

Newsletter



Dear Readers



COVID-19 Update

Just like you, we have been monitoring the easing of restrictions with interest. We are pleased with the effectiveness of the vaccine in keeping death rates low, but we will remain vigilant and continue to wear masks, sanitise frequently and maintain social distancing at work. The labs will soon return to their full capacity and we are looking forward to seeing a bit more of each other in person. We are planning an outdoor lab day out and the next public and patient involvement activity. **Please let us know if you have any suggestions about how this could be organised to suit your preferences.** For example, we could have an informal gathering outside or use the large seminar room with plenty of space to spread out (with tea and cakes of course!). We will only go ahead when the virus threat has reduced substantially and everyone is comfortable with the arrangements. Please get in touch! It would be great to see you again.

Genever Lab Highlights

- We have been awarded the green impact platinum labs award and we were winners for most improved team in green impact this year!
- Alison has now published her research on how stem cells are tested before being used in clinical trials.
- David has been working on translating our work into usable clinical therapies: he has participated in Innovate UK and National Institute for Health Research (NIHR) funded accelerator programmes to explore the commercial feasibility of our potential clinical interventions. The aim is to work with industry to accelerate our development and to ensure it can be deployed as widely as possible. We've had some fruitful conversations with some strong commercial partners, so watch this space for more news!

- Jordan won the KM Stott prize for best 2nd year PhD student presentation.
- Alasdair, Alison and Savvas submitted abstracts for TERMIS 6th World Congress meeting this November and were awarded oral presentations for their research.
- Emilia joined the lab as part of her MSc degree, she will be with us till the end of the summer.

Alison's research has been published

Characterisation of mesenchymal stromal cells in clinical trial reports: analysis of published descriptors

Summary: We were interested in seeing how mesenchymal stem cell (MSC)-based products are tested before being used in clinical trials. We examined over 80 published papers on trials using MSCs and analysed the information provided by the authors. This included location of the trial, early or late stage trial, indication (disease being treated), tissue source of the MSCs, and details of testing of the cell populations being given to patients in the studies.

We found that one third of the papers did not report any testing data at all. Around half of the papers reported some data based on average results for the tests they performed. Fewer than 30% of papers evaluated the cells' ability to form useful structural tissues such as bone or cartilage, and less than 10% of studies included specific tests to determine whether the cells could have the biological effects intended in the trial patients. Alarmingly, more than 40% of the studies did not test the cells to confirm that they were still viable (alive) before being given to the patients.

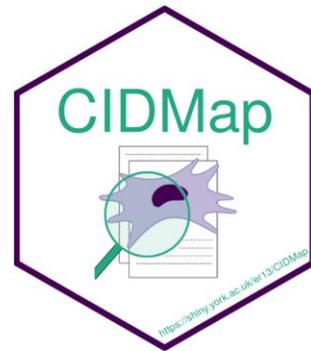
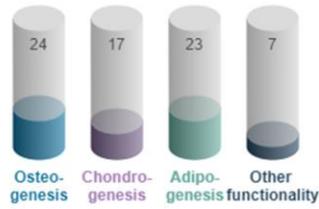
These findings are concerning because it is important in science to be able to compare the results of different studies from different researchers. Particularly in medicine it is critical that the test product being given to patients is clearly identified so that the overall safety and effectiveness of a treatment can be assessed. In the case of MSCs, this is even more important and challenging: we know that "stem cell therapy" is being offered in clinics across the world for all sorts of conditions, including stroke, spinal cord injury, osteoarthritis and heart disease, often without proper controls or oversight. If we do not properly identify exactly what has been tested in a clinical trial, it makes it very difficult to draw conclusions about the reliability of evidence for an MSC product in any particular disease. Further, study results could be misappropriated by unregulated stem cell clinics to give patients a false impression of the benefits of their treatments.

Based on our findings, we are recommending that medical and stem cell research journals insist on publication of full details of the testing done on cell-based medicines used in clinical trials; hopefully we will be contributing to raising standards of clinical trial reporting in the medical and academic literature.

We also produced an free online tool called "CIDMap" so that researchers across the world can perform their own analyses using the data we generated. A diagram summarising our findings is provided below.

If you would like to read the paper in full, you can find it [here](#).

Functionality Assays – number of studies



84 MSC clinical trial papers

Locations

MSC trials conducted in 27 countries

Clinical Phase

54 trials in Phase I, 28 Phase II and 2 phase III trials

Indication

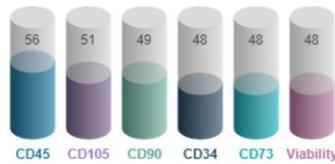
25 indications across 10 broad classes

Route

11 different routes of administration

Tissue Source

Bone marrow, adipose and neo-natal tissue sources



Most frequent characterisation tests – number of studies

- Findings**
- 1 Poor characterisation
 - 2 Trial drug identity/purity uncertain
 - 3 Relevant biological activity not addressed
 - 4 Comparison between trials difficult
 - 5 No reporting standards



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