



Invest in ME Research

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Input to UKCRC ME Research Working Group Research Strategy and Building Capability and Capacity



The next meeting of the research UK Clinical Research Collaboration (UKCRC) research working group is scheduled for 14th October 2022 - only the second time Invest in ME Research has been invited to attend one of these meetings.

See **Background** to this below.

An Overview of Requirements

Professor Simon Carding, from the Quadram Institute in Norwich Research Park, has input to this planned meeting the following list of requirements that are seen as necessary to build the capability and capacity for real progress to be made for ME.

Invest in ME Research endorses all of these points. Indeed, we have made many of these same points continuously over the years as well as facilitating some of them to become reality - and these points have also been discussed by the European ME Research Group (EMERG) in discussions over the last years.

❁ Objective outcome measures need to (must) be deployed in research studies and clinical trials

Historically, too much emphasis has been placed on subjective questionnaires the outcomes of which are of limited use for comparison across studies. For our upcoming clinical trial [4], we will be using objective measures of activity and cognition to assess outcomes as well as quantitative blood-based biomarkers.

From IiMER:

The European ME Research Group (EMERG) worked with the NIH to form a working group for outcome measures following the #BRMEC10 Colloquium held in 2021.

This work is ongoing.

As Professor Carding writes above the RESTORE_ME clinical trial will use objective measures and collaboration has been set up with other departments and disciplines in Norwich Research Park to effect and analyse these measures.

A good basis is therefore becoming available for future research.

❁ Stratification of clinical subtypes and uniform acceptance and adoption of single diagnostic criteria

This is essential for comparing findings across different studies.

from IiMER

Use of standardised criteria is long overdue in research into ME.

Any research into ME that receives public funding ought to have as a pre-requisite that standard and consistent criteria have been used for stratification [5]

For the RESTORE_ME clinical trial the research criteria being used are the ICC criteria.

✿ **Inclusion of marginalised groups of patients, particularly those that have severe ME/CFS and are house/bed bound**

Extreme phenotypes can often provide unique insights into disease aetiology.

from IiMER

The charity has often stated that severely affected patients should not be excluded from research into ME where practical.

Despite limited resources this has been evident from early on in the first research project funded by Invest in ME Research the research team were involving severely affected, sometimes even travelling for a day to reach patients who would not otherwise have been included.

Some comments from the IIMEC8 international conference in 2013.

✿ **Consideration of environmental factors in disease progression**

Consideration of whether environmental factors play a role in disease progression needs to be made. To this end patients from different geographical and socioeconomic groups need to be included in studies – as diverse and as broad a group of participants as possible is needed.

✿ **Control Groups**

More thought needs to be given to control groups (beyond age/gender) and ensuring that they are appropriate for the type of study being undertaken. Healthy individuals from the same household as the patient would aid in controlling for local environmental factors in studies looking at immune, diet, microbiome aspects.

⚙️ **Funding to Reflect Multi-organ/system nature of ME**

ME/CFS is a multi-organ/system disorder and research studies to date rarely reflect that, focusing instead on one system in isolation.

Multi-disciplinary groups of researchers are needed therefore, which requires more funding than can be provided by conventional UKRI-response mode grants. Multi-partner/PI centre/programme grants are more effective in delivering impact and establishing/supporting multiple research groups working in collaboration and not competition.

from IiMER

This is one of the reasons for forming the European ME Research Group (EMERG) where experienced research teams can collaborate across disciplines and more funding could be attained due to the increased capacity offered.

EMERG has already begun this process.

⚙️ **Advocate(s) for ME research in UK funding agencies**

There is an urgent need for a strong advocate(s) for ME research in UK funding agencies. The MRC has made a faltering attempt at this but it has failed to achieve the required degree of commitment, advocacy and momentum to make a sustained impact.

from IiMER

In fact, the MRC record over the decades has been extremely poor, bordering on the inept. Despite communicating several times to Sir John Savill - CEO of the MRC [6] [7] - and being assured that this was in hand nothing tangible has been done.

There have been no worthwhile champions for ME in the agencies dispensing public funding in the UK. One can look back as far as 2003 and 2011 [8] to see words, but no actions.

This is another reason for recommending further development of the Centre of Excellence for ME in Norwich Research Park that the charity has been proposing and facilitating since 2010.

Imagine what could have been achieved if the MRC had invested in our proposal instead of spending years of ineffective sideshows and funding of the wrong type of research? [9]

An International View

Any ME/CFS research strategy needs to be outward looking and include international researchers particularly in the rest of Europe and North America – establishing links not only with researchers but funders which have, by comparison to the UK, made more significant contributions to funding ME/CFS research (e.g., USA-NIH, Netherlands)

from IiMER

Invest in ME Research has had this view since our 2nd International ME Conference in 2007. Since 2011, the charity has been organising annual international research Colloquiums bringing international researchers together [[10](#)] and has been working with European partners in the European ME Alliance (EMEA) and initiating the European ME Research Group (EMERG) and Clinicians Group (EMECC), with joint research projects being developed.

We have been talking to our Dutch colleagues over the past years and seeing them develop their research agenda and this could easily be harmonised as we have links already established [[12](#)].

We have suggested already to the UKCRC that the research agenda created in the Netherlands should be considered [[3](#)] as there is no need for reinvention and a possibility could be created to create synergy between the projects and share funding costs with a European collaborative venture.

We also suggest that the model already established and underway in the Netherlands should be considered.

International Research Community

An international annual ME/CFS research conference would be an effective means of bringing together ME/CFS researchers to promote collaborative research. The Invest in ME Research charity has been arranging annual international conferences and international research meetings for researchers since 2006, regularly bringing researchers from twenty countries (including USA and Australia) to London.

from IiMER

This is true and only the pandemic and lock downs have paused this and forced us to use online meetings.

Our international ME research Colloquiums and public conferences have brought together researchers and clinicians and allowed patients to interact [[13](#)].

We return to in-person meetings in 2023.

We have already created a family of international researchers and this group has been growing in number.

Proactively Foster Increased Research Capacity

Doctoral training programmes involving different institutions that share responsibility for individual PhD projects would be a cost-effective means of initiating and promoting collaborative multidisciplinary research programmes.

from IiMER

We have already tried to create such an environment, albeit with limited resources. PhDs funded by the charity have worked with institutes in Norway and Sweden and with the EMERG research group we have supported the development of cross-site projects. [[14](#)]

With our partners in EMEA we have offered to co-fund joint studentships that will bring institutes in multiple countries together.

The charity has also funded and involved medical students in the research.

From page 5 of our *Journal of IiMER 2015* - describing two IiMER funded medical students (Navena and Bharat) - [[15](#)]

"The charity has for a long while stated the importance of international collaboration and we are pleased that Professor Maureen Hanson enabled Navena to spend over three months at Cornell University in Itacha USA to learn about their gut microbiota research.

Meanwhile Bharat is currently working intensely with Professor Angela Vincent in her laboratory at Oxford University. This is the essence of the IiME approach to research.

Finding the cause, working in collaboration, using opportunities for international collaboration, bringing new expertise into studying ME and facilitating the education of healthcare staff. "

✿ Centre of Excellence for ME

Identifying a small number of centres for ME/CFS research that already have established specialisms in biomedical/fundamental research that can establish and develop collaborations and joint projects with other research groups across the UK that might otherwise lack the required critical mass/expertise to undertake research projects in a hub and spoke type model should be seriously considered.

from IiMER

One such centre in Norwich Research Park has been established [[16](#)]. The research team at Quadram is already doing this and has the experience and capability to expand this.

We already see the overlap between disciplines and research teams in Norwich Research Park and this has enhanced the research being performed - in the clinical trial, in development of objective outcome measures, in raising awareness of ME.

Therefore, the model is proven - it just needs more investment to augment what Invest in ME Research has been able to fund so far. [[20](#)] The charity has already facilitated collaboration with other European hubs.

🌟 Investment. Funding

Without long-term investment and reliable sources of significant levels of funding attracting new young investigators to ME/CFS research is unlikely to be successful.

Targeted young/new investigator grant schemes for ME/CFS research would be a good place to start.

from IiMER

We suggested to the UKCRC working group that a statement should be issued to the health minister that funding for research should be established and made available up front - already before any plan is established.

If capacity is required to be increased in the research community and if interest and awareness is required to be gained then funding is a pre-requisite. Otherwise, the end result will just be more documentation that will be left on the shelf.

None of the above will be possible without required funding.

It was a flawed decision from the Secretary of State for Health that no new funding would be available. Existing methods of applying for funding for research into ME have obviously been failures and attracted little interest or any long lasting change for people with ME.

This has to change.

Consideration ought to be made to the IiMER proposal to demand funding for the steps outlined above to be performed.

Regarding targeting young/early career investigators - Invest in ME Research had already started this process with our *Thinking the Future Young/ECR workshops* that were attached to our research Colloquium events [[17](#)].

We collaborated with the NIH to create three workshops in 2018 and 2019, and only paused due to the pandemic situation.



Making a Rapid Start to Change

We have already suggested that we need to make use of what exists already rather than building an extensive list of funding requirements that will likely not be funded [3].



What is already present, supported and functioning should be considered for further investment rather than reinvention or using up more time to delay progress.

Using the points above then a start can be made already to augment foundations in place.

Nothing will happen without adequate funding.

Therefore, we restate that the working group should provide a push back to the Department of Health and demand adequate public funding already to be allocated for research into ME (18).

Background

The first invitation to Invest in ME Research to participate in the UK Clinical Research Collaboration (UKCRC) [1] Working Group meetings was to a meeting held on 1st September 2022, after other meetings had already taken place and decisions already made.

Our submission to that 1st September meeting can be seen here [2].

We commented in our submission document [3] that what has been achieved and developed and is present already ought to be considered for investment (such as the centre in Norwich Research Park) rather than reinvent the same. We suggested looking at what our colleagues in the Netherlands had already set in motion with a research agenda that had been funded and was underway, and was covering much of what needs to be started.

At least we can see that this point has been included as an item for the next meeting.

We also stated that the UKCRC needed to push back and request funding up front for research.

References

1. [Sajid Javid – 2022 Statement on ME/CFS](#)
2. [Input to 1st September UKCRC Working Group meeting](#)
3. [Input to UKCRC ME Research Working Group - A Different Approach](#)
4. [RESTORE ME Clinical Trial](#)
5. [Guidelines](#)
6. [MRC Letter to MRC CEO](#)
7. [MRC Letter to MRC CEO](#)
8. [MRC Funding of Research into ME/CFS](#)
9. [The Wrong Stuff](#)
10. [International colloquiums - collaboration](#)
11. [European Research Collaboration](#)
12. [Dutch research agenda](#)
13. [13 colloquiums and conferences](#)
14. [PhDs in Europe](#)
15. [Journal of IiMER 2015 Page 5](#)
16. [UK Centre of Excellence for ME](#)
17. [Thinking the Future - Young/Early Career Investigators Workshops](#)
18. [Our proposal in UK parliamentary debate 2019 to provide funding for research into ME year for five years](#)
19. Young/Early Career Researcher Conferences

Overview of UKCRC Comments



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