DEFERIPRONE EVALUATION IN PAEDIATRICS

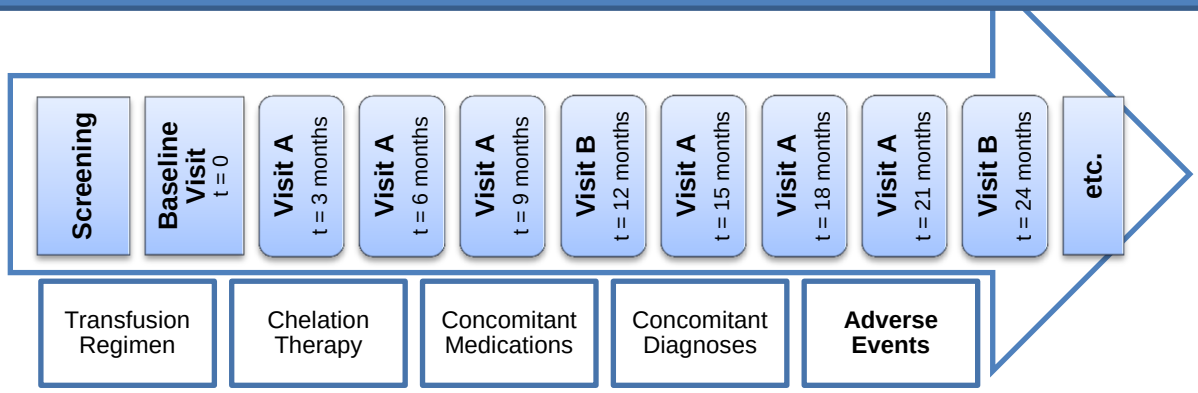
SEVENTH FRAMEWORK PROGRAMME

DEEP-3 STUDY NEWSLETTER
Issue 1 – October 2013

Dear Investigators and Study Staff, **WELCOME** to the first newsletter for the DEEP-3 study. In this and the following editions we will provide you with a study update and hints for using the e-CRF and data collection.

WHAT IS DEEP-3?

DEEP-3 is an observational study evaluating the safety of deferiprone in children with beta-thalassaemia major. We are collecting chelation therapy related patient information retro- and prospectively from start of deferiprone therapy. The focus is on **adverse events** that occurred during deferiprone therapy and that are or might be related to deferiprone.



PATIENT RECRUITMENT

At the moment we have a total of 12 actively recruiting study centres: 9x Italy, 1x Egypt, 1x Greece, 1x Albania. These 12 study centres enrolled 34 subjects into the study. Please find further details of the recruitment status in the table below:

THANKS to all investigators and study staff for your good work!

We anticipate enrolling as many subjects as possible for the first report in December 2013. Please keep up with your good work recruiting patients and documenting data!

Country	City	Centre	Subjects Screened	Subjects Enrolled	Subjects Completed
Egypt	Cairo	EG-CO-1	14	14	0
Greece	Athens	GR-AS-1	12	12	10
Albania	Tirana	AL-TA-1	3	2	2
Italy	Modena	IT-MA-1	2	2	0
Italy	Bari	IT-BI-1	1	1	0
Italy	Cosenza	IT-CA-1	1	1	0
Italy	Naples	IT-NS-1	1	1	0
Italy	Sassari	IT-SI-1	1	1	0
Italy	Lentini	IT-LI-1	0	0	0
Italy	Padua	IT-PA-1	0	0	0
Italy	Palermo	IT-PO-1	0	0	0
Italy	Palermo	IT-PO-2	0	0	0

CENTRE APPROVAL

We successfully received the ethical approval for our centre in Nicosia (Cyprus) this month. **Congratulations!**
CVBF and UKER are currently working on the ethical approvals for the centres in Tunis (Tunisia) and Cagliari and Florence (both Italy). We anticipate to also start soon in those centres.

E-CRF DATA ENTRY

We regularly receive questions regarding data entry in the e-CRF. We would like to present a few issues:

► **Concomitant Medications**: If an adverse event occurred, please record the complete medication history (**acute** and **chronic**) at the time of the event.

► **Adverse Events**: When recording an adverse event, please provide as much information as possible in the comment field (e.g. laboratory data before, during, after the event; clinical appearance)

► **End of Therapy**: Please remember to add a reason for the discontinuation of deferiprone in the comment field of "chelation therapy" (e.g. efficacy, adverse event) if a patient stopped taking deferiprone or switched to another chelation medication.

► Please note that you only have to record chelation therapy for patients ≤17 years of age. If a patient turns 18 during observation, set the last study visit on the date of the patient's birthday.

► When you are finished recording a patient, please set the subject status in the tab "Subject" to "completed". The monitoring team will then start to review your entries.

STUDY DOCUMENTS

You are looking for a specific study document? Just log in to the e-CRF! You can download the latest version of all documents in the menu *CRF Management – Download Documents*.

STUDY CONTACTS

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QUESTIONS?

If you have any questions regarding subject selection, data collection or use of the e-CRF please do not hesitate to contact the study support team at the contact details listed below. We are pleased to hear from you!