



MID Frail

SEPTEMBER 2013

Welcome to the latest issue of the MID-Frail newsletter!

This essential reading brings you a round-up of news on the latest events in this exciting pan-European study on diabetes in older people. In this issue...

- New Team Members
- Study Status
- The Protocol Manuscript

New Look

We are pleased to bring you the latest edition of the MID-Frail newsletter. As you may have noticed, we have refreshed the design to make it more modern and approachable. We hope that you like it. Why not tell us what you think? Read-on to see the latest news and updates on our study.

A lot of changes have taken place on the "MID-Frail team". We have a new Clinical Project Manager, María Ángeles Martín from Fundación para la Investigación Biomédica del Hospital Universitario de Getafe, and a new Communications Project Manager, Severina Moreira from Niche Science and Technology. Also new to the team is Mike Howkins who will be providing guidance on pharmacovigilance.

New Team Members

María Ángeles Martín

Please join us in welcoming María Ángeles Martín who joined the MID-Frail team at Fundación para la Investigación Biomédica del Hospital Universitario de Getafe, as the Clinical Project Manager. María will act as the primary contact for all MID-Frail project-related activities and is happy to be contacted via

email mmsierrasanagustin@salud.madrid.org
or phone [+34 91 6839360](tel:+34916839360)

María will be replacing Marta Pavía Hernández and is highly experienced in clinical operations having previously managed both public and private sector-sponsored clinical studies. María is responsible for ensuring that MID-Frail runs smoothly. To achieve this, María will be in regular contact with everyone helping to co-ordinate the many study activities.



New
Team Members
continued...

Severina Moreira

Severina Moreira is a key member of the medical writing team at Niche Science and Technology and has been with the company for over 2 years. Highly experienced in medical communications and scientific consulting, Severina has written, edited and published many manuscripts in the areas of hepatitis C infection, respiratory, diabetes and dermatology as well as on pure laboratory research.

Severina is also an experienced post-doctoral scientist and has authored several journal articles. Please let Severina know every time you prepare an abstract, poster or oral presentation for a conference. As Niche is serving as a repository of all publications, you can also contact Severina to obtain information on what the other partners have presented. Severina is happy to be contacted by

email severina.moreira@niche.org.uk
or phone +44 (0)20 8332 2588



New
Team Members
continued...

Mike Howkins

Mike Howkins brings a wealth of experience acquired by working in both the National Health Service (United Kingdom) and the Pharmaceutical Industry. He has held a variety of senior management roles and positions within the pharmacovigilance and risk management areas, including serving as Deputy EU Qualified Person for Pharmacovigilance.

Since 2006, Mike has been running his own consultancy, PROVIGILANCE® Limited. Since working as an independent consultant, Mike has conducted over 100 pharmacovigilance audits across more than 40 countries, and provided an extensive range of pharmacovigilance and quality assurance services within the pharmaceutical sector.



Study Status

The MID-Frail study is progressing at a good pace with site selection being complete in Belgium, the Czech Republic, Germany, Italy, France-Bordeaux and the United Kingdom-England.



Site selection is on-going in France-Toulouse and United Kingdom-Wales. Two Clinical Research Organisations (CROs) will manage the submission of study documentation in all countries other than Spain.

Phamos will be the CRO for the Czech Republic and Businessdecision-Lifesciences the CRO for Belgium, France, Germany, Italy and the United Kingdom. The translation of essential documents into local languages is complete and the documents were

sent to the study partners who took on the responsibility of reviewing them.

Spain appears to be leading the way with all trial sites selected and ethics approval being confirmed for every site. A third version of the protocol was submitted as an amendment in March this year. An Investigators' meeting took place on June 20th at the Hospital Universitario de Getafe in Madrid. Professor Mikel Izquierdo explained in detail the exercise

program described in the study protocol and made a demonstration with the machines that will be used. Our new Clinical Project Manager, María Ángeles Martín, made a brief presentation on the practicalities surrounding each of the sub-studies and the meeting ended with a short discussion regarding data collection and the electronic case report form (eCRF). Currently, the Spanish team is working hard to finalise all contracts with the study sites so that recruitment of subjects can be initiated soon.



gave a presentation focused on the nutritional component of the study and Professor Mikel Izquierdo reviewed the exercises to be performed by the study participants and demonstrated the equipment. Dr Mark Kelly described data collection methods and the eCRF and Julian Backhouse described the logistics surrounding the ordering, delivery and assembly of study equipment.

The MID-Frail study is also making good progress in the United Kingdom in both England and Wales. An Investigators' meeting was held at the Institute of Diabetes for Older People (IDOP) on June 4th. The MID-Frail scientific coordinator, Professor Alan Sinclair, opened the meeting with an introduction of the MID-Frail study and the MID-Frail study team. The dietician Claire Phipps

The Protocol Manuscript

You may not be aware that a manuscript describing the study protocol has been submitted to the journal 'Trials'.

The manuscript entitled 'A randomised clinical trial to evaluate the effectiveness of a multi-modal intervention in frail and pre-frail older people with type 2 diabetes: the MID-Frail study' by Professor Leocadio Rodríguez Mañas, Dr Anthony Bayer, Dr Mark Kelly, Dr Andrej Zeyfang, Professor Mikel Izquierdo, and Professor Alan Sinclair is currently under editorial review.

The screenshot shows the TRIALS journal homepage. At the top left is the TRIALS logo with an impact factor of 2.21. A search bar is located at the top right. Below the logo is a navigation menu with links for Home, Articles, Authors, Reviewers, About this journal, and My Trials. The main content area is divided into several sections: 'Articles' with a 'Latest' and 'Most viewed' filter, 'Trials reporting' with a call to action to 'Extend or update previously published trials', and an 'Editor's profile' for Curt D. Furberg. A BioMed Central advertisement is visible on the right side of the page.

A big thank you to all contributors for their hard work. We believe that this manuscript will help to raise the profile of MID Frail and will be an important reference to be included in future publications. I would also like to make a quick reminder that if you need further information or advice in MID-Frail publications and presentations, please contact Severina Moreira.

KEEP UP TO DATE

Keep up to date on all that is happening in MID-Frail: watch out for the next regular issue of MID-Frail News.

Website: www.midfrail-study.org

Facebook: [MID-Frail Clinical Study](#)