



**Newsletter Issue 18
October 2017**

**SPECIAL EDITION
from the Data Management Team**





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1. Message from the Executive Committee



Welcome to this special edition of the EUMDS newsletter.

A number of large-scale changes and updates to EUMDS have taken place over the summer and we are using this edition to explore some of these. We would like to thank you for your patience during these updates and also to thank James Doughty for all the work he has done this year in making the necessary changes to the database.

Further updates to the recording of intensive chemotherapy and stem cell transplant treatments are coming soon. Once these database changes are in place we will also issue updated follow-up data training manuals.

As always, the continued success of the study is only possible thanks to your ongoing support and hard work – the whole executive committee would like to take this opportunity to offer sincere thanks.

We are looking forward to continuing working with you all – the study is at an exciting stage.

Alex

Alex Smith
on behalf of the EUMDS Executive Committee



2. Meet the team: Data Management Centre (York)



Alex Smith

Alex is a member of the EUMDS Executive Committee, Steering Committee and Operational Team and oversees all aspects of EUMDS at the Data Management Centre in York. She provides analyses for the Steering Committee and study publications.



John Blase

John is a member of the EUMDS Operational Team. He produces database training materials and CRFs and also assists with user queries.



Ge Yu

Ge is a member of the EUMDS Operational Team and performs statistical analysis for the study. He also assists with database queries.



James Doughty

James is a programmer and built the EUMDS database. He is responsible for all updates to the database and creating user accounts.



William Curson

Will is a web developer and is responsible for the EUMDS website and creating user accounts.

For all database enquiries, please email the data management centre helpdesk:
enquiries@eumds.org



3. Database updates: a guide

Alongside the new project protocol (Version 5.1), we launched an updated version of the EUMDS database on July 3rd (eCRF), and paper Case Report Forms (CRFs) have also been updated (see section 5 - New documentation). Here we will take a brief look at the new data that should be collected.

We now distinguish 3 levels of data (each with their own fee):

1. **Core data** (*obligatory*)

Registration & follow-up CRFs (except data marked yellow, which are optional) + EQ5D

2. **Extended data** (*preferred*)

QUALMS, sample collection and health resource usage

3. **Additional data**

Collection requests for specific substudies (not further addressed in this newsletter)

3.1 Changes to eligibility and withdrawal

Patients no longer need to have lower- risk MDS to be eligible for the study – patients with higher-risk MDS, CMML and AML with <30% blasts can now be included. Please note that patients with AML with inv(16), t(15;17) or t(8;21) remain ineligible. A full list of eligible diagnoses can be found in the database training manual (core data), in the database and in the protocol V5.1 (page 11-12).

Cytogenetic data form the basis of MDS risk stratification and proper state-of-the-art treatment of MDS patients. As of February 2015 cytogenetic assessment is mandatory for inclusion in the EUMDS Registry.

If cytogenetics information is unavailable at the point of registration, this can be set as 'pending' to allow other registration data to be entered. The cytogenetics information will need to be completed at a later date (within one month). If cytogenetic data is not entered within one month of inclusion, the patient will be excluded.

Since introduction of the new protocol, if patients progress to AML, they will continue to be followed, and data should be recorded at 6-monthly intervals. Patients are now only withdrawn if they withdraw consent, die or are lost to follow-up.

3.2 Core data - changes to existing database sections

3.2.1 MDS treatment

The new database now asks for the treatment intent for each patient – a list of intent categories is provided for you to choose from.

For drug categories a range of individual drugs are provided for you to select from. If a required drug category is not available, you can contact the data management centre to request it to be added to the database.

At follow-up, response to treatment and haematological improvement should be recorded where indicated.

History of MDS Treatment	
Visit Date: 29 June 2017 EUMDS ID: TEST-C1-0149	
Treatment intent: <input type="text" value="ESA"/> Intent for stem cell transplant? <input type="text" value="No"/>	
Treatments received? <input type="text" value="Yes"/>	
Hydroxyurea: <input type="text" value="Yes"/> Start Date: <input type="text"/> Ongoing? <input type="text"/>	Hypomethylating: <input type="text" value="Yes"/> Start Date: <input type="text"/> Ongoing? <input type="text"/>
Erythropoietin: <input type="text" value="Yes"/> Start Date: <input type="text"/> Ongoing? <input type="text"/>	Azacitidine: <input type="text" value="Yes"/>
Binocrit: <input type="text" value="Yes"/>	Dosage: <input type="text"/>
Serum epo: <input type="text"/> u/l	Schedule: <input type="text"/>
Dosage: <input type="text"/>	Mode: <input type="text"/>
Schedule: <input type="text"/>	Cycles: <input type="text"/>
Eprex: <input type="text"/>	Decitabine: <input type="text"/>
Retacrit: <input type="text"/>	Immunosuppressive: <input type="text"/>
NeoRecormd: <input type="text"/>	G-CSF: <input type="text"/>
Aranesp: <input type="text"/>	Prednisone: <input type="text"/>
ESA biosimilars: <input type="text"/>	Lenalidomide: <input type="text"/>
Other: <input type="text"/>	Intensive chemotherapy: <input type="text" value="No"/>
	Other Agent (1): <input type="text" value="Yes"/> Class: <input type="text"/> Start Date: <input type="text"/> Ongoing? <input type="text"/>
	Other Agent (2): <input type="text"/>
	Other Agent (3): <input type="text"/>
	Clinical Trial? <input type="text" value="No"/>

3.2.2 General medical history and concomitant disease

The list of conditions of interest has been reduced and the database now requires only the year to be provided for start and stop dates.

3.2.3 Concomitant treatment

The list of treatments of interest has been reduced and the database now requires only the year to be provided for start and stop dates. For a limited number of treatments (e.g. anti-diabetic), more detail on treatment type and dosage is required.

Visit Date: 29 June 2017 EUMDS ID: TEST-C1-0149	
Cardiac Disease	Previous Myocardial Infarction: <input type="text" value="Yes"/> Start Date (dd/mm/yyyy) <input type="text"/> Ongoing? <input type="text"/> Stop Date (dd/mm/yyyy) <input type="text"/>
	Angina: <input type="text" value="No"/>
	Arrhythmia: <input type="text" value="No"/>
	Heart failure requiring drug treatment: <input type="text" value="No"/>
	Heart valve disease: <input type="text" value="No"/>
	Ejection fraction ≤ 50%: <input type="text" value="No"/>
Visit Date: 29 June 2017 EUMDS ID: TEST-C1-0149	
Anti-platelet: <input type="text" value="Yes"/> Start Date (dd/mm/yyyy) <input type="text"/> Ongoing? <input type="text"/> Stop Date (dd/mm/yyyy) <input type="text"/>	Corticosteroids: <input type="text" value="No"/>
Anti-coagulant: <input type="text" value="No"/>	Oestrogen replacement: <input type="text" value="No"/>
Cholesterol lowering: <input type="text" value="No"/>	Other hormonal therapy: <input type="text" value="No"/>
Diuretics: <input type="text" value="No"/>	Proton pump inhibitors: <input type="text" value="No"/>
Comments: <input type="text"/>	

3.2.4 Laboratory data

Data for more subtypes of white blood cell have been added and data relating to biological samples for correlative samples has been moved to the Biological Samples for Correlative Studies section of the database.

Visit Date: 29 June 2017 EUMDS ID: TEST-C1-0149	
Date Blood:	<input type="text"/>
Blasts:	<input type="text"/> %
Haemoglobin(Hb):	<input type="text"/> <input type="text"/>
WBC:	<input type="text"/> <input type="text"/>
Platelets:	<input type="text"/> <input type="text"/>
RBC:	<input type="text"/> 10 ¹² /l
MCV:	<input type="text"/> fl
Neutrophils:	<input type="text"/> %
Lymphocytes:	<input type="text"/> %
Monocytes:	<input type="text"/> %
Eosinophils:	<input type="text"/> %
Basophils:	<input type="text"/> %
CRP:	<input type="text"/> µg/L
Reticulocytes:	<input type="text"/> %
Albumin:	<input type="text"/> g/L
Immature granulocytes:	<input type="text"/> %
Erythropoietin:	<input type="text"/> U/l
LDH:	<input type="text"/> iU/l
ALT:	<input type="text"/> iU/l
AST:	<input type="text"/> iU/l
Serum Creatinine:	<input type="text"/> <input type="text"/>
Creatinine Clearance:	- (recalculated upon save)
Serum Glucose:	<input type="text"/> <input type="text"/>
Serum Iron:	<input type="text"/> <input type="text"/>
Iron Binding Capacity:	<input type="text"/> <input type="text"/>
Ferritin:	<input type="text"/> <input type="text"/>
Transferrin sat. level:	- (recalculated upon save)

3.2.5 Bone marrow assessment

For both bone marrow aspirate and biopsy samples, you are now required to record the dysplasias found and the degree of cellularity. For biopsy samples, you will also need to record the degree of fibrosis.

BONE MARROW ASSESSMENT	
Any aspirate assesment?:	<input type="text" value="Yes"/>
Aspirate:	
Date:	<input type="text"/>
BM Blasts:	<input type="text"/> %
Ringed sideroblasts:	<input type="text"/> %
Dysplasias:	<input type="checkbox"/> Dyserythropoiesis <input type="checkbox"/> Dysgranulopoiesis <input type="checkbox"/> Dysmegakaryopoiesis
Cellularity:	<input type="text"/>
Any biopsy assesment?:	<input type="text" value="Yes"/>
Biopsy:	
Date:	<input type="text"/>
BM Blasts:	<input type="text"/> %
Ringed sideroblasts:	<input type="text"/> %
Degree of fibrosis:	<input type="text"/>
Dysplasias:	<input type="checkbox"/> Dyserythropoiesis <input type="checkbox"/> Dysgranulopoiesis <input type="checkbox"/> Dysmegakaryopoiesis
Cellularity:	<input type="text"/>
CYTOGENETICS	
No. of normal metaphases:	<input type="text"/>
No. of abnormal metaphases:	<input type="text"/>
IPSS Cytogenetics:	<input type="text"/>
IPSS-R Cytogenetics:	<input type="text"/>
ISCN karyotype string:	<input type="text"/>
Date of Assessment:	<input type="text"/>
	[Select from list]
	[Select from list]

3.2.6 Cytogenetics

Fields are now present for the recording of IPSS and IPSS-R cytogenetic information. This data should be completed as soon as possible, particularly for the registration visit.

3.3 Extended data

Protocol 5.1 classifies some data as extended - collection of this data is optional but strongly encouraged. These are presented in the Registration and Follow-up paper CRFs with a yellow background.

3.3.1 Biological samples

A new paper CRF (see section 5) and database section are provided for collection of biological sample data. This section requires collection of information relating to samples provided by the patient as well as information about the patient's re-consent and preferences for reporting of unsolicited findings.

Collection of certain samples is optional (protocol V5.1 page 13-14, 15), however, information for all samples that have been collected needs to be recorded.

Each patient's re-consent and preferences for reporting of unsolicited findings needs to be recorded as soon as possible after implementation of protocol V5.1 at your site.

3.3.2 Health resource usage

A new paper CRF (see section 5) and database section are provided for collection of health resource usage data. This section requires collection of information relating to hospitalisation events, emergency visits, outpatient visits and primary care appointments.

3.4 Implications for sites working with protocol 2.2

Currently, protocol V2.2 and 5.1 are in use in parallel. Most sites have implemented protocol 5.1 whilst the remaining sites are still working with protocol 2.2 (until 5.1 is approved and implemented).

The new version of the database is adapted for data according to protocol 5.1, having implications for sites working with protocol 2.2. For example:

- Sites working under protocol 2.2 are barred from including high-risk MDS patients (until ethical approval of 5.1 at the site)
- The Biological Samples section is adapted to 5.1 and its new consent form. Under 2.2, the following should be completed in the CRF*:
 - Unsolicited findings: no technologies with a chance of unsolicited findings (option 3)
 - Withdrawal: all items should be completed with the 'unknown/?' response
 - Only serum can be answered positively (or negatively, if not collected).

*Once 5.1 is approved for the site, patients will need to provide re-consent and the data mentioned here should be updated accordingly.



4. Common queries and top tips

How do I access the new database?

In exactly the same way as before - by visiting www.eumds.org and logging in. Your login details have not changed.

Can I practice entering data in the updated database?

Yes - the Test Centre has been updated to reflect the changes to the database. All registered users have access to the Test Centre.

The database is telling me data is missing but this is optional data - what should I do?

We are in the process of updating the warnings and incomplete visit summary to allow for non-completion of optional data - in the meantime, you can disregard this.

Do I need to know exact dates for concomitant disease and treatments?

No - we now only require you to enter the year for start and stop dates for concomitant diseases or treatments. As before, if you do not know the year, you can still enter a missing value code.

I have no data to enter for QUALMS/Health Resource Usage/Samples - what should I do?

If you have no data to enter for QUALMS (e.g. if QUALMS is not available in your country), Health Resource Usage or Samples, you can leave these areas of the database blank.

Where is the save button on the new Health Resource Usage page?

There is no save button on this page - data is saved automatically whenever you add a new entry or make an edit to existing data.

My centre is still working under protocol V2.2 - how do I withdraw a patient that has progressed?

If a patient progresses to high-risk MDS or AML, select 'Lost to follow up' on the outcomes page of the database and add a comment to explain the patient's progression and withdrawal under protocol version 2.2. (*Under protocol V5.1, these patients should not be withdrawn*).

Having trouble logging in?

Don't copy and paste your details into the database - try typing them in instead. If you enter your details incorrectly three times your account will be locked - email us to unlock it.



5. New documentation

All new documents are available via the Documents section of the database. The new paper format CRFs are colour coded to help identify the correct document (details below).

Protocol

Version 5.1

Clinical Study Protocol

Protocol Number 5.1

Clinical Study Protocol

Study Title:
A prospective, multicentre European Registry for newly diagnosed patients with Myelodysplastic Syndromes (MDS), including acute myeloid leukaemia with 20-30 percent marrow blasts (former RAEB-II), and Chronic Myelomonocytic Leukemia (CMML).

Short Title:
A prospective, multicentre European Registry for newly diagnosed patients with Myelodysplastic Syndromes (EUMDS).

Protocol Number:
5.1

Protocol Status:
Final (modification of protocol V2.2)

Author(s):
Theo de Witth, David Bowen, Eva Hellström-Lindberg, Pierre Fenix, Argita Symeonidis, Saskia Langemeijer, Corine van Marrewijk

Sponsor:
Radboud university medical center, Nijmegen

Release Date:
18th of April 2016
February 2017: correction of typing errors

Number of Pages:
41

Version 5.1 | 18 April 2016
Confidential | Page 1

Current protocol for EUMDS

Data Training Manual Core Data (Registration)

Version 3, June 2017



Training manual for registration visits
(follow-up manual will be available soon)

**Case Report Form
Core Data (Registration)**

Version 17, June 2017

Local ID EUMDS ID
Visit number Visit date

LeukemiaNet[®]
EUMDS
REGISTRY

CASE REPORT FORM (REGISTRATION)
CORE DATA SET

EUMDS CRF (Registration) Version 17, June 2017

Paper CRF for registration visit core data.

Blue logo.

**Case Report Form
Core Data (Follow-up)**

Version 17, June 2017

Local ID EUMDS ID
Visit number Visit date

LeukemiaNet[®]
EUMDS
REGISTRY

CASE REPORT FORM (FOLLOW UP)
CORE DATA SET

EUMDS CRF (Follow-up) Version 17, June 2017

Paper CRF for follow-up visit core data.

Blue outline logo.

**Case Report Form
Biological Samples for Correlative
Studies (Registration & Follow-up)**

Version 17, June 2017

Local ID EUMDS ID
Visit number Visit date

LeukemiaNet[®]
EUMDS
REGISTRY

CASE REPORT FORM (REGISTRATION & FOLLOW UP)
BIOLOGICAL SAMPLES FOR CORRELATIVE STUDIES

EUMDS CRF (Biological Samples) Version 1, March 2017

Paper CRF for registration and follow-up visit biological sample data.

Red logo.

**Case Report Form
Health Resource Usage
(Registration & Follow-up)**

Version 17, June 2017

Paper CRF for registration and follow-up visit health resource usage data.

Green logo.

**Case Report Form
Quality of Life in Myelodysplasia
(Registration & Follow-up)**

Version 17, June 2017

Paper CRF for registration and follow-up visit QUALMS data.

Purple logo.

Where do you access the new documentation?

Via the Documents link in the top menu from any screen in the database.

European MDS Registry

Documents | Publications | Help | FAQs | Announcements [03/02/2017] | Print | Logout

Welcome John Blase
TEST CENTRE 1, TEST COUNTRY. Logged on as Project Manager

Summary

- Settings
- Reports
- Centre Administration
- EGU Admin.
- Project Admin.
- My Account

Recruitment Summary

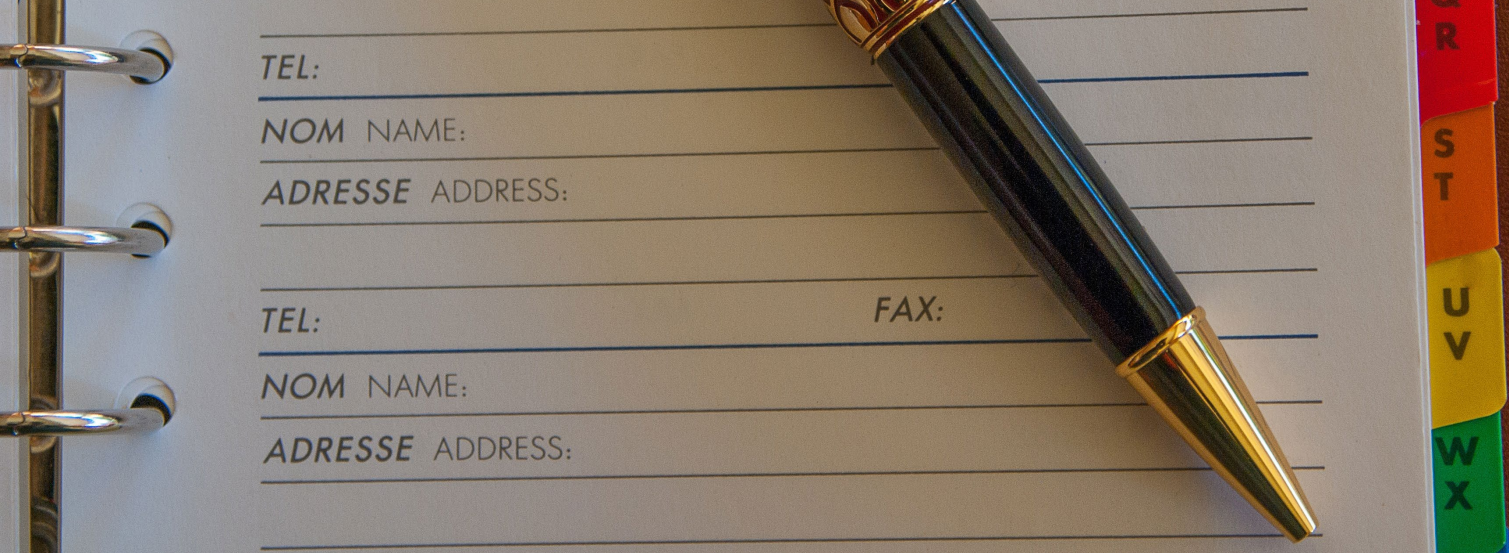
Recruitment target for country: 500

143 patients on record, of which 81 are active.

80 patient due a visit, of which 77 are overdue.

Total warnings: 26

Fe
312 incl.



6. Centre contact details and affiliation information

A section 'Contact details for centre' has been added to the database (as announced in the previous Newsletter [No. 17, June 2017]). As we do not have complete and up-to-date contact information for all participating sites, many medical specialists and others involved in EUMDS do not receive our communications - e.g. newsletters, (sub) study information, invitations.

When this new section is completed, we will be able to send EUMDS communication(s) to all local site investigators and coordinators. This information is also important as it will be used to acknowledge your contribution in manuscripts arising from the EUMDS Registry. Contact details will only be used for internal EUMDS purposes and will not be provided to external parties.

Contact information of the 'Local Principle Investigator' as well as 'Local Study Coordinator' should be completed by one person with a registered log-in for each participating site (or the country coordinator), and should be kept up to date. As this information is also used for affiliations, we ask you to provide the formal local as well as English names of the hospital and the department.

Additional local staff involved in the EUMDS Registry who want to receive Newsletters and other EUMDS communications, but do not have a registered log-in can be added at 'Administrator email addresses for centre'.

How to access, enter or edit centre contact details

1. Click Centre Administration on the home screen
2. Click Edit contact addresses for centre
3. Complete the form
4. Return to home screen
5. Click Administrator email addresses for centre to add further local staff who would like to receive EUMDS communications





MDS EUROPE

mds-europe.eu

All the MDS-related information you need, in one place

discussion articles
publications
MDS-RIGHT
news and events
and more

