



The Cell Therapy Catapult UK Clinical Trials Database

The UK Clinical Trials Database covers cell therapy clinical trial activity that the Cell Therapy Catapult believes to be ongoing in the UK as of May 2015. It supersedes the database of April 2014, and both are available on our website.

It has been compiled and verified by the Cell Therapy Catapult team, and includes:

- academic and commercial trials approved for inclusion by the sponsor
- ongoing trials in the UK, regardless of the nationality of the sponsor
- all trials involving cells as therapeutic agents*

*excluding trials of haematopoietic stem cell transplantation regimens

Significant changes versus the previous version of the database are discussed in more detail below.

The database is updated annually, and provides what we believe to be the most comprehensive and accurate review of the UK cell therapy clinical trial landscape as of May 2015. The data presented here for 2015 were collected between end of March 2014 and end of May 2015. The input of the cell therapy community is important to help us maintain its relevance, and we welcome your updates, additions and corrections, which you can send to us [here](#).

The purpose of the Cell Therapy Catapult UK Clinical Trials Database

As a centre of translational excellence in the UK, the Cell Therapy Catapult is progressing a portfolio of projects with the UK and international community. The UK Clinical Trials Database forms an important part of the mechanism by which the Cell Therapy Catapult identifies potential programmes for investment or partnership, and provides a highly relevant measure of progress in the field. Finally, we hope that the database will be of use to academics, researchers and commercial organisations operating in the cell therapy space by allowing them to understand the extent of cell therapy activity in the UK.

It is complemented by a UK Preclinical Research Database, also available on our website, which covers cell therapy projects that have been reported to us to be two or less years from the clinic (characterised by their technology readiness level) and enables us to track trends, make predictions about clinical pipeline development and plan strategically.



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Commentary on Key Findings 2015

1) Progressive increase in the number of ongoing trials in the UK

There are 51 cell therapy clinical trials ongoing in the UK, with the majority in the recruitment phase, according to the information in the Cell Therapy Catapult database for which approval and verification was available. This is an increase of 10 (24%) on the 41 ongoing clinical trials in 2014.

We believe 17 of the 51 trials in the 2015 database to be new, 2 of which progressed from the pre-clinical database. Three studies from the 2014 database have completed and 2 have been suspended.

The data, compared with that collected in 2013 and 2014 below (Figure 1) shows that the number of cell therapy clinical trials has been consistently growing in the UK over the past 3 years.

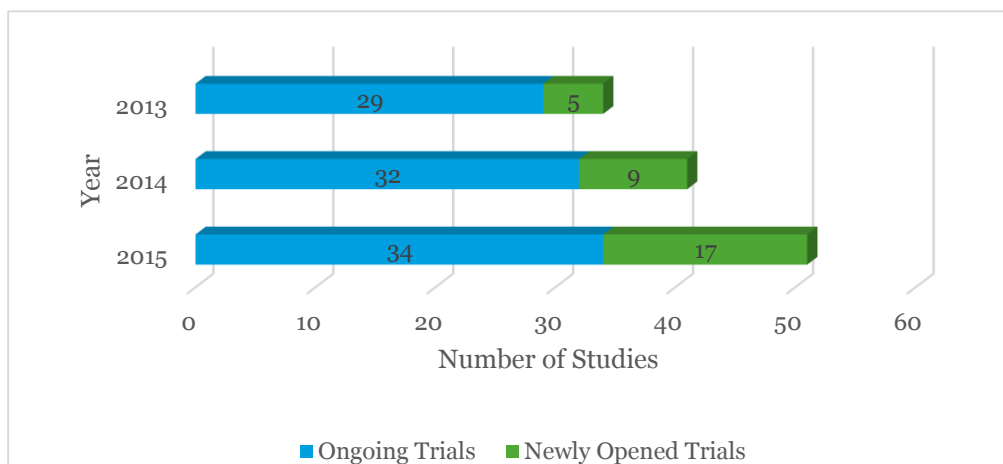


Figure 1. Number of ongoing clinical trials in the UK from 2013-2015



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2) Majority of UK trials in recruitment phase

The majority of UK cell therapy clinical trials are in the recruitment stage, as shown below (Figure 2). An increased number of studies have moved from the recruitment phase into the follow-up phase compared to that seen in 2014, with an even larger increase in the number of studies currently in-set up. This shows the steady movement of trials along the different stages of the course of a clinical trial, meaning that an increased number of subjects have been treated with cellular-based medicinal products in the UK.

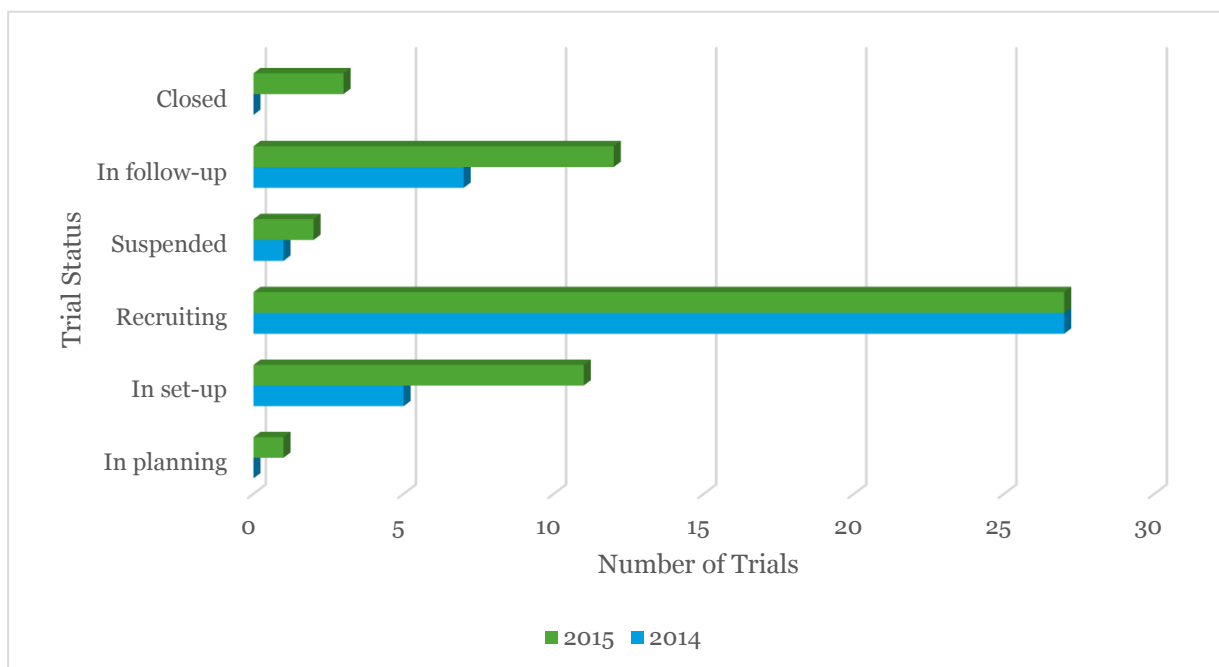


Figure 2. Distribution of UK clinical trials according to trial status from 2014-2015
(Data for 2013 not available)

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3) Oncology indications remain the largest sector

Oncology remains the dominant therapeutic area (23%) as was observed in previous years, with trials in Neurology the second biggest therapeutic sector (17%). An increase is also observed in trial activity involving gastroenterology (an increase of 3 trials), musculoskeletal disorders (an increase of 2 trials), and skin disease (an increase of 1 trial). The 2015 database also sees cell therapy clinical activity in two new therapeutic areas; respiratory, and renal / urogenital (Figure 3).

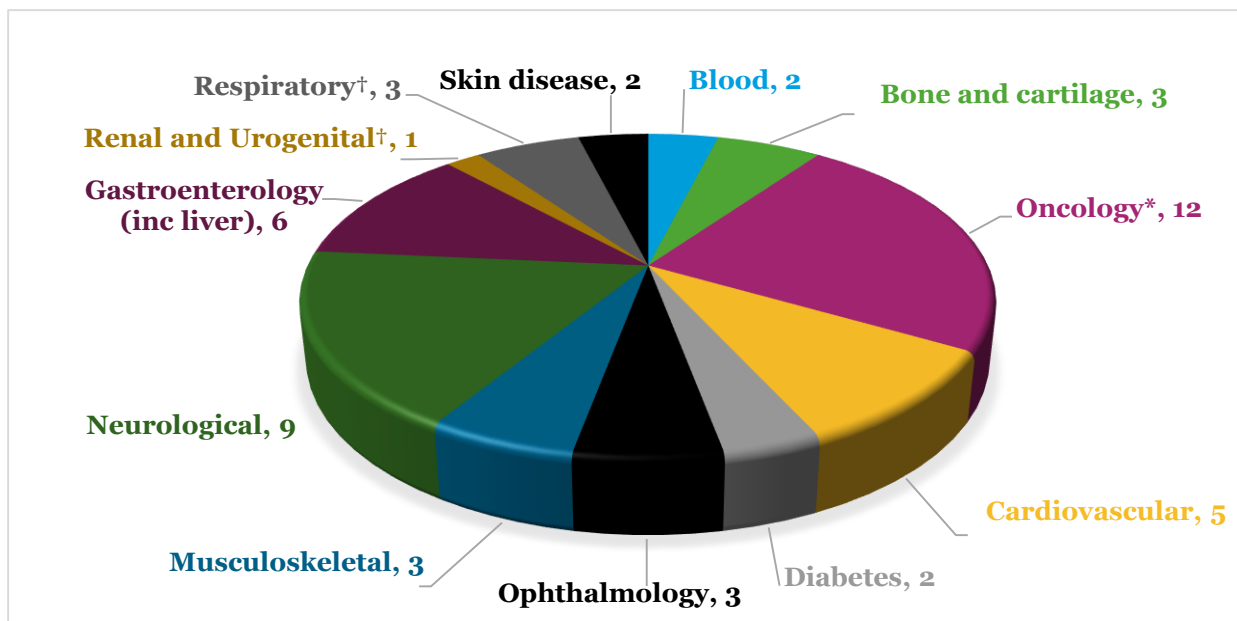


Figure 3. Distribution of UK cellular-based therapy clinical trials according to therapeutic area in 2015

† Therapeutic areas new to the UK Cell Therapy Clinical Trials Database
 *Includes haematology

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4) Diverse cell types with bone marrow-derived and T cells predominant

There is a diversity of cell types in development, with T cells (14 trials, 27%) and bone marrow-derived cells (21 trials, 41%) predominant in 2015 (Figure 4). Both T cells and bone marrow-derived cells also dominated the landscape in 2014.

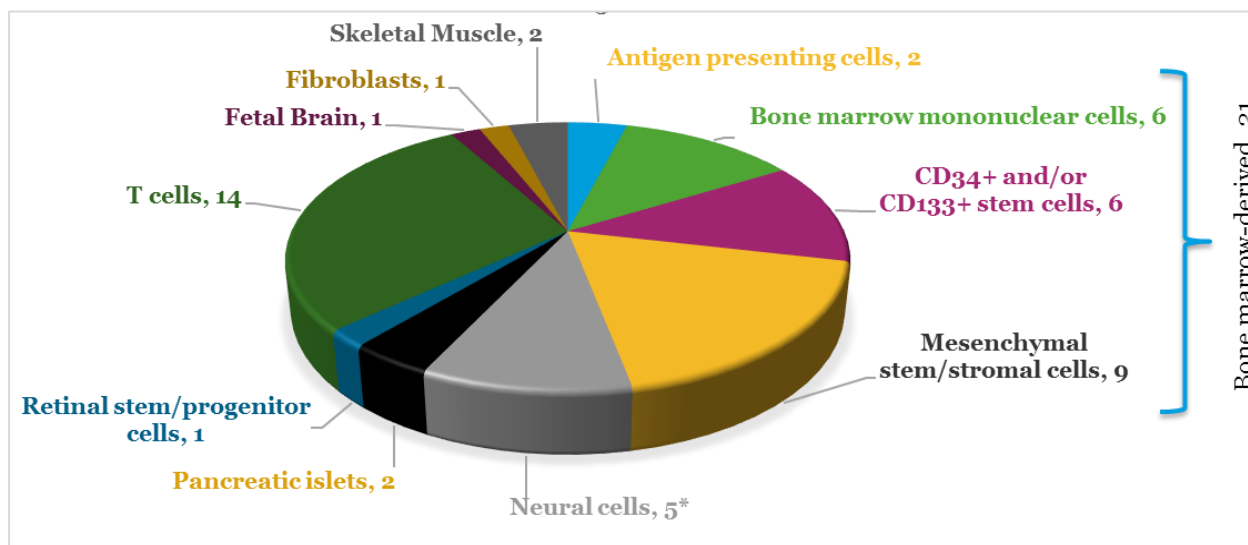


Figure 4. Breakdown of UK cell therapy clinical trials by cell type in 2015

5) Split between autologous and allogeneic 2:1 in 2015

Autologous cells are used more frequently than allogeneic cells in the 2015 database, with a 2:1 ratio (Figure 5).

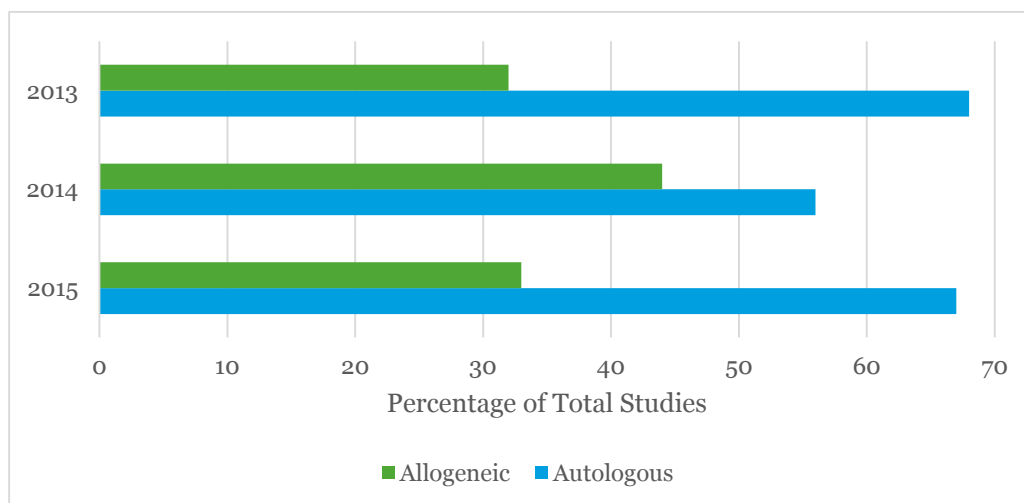


Figure 5. Distribution of autologous and allogeneic cell therapies in the UK clinical trials database from 2013-2015

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6) Majority of cell therapies are non-genetically modified

The 2015 clinical trials database shows that 878% of cell therapies currently used in clinical trials in the UK do not involve genetic modification (Figure 6).

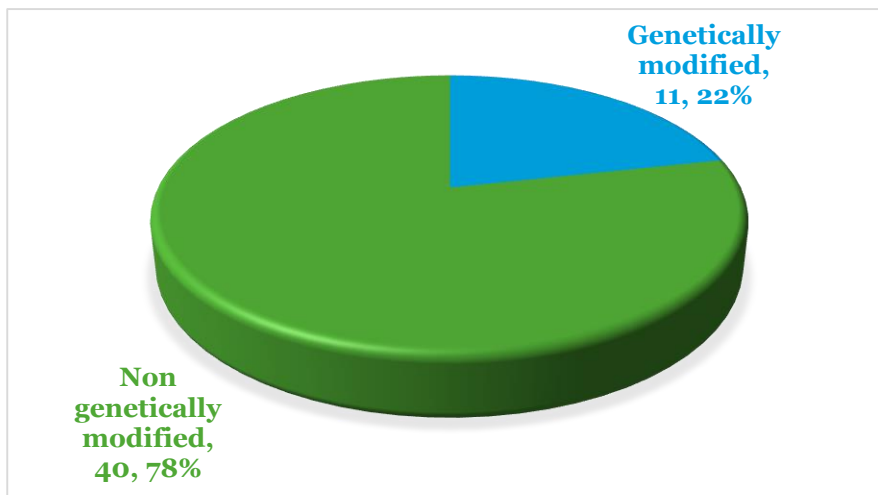


Figure 6. Genetically modified cell therapies used in UK clinical trials in 2015

7) The majority of cell therapies are in early phase trials

There has been a steady increase in the number of trials in phase I and phase II since 2013 as new entities enter development and therapies previously at Phase I progress to Phase II (Figure 7). However, the UK portfolio of activity remains at an early phase with relatively few therapies in Phase II/III or Phase III.

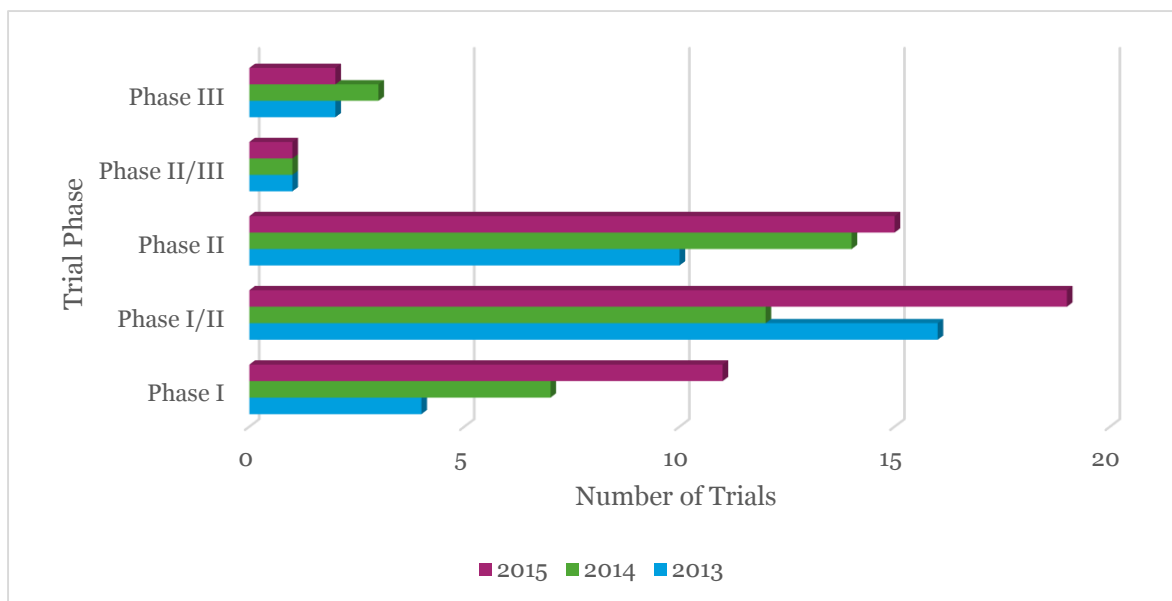


Figure 7. Cell therapy clinical trials in the UK by clinical phase from 2013-2015

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8) [Majority of UK clinical trials are sponsored by a research institution](#)

The number of commercially-sponsored ongoing clinical trials has increased from 11 in 2014 to 14 in 2015. However, this remains a relatively small proportion (27%) of the total (Figure 8), due to a larger increase in the number of trials sponsored by research institutions from 30 in 2014 to 37 in 2015. Therefore the majority of clinical trials using cell therapies in the UK are sponsored by academic and research institutions (73%). This split reflects the relatively early stage of the clinical trial pipeline.

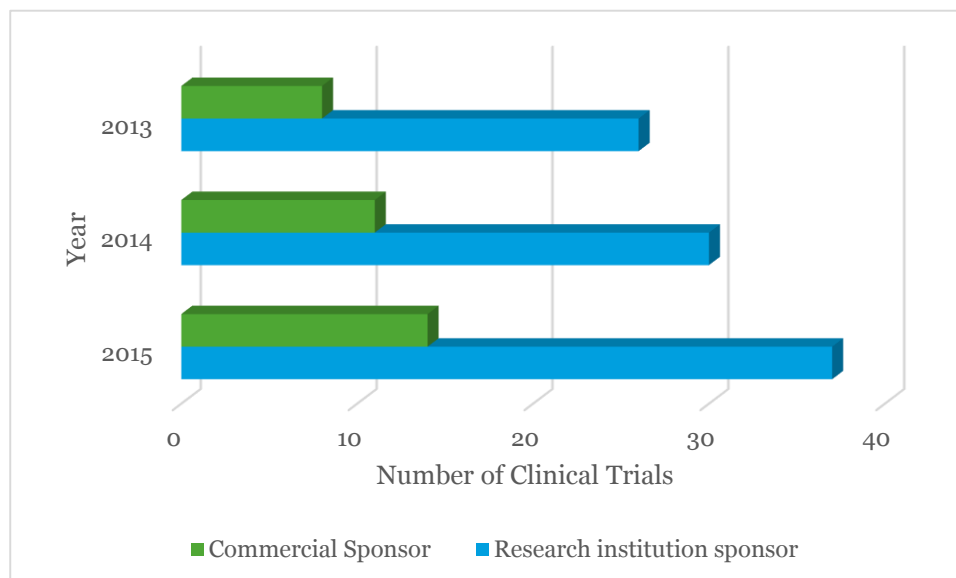


Figure 8. Proportion of commercial and research institution trial sponsors from 2013-2015

9) [Database utility for cell therapy developers](#)

As well as providing the Cell Therapy Catapult with an important measure of industry progress, the database provides the cell therapy community with an interrogatable resource for planning future trials. For example, knowledge of which UK hospitals have experience in cell therapies for particular therapeutic areas or in the use of a certain cell type can be important information in clinical trial planning.



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10) UK Cell Therapy Clinical Trials Database – 2015 conclusions

With the Cell Therapy Catapult's analysis of UK clinical trial activity starting in 2012 and the long timelines associated with studies, it is still early to draw many detailed and definitive conclusions about progress so far. However, with the number of ongoing trials in the database having increased from 24 in November 2012 to 51 in 2015, an increase of 113%, it is fair to say that the UK cell therapy industry is healthy and growing, albeit relatively youthful with regard to late-stage development and commercialisation.

We hope that cell therapy researchers and organisations will find our UK Clinical Trials Database informative and useful. As the Cell Therapy Catapult and others focus on translational activities, we expect the analyses of future years to show an industry undergoing significant growth and moving towards maturation.