	10	11	0	11	0
EGY/02	El-Beshlawy	130	133	39	94	0
GRE/03	Kattamis	12	11	3	8	0
ALB/04	Kreka	20	27	2	25	0
CYP/05	Christou	12	8	7	1	0
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	15	3
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	9	14	0
ALB/31	Zaka	12	12	0	12	0
<b>TOTAL</b>		<b>392</b>	<b>393</b>	<b>77</b>	<b>313</b>	<b>3</b>



## DEEP-2 STUDY NEWSLETTER ISSUE 28 - JUNE/JULY 2017

### Frequently Asked Questions (FAQs)

#### What if the patient didn't return the IMPs?

The CRA has to:

1. report an asterisk near the treatment number in the **Drug Dispensing and Accountability Log**, write below the table: "The patient didn't return the bottle", then date and sign it,
2. collect the deviation to the protocol as stated in the **SD.060 "Standard Operating Procedures for handling deviations and violations"**.

The PI has to:

1. make a statement, signed by the PI, declaring that some IMPs didn't return, specifying the batch number, the expiration date, the dispensation visit and the reason.

### Study Contacts

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

#### Trial Leader:

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#### Trial Coordinating Investigator:

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#### Trial Management Team:

- » Clinical Research Coordinator: **Gabriele Morselli** - [gmorselli@cvbf.net](mailto:gmorselli@cvbf.net)
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- » Administrative Manager: **Marina Montanaro** - [mmontanaro@cvbf.net](mailto:mmontanaro@cvbf.net)

#### Regulatory Submission Manager and Clinical Trial Archivist:

**Elisa Cattani** - [ecattani@cvbf.net](mailto:ecattani@cvbf.net)

#### Pharmacovigilance:

- » Safety Contact: **Cristina Manfredi** - [pharmacovigilance@deep-project.net](mailto:pharmacovigilance@deep-project.net)
- » Qualified Person for Pharmacovigilance: **Mariagrazia Felisi** - [mariagraziafelisi@cvbf.net](mailto:mariagraziafelisi@cvbf.net)
- » Medical Monitor: **Maria Marsella** - [mariamarsella@deep-project.net](mailto:mariamarsella@deep-project.net)

#### Ferritin Evaluation Centers:

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#### MRI Centre:

- » Resonance Health LTD - Help Desk - [support@ferriscan.com](mailto: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**