DEFERIPRONE EVALUATION IN PAEDIATRICS

This project has received funding from the European's Union's Seventh Framework Programme for research, technological development and demonstration under Grant Agreement n° 261483

DEEP-2 STUDY NEWSLETTER
ISSUE 30 - OCTOBER/NOVEMBER 2017

Dear DEEP-2 Investigators,
we are at the final rush carrying out the final activities of the study!

Closure Study Activities

At this phase of the DEEP-2 study, the Investigators, the CRAs and members of the study team are involved in performing the **closure activities** with the aim to properly close down the experimental sites and to ensure the **integrity of all study data** that should meet the protocol-specified parameters and comply with the GCP requirements:

- the **Investigators** have to properly solve all the queries arisen by the CRAs, complete and validate all the e-CRF sections that are still empty or in entry process;
- the **CRAs** have to perform the **Close Out Visits** (COVs) at the experimental centers. During the COVs, the CRAs are responsible for:
  - » reviewing all the data in the e-CRF ensuring that all queries have been appropriately resolved,
  - » verifying that all SAEs have been notified to the PharmacoVigilance Team and recorded in the Adverse Event log of the e-CRF,
  - » ensuring that all documents required to be retained by the Investigators (including Informed Consent Forms and all study specific forms) are available, properly completed and filed in the Investigator's Folder (IFs),
  - » finalizing the process of Investigational Medicinal Products' (IMPs) destruction in coordination with the Drug Manager,
  - » collecting original or copy as appropriate) of study documentation for Trial Master File (TMF),
  - » ensuring that all trial closure communication (e.g. to the Ethics Committee) have been sent to all who are concerned;
- the **Data Manager** has to perform the data cleaning activities with the aim to ensure that data on the e-CRF are complete, reliable, and processed correctly;
- the **Drug Manager** has to conclude all the activities of the IMPs' destruction process in coordination with the CRAs and the site personnel;
- the **Clinical Trial Archivist** (CTA) has to review site specific TMF before COVs.

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.

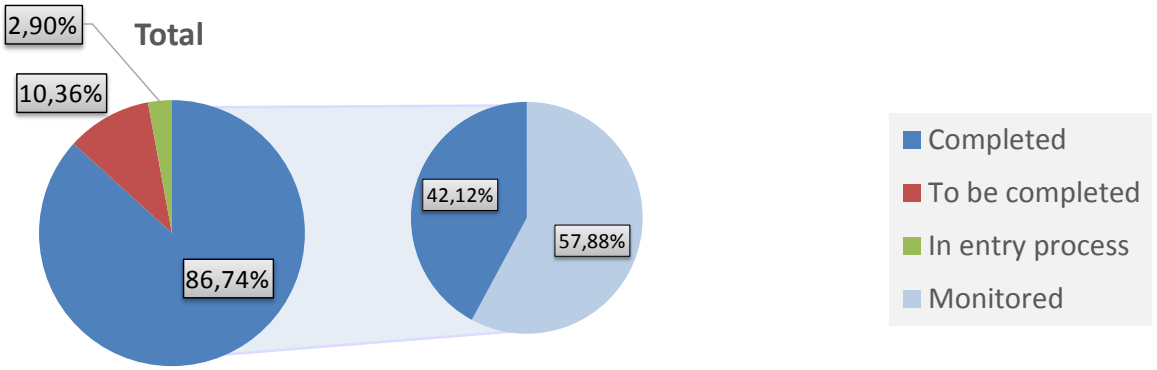
DEFERIPRONE EVALUATION IN PAEDIATRICS

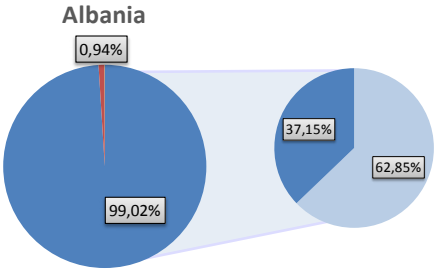
This project has received funding from the European's Union's Seventh Framework Programme for research, technological development and demonstration under Grant Agreement n° 261483

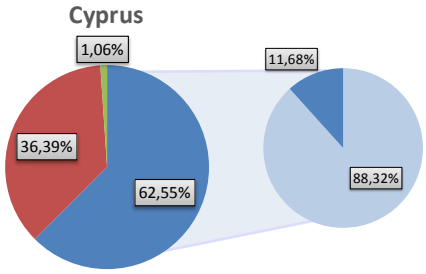
DEEP-2 STUDY NEWSLETTER
ISSUE 30 - OCTOBER/NOVEMBER 2017

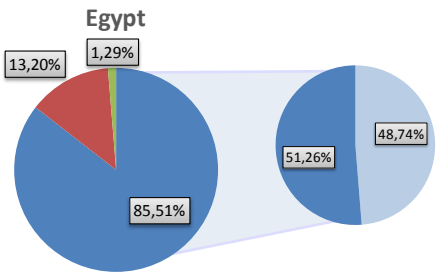
e-CRF Form Review Status at different centres

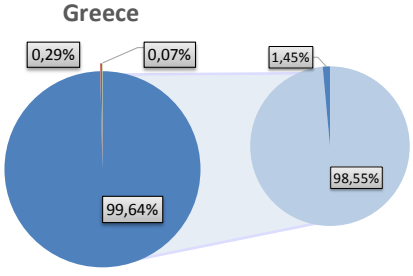
The Trial Management Team wishes to remind Investigators **to correctly complete and validate all data in the e-CRF sections** to allow the CRAs appointed to each study center to perform the check during the monitoring visits.

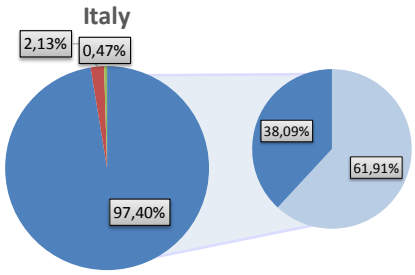


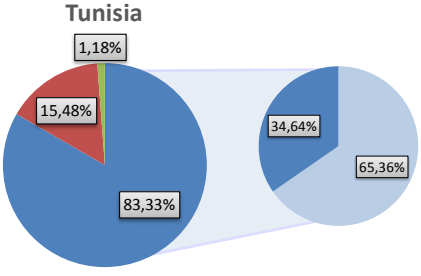


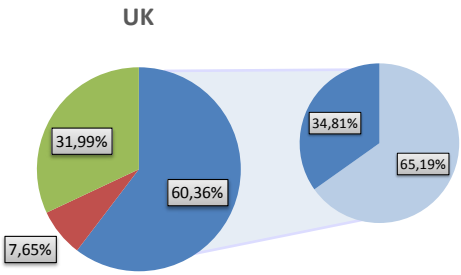












DEFERIPRONE EVALUATION IN PAEDIATRICS

This project has received funding from the European's Union's Seventh Framework Programme for research, technological development and demonstration under Grant Agreement n° 261483

DEEP-2 STUDY NEWSLETTER
ISSUE 30 - OCTOBER/NOVEMBER 2017

Patients' Status

Site ID	PI	Planned	Randomized	Early termination	Completed	SAEs confirmed at COV	COVs' Status
ITA/01	Maggio	10	11	0	11		Planned on 12 Dec 2017
EGY/02	El-Beshlawy	130	133	39	94		To be planned
GRE/03	Kattamis	12	11	3	8	10	Performed on 18/10/2017
ALB/04	Kreka	20	27	2	25		To be planned
CYP/05	Christou	12	8	7	1		To be planned
ITA/06	Filosa	14	14	4	10		Planned on 4-5/12/2017
TUN/07	Bejaoui	30	56	2	54		To be planned
ITA/08	Putti	9	9	1	8	7	Performed on 6/11/2017
ITA/09	Del Vecchio	12	6	0	6	0	Performed on 23/11/2017
ITA/10	Cuccia	4	3	3	0		Planned on 11/12/2017
ITA/11	Bisconte	4	1	0	1		To be planned
ITA/12	Commendatore	6	1	0	1	tbc	Performed on 1/12/2017
ITA/14	Cosmi	5	5	1	4	3	Performed on 16/11/2017
ITA/15	Origa	7	5	2	3	tbc	Performed on 29-30/11/2017
ITA/16	Casini	4	3	0	3	0	Performed on 2/8/2017
ITA/17	Caruso	6	2	0	2		To be planned
UK/18	Telfer	20	19	1	18		To be planned
UK/19	Grant	5	4	0	4		To be planned
UK/20	Harewood	5	0	0	0		To be planned
EGY/23	Metwally Sherief	40	40	3	37		To be planned
EGY/24	Hassab	25	23	9	14		To be planned
ALB/31	Zaka	12	12	0	12		To be planned
TOTAL		**392**	**393**	**77**	**316**	**20**	

DEFERIPRONE EVALUATION IN PAEDIATRICS

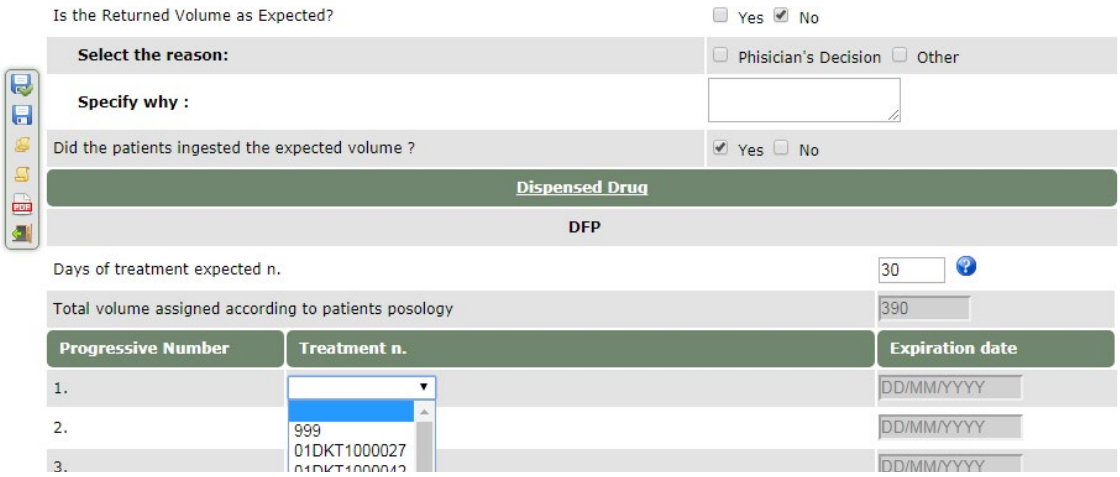
This project has received funding from the European's Union's Seventh Framework Programme for research, technological development and demonstration under Grant Agreement n° 261483

DEEP-2 STUDY NEWSLETTER
ISSUE 30 - OCTOBER/NOVEMBER 2017

What if does not appear the correct treatment number in the drop down menu of the field "returned drug" or "dispensed drug" of the drug management section on the e-CRF?

FAQ

A fake number as 999 can be chosen by the Investigators as shown below:



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

» 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 Evalutation Centers:

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

AORC Villa Sofia - Cervello, U.O.C. di Ematologia delle Malattie Rare del Sangue e degli Organi Emopoietici - Via Trabucco, 180 - 90146 Palermo, Italy

Ph.: +39 091 680 2770

» **George S. Gorgy** - gsgorgy@gmail.com

Egyptian Company For Biological Sciences (ECBS), 4 Kassem street, off Dokki street, Dokki, Giza, Egypt

Ph.: +2 02 33377593 - 333 84 684

Fax: +2 33377578 - 333 84 679

MRI Centre:

Resonance Health LTD - Help Desk
support@ferriscan.com

Postal Address: PO Box 1135 Nedlands, Western Australia, 6909 Australia

Courier Address: 278 Stirling Highway, Claremont, Western Australia, 6010 Australia

Ph.: +61 08 9285 300

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