Cell therapy clinical trials – 2014 Report

by ALEXEY BERSENEV *on* JANUARY 22, 2015 · 3 COMMENTS
in ANNUAL REPORTS

This is 2014 report of registered cell therapy clinical trials. Every year I give a snapshot of some tracked data, captured from international clinical trials databases. You can see previous annual reports here.

Definitions and criteria

I tracked clinical trials which fall in definition of **cell therapy: administration of living cells in human with therapeutic purpose**. Besides "traditional cellular products", I also included tissue engineered constructs with cells, cellular gene therapy and use of cells as a vehicles for therapeutic agent delivery. I tracked all clinical trials which were **registered from Jan.1, 2014 to Dec. 31, 2014 in international registries**.

The following categories were excluded from analysis:

1. Cells for homologous use:
   - hematopoietic cells for recovery of blood formation in hematological malignancies or for recovery of hematopoiesis after chemotherapy for treatment of solid tumors;
   - gene-modified hematopoietic cells for correction of metabolism errors and inherited immune diseases (example: SCID);
   - *ex vivo* expanded hematopoietic cells for enhancement of engraftment in hematological malignancies;
2. Platelet rich plasma trials
3. Extracorporeal devices with cells (no administration of cell inside of body).

Total number of trials tracked: **372**

Number of duplications between databases: **8**

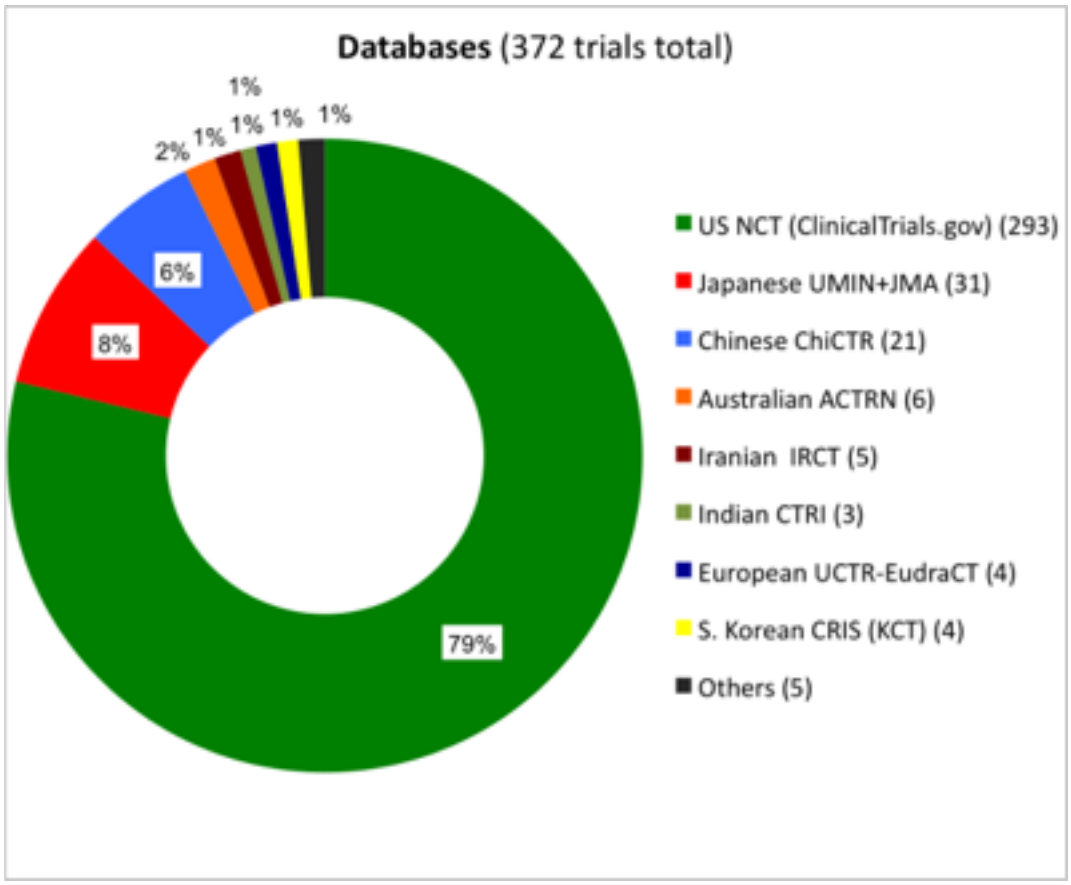
Databases

The following databases were scanned:

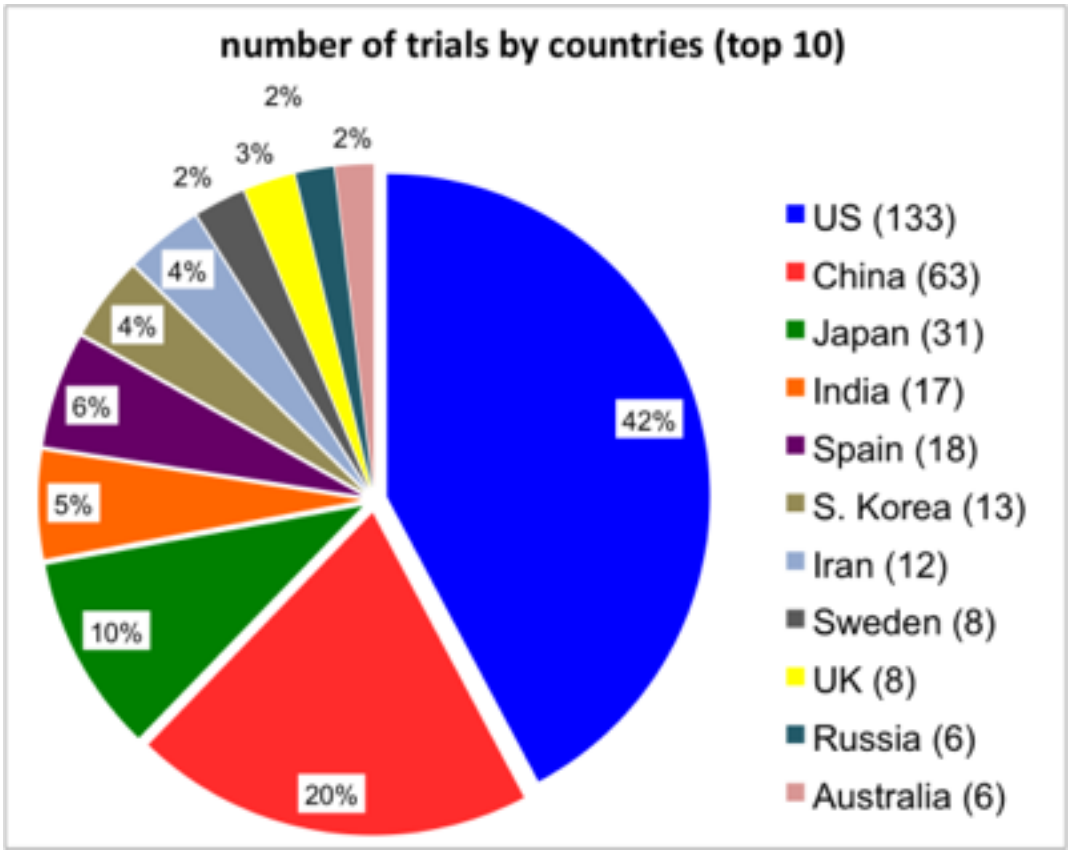
US NCT (NIH-FDA)
European EUCTR (EudraCT)
Japanese UMIN, JMA CCT
Indian CTRI
Chinese ChiTCR
Iranian IRCT
Australian/NZ ANZCTR
UK ISRCTN
Dutch NTR
South Korean CRIS

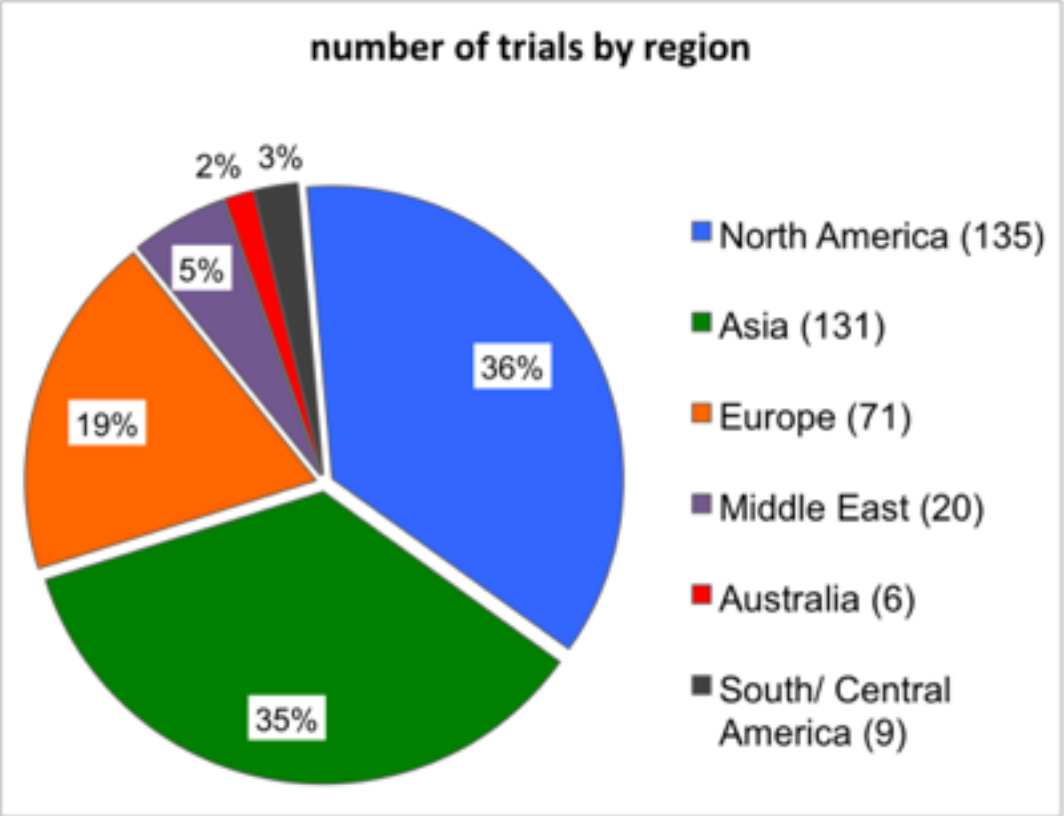
All international databases, except NCT, were scanned via WHO Search Portal (ICTRP). Each database was checked separately to capture everything, missed by ICTRP.

Databases representation:



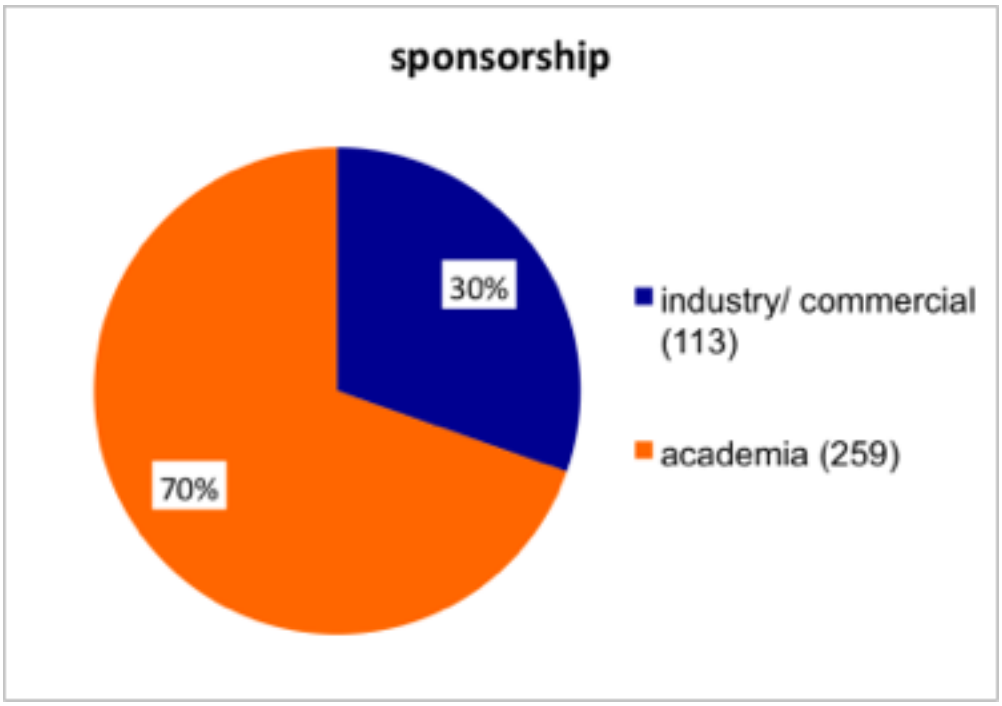
Demographics:



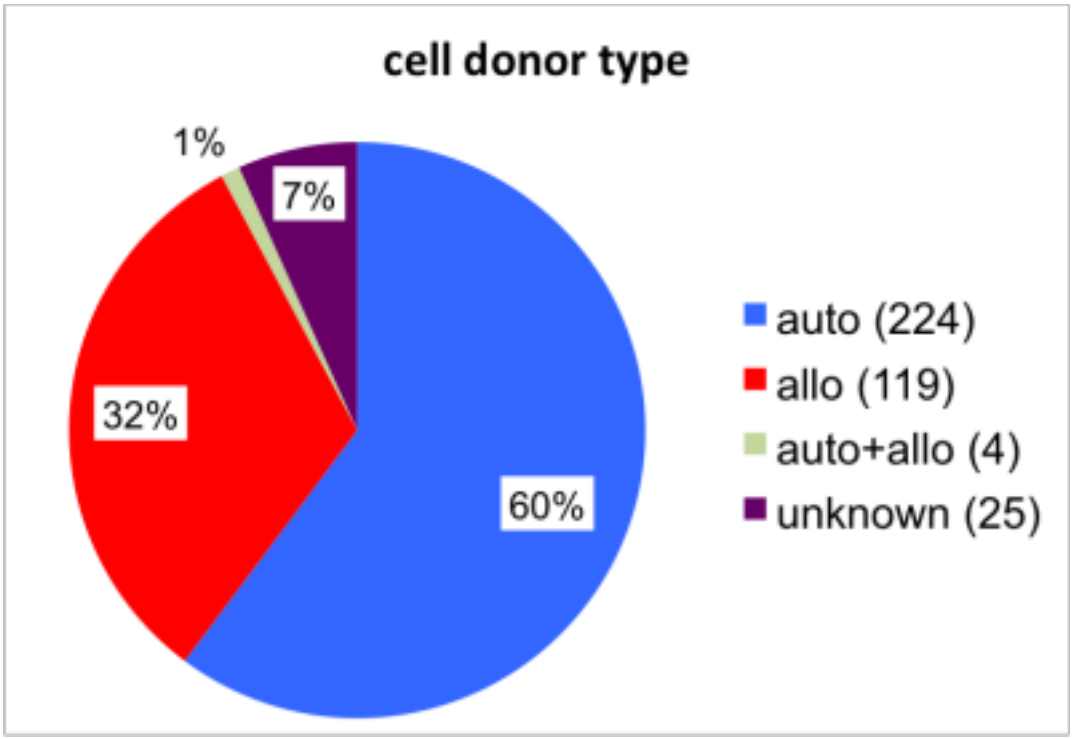


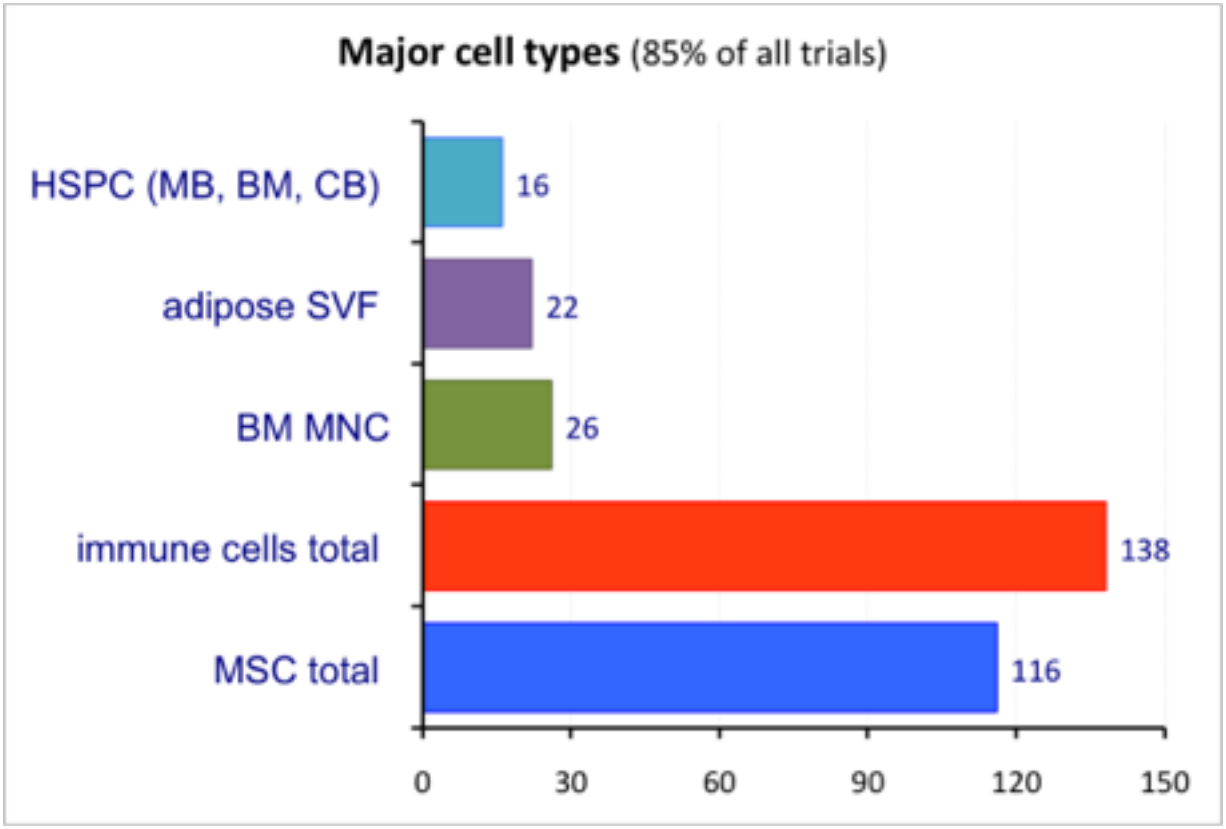
Sponsorship

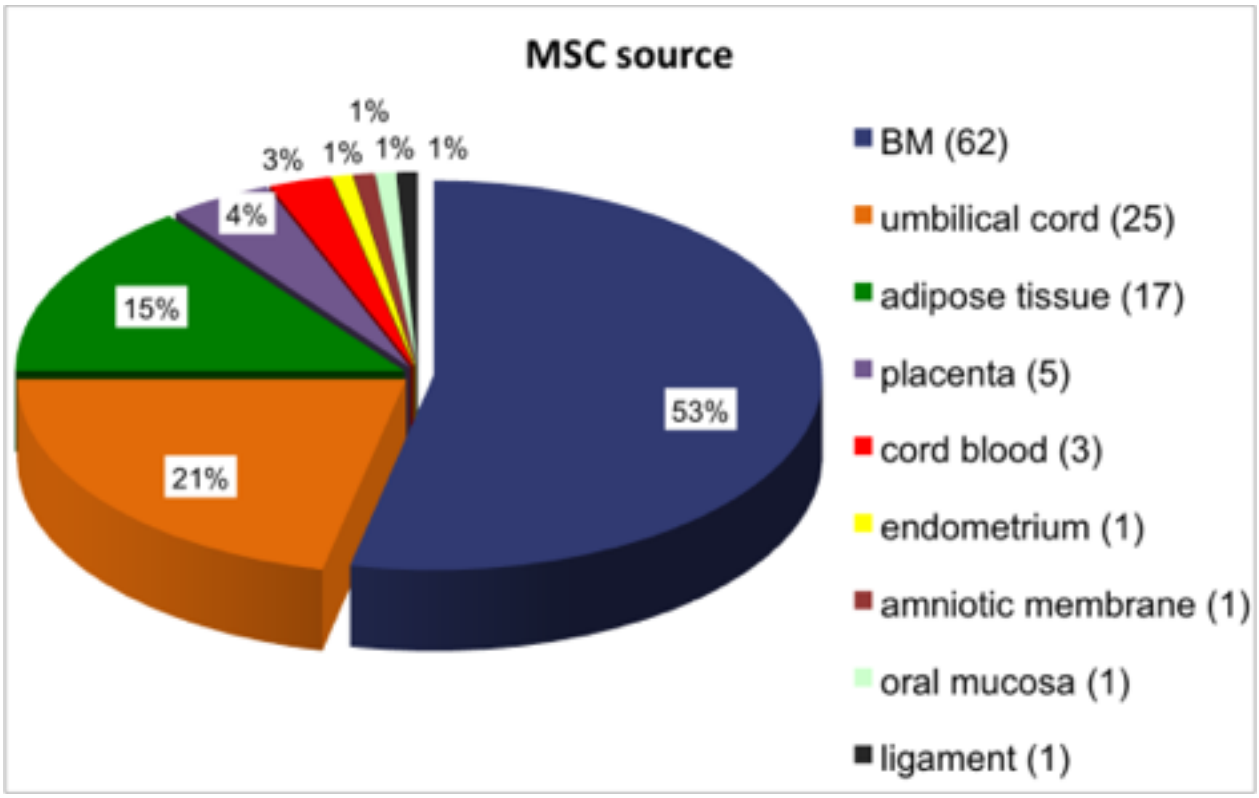
All trials were divided on 2 categories – “academic” or “industry”. The term “academic” combined any monetary support (governments, funds, charities…) other than company-sponsored. Term “industry” also includes (1) companies – collaborators, when sponsorship is not clear from trial description and when company manufactured/ provided cellular material, (2) commercial for-profit clinics with unclear regulatory authorization.

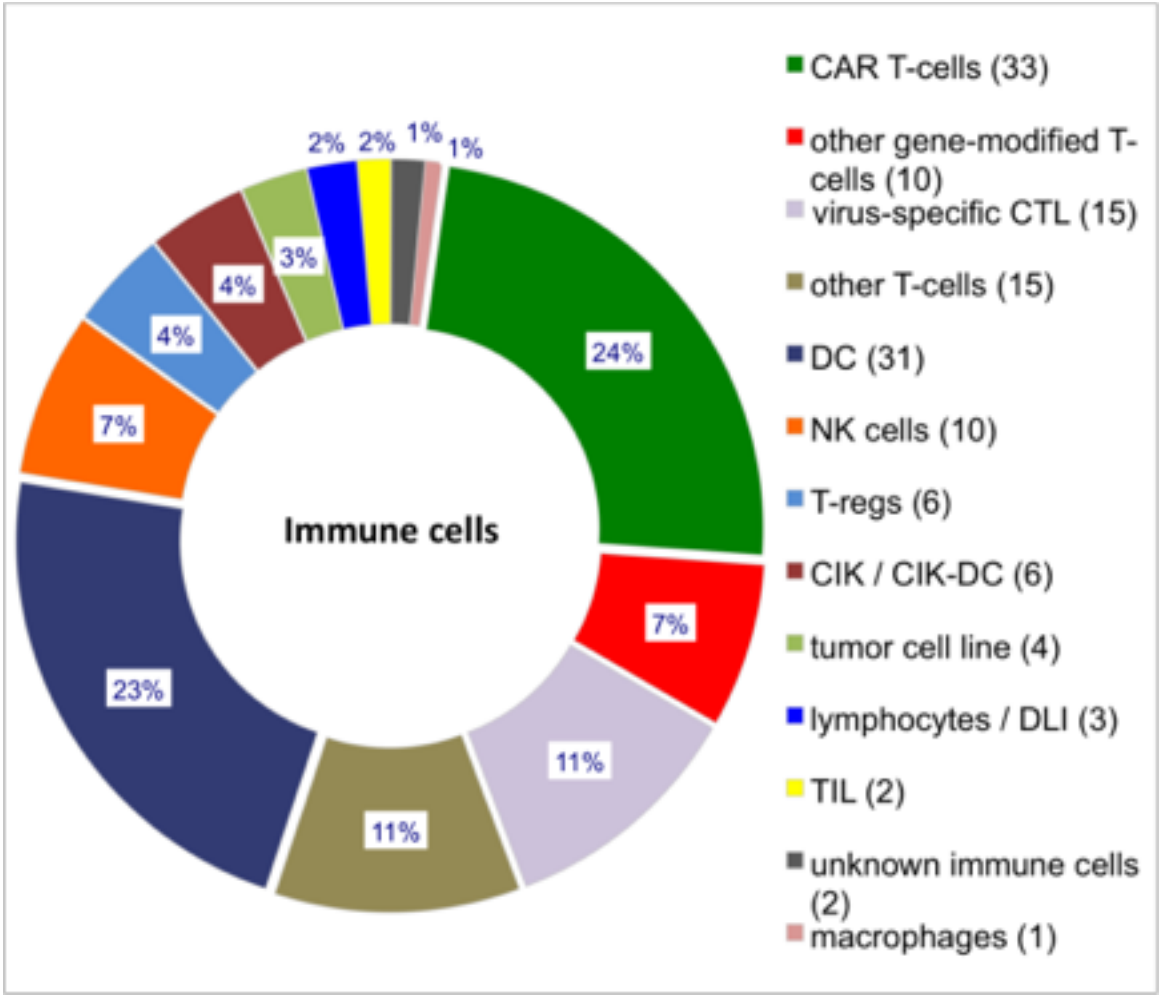


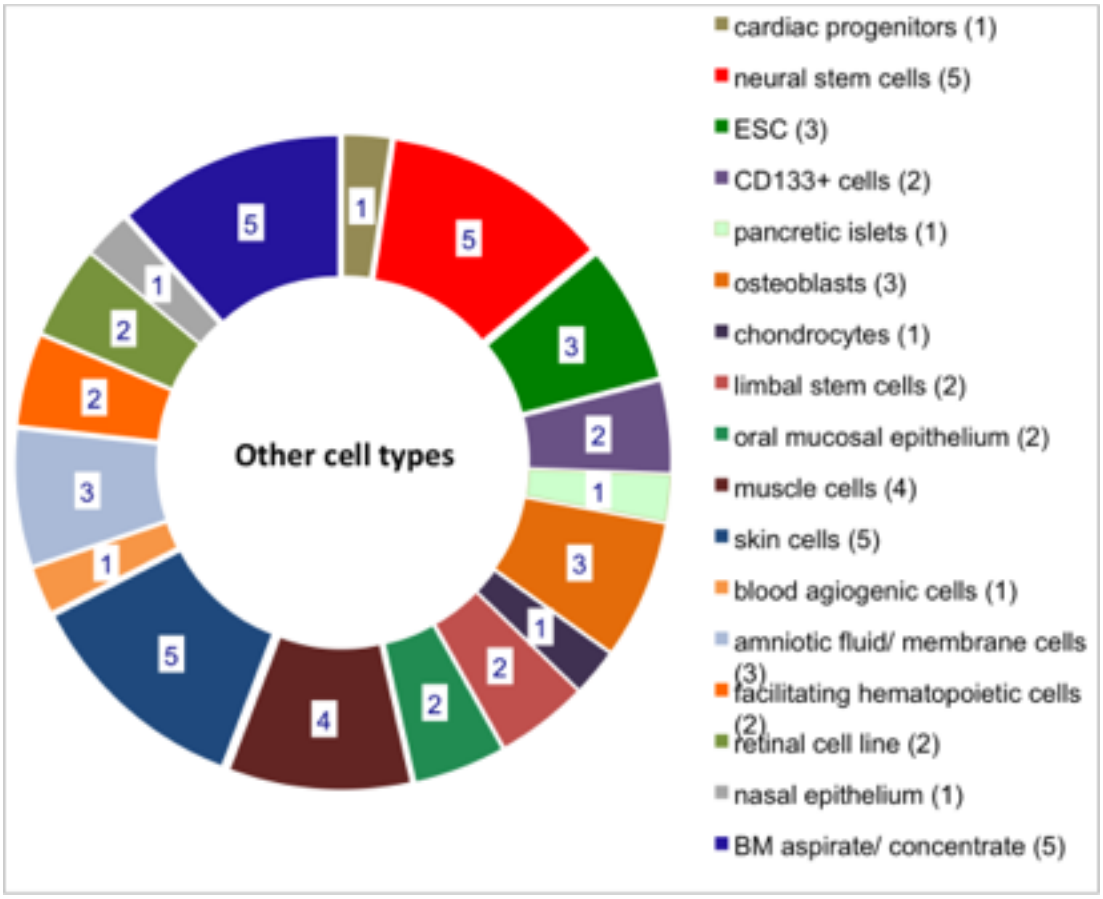
Cell types


cell donor type
1%
7%
32%
60%
auto (224)
allo (119)
auto+allo (4)
unknown (25)


Major cell types (85% of all trials)
HSPC (MB, BM, CB)
16
adipose SVF
22
BM MNC
26
immune cells total
138
MSC total
116
0
30
60
90
120
150


MSC source
53%
21%
15%
4%
3%
1%
1%
1%
1%
BM (62)
umbilical cord (25)
adipose tissue (17)
placenta (5)
cord blood (3)
endometrium (1)
amniotic membrane (1)
oral mucosa (1)
ligament (1)


Immune cells
24%
7%
11%
11%
23%
7%
4%
4%
3%
2%
2%
1%
1%
CAR T-cells (33)
other gene-modified T-cells (10)
virus-specific CTL (15)
other T-cells (15)
DC (31)
NK cells (10)
T-regs (6)
CIK / CIK-DC (6)
tumor cell line (4)
lymphocytes / DLI (3)
TIL (2)
unknown immune cells (2)
macrophages (1)



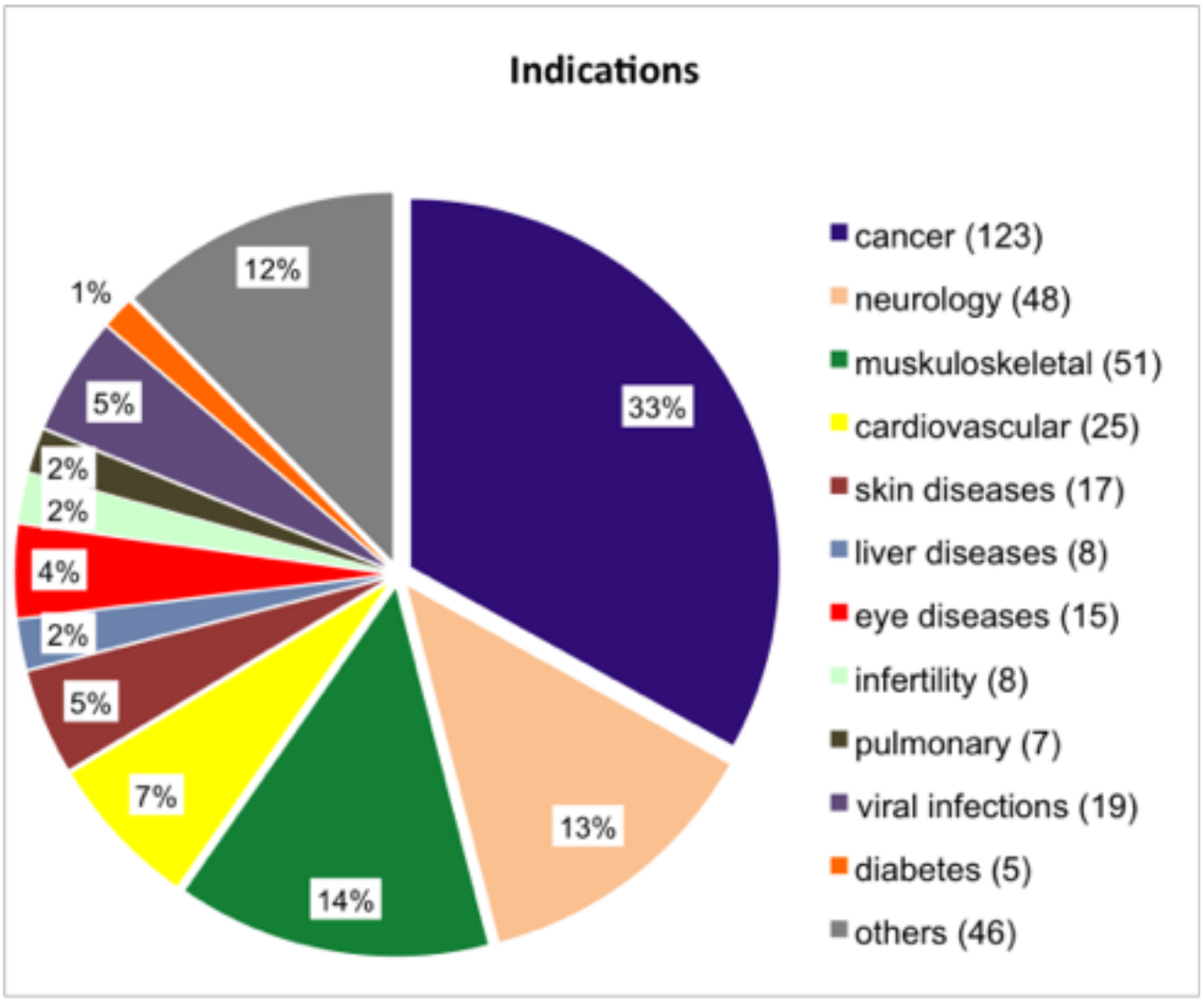
Abbreviations: MSC – mesenchymal stromal cells, HSPC – hematopoietic stem/ progenitor cells, TIL – tumor-infiltrating lymphocytes, DC – dendritic cells, BM – bone marrow, MNC – mononuclear cells, NK – natural killer cells, CIK – cytokine-induced killers, SVF – stromal vascular fraction; MB – mobilized blood; T-regs – regulatory T-cells; ESC – embryonic stem cells; CAR – chimeric antigen receptor; CB – cord blood; DLI – donor lymphocyte infusion.

Indications:

This is a first snapshot from 2014 report. I'm planning to post trends analysis, trials results analysis and some other data. Stay tuned!

How to cite:

Bersenev Alexey. Cell therapy clinical trials – 2014 report. CellTrials blog. January 22, 2015. Available: http://celltrials.info/2015/01/22/2014-report/



Cell Trials

Current Trends in Cell Therapy

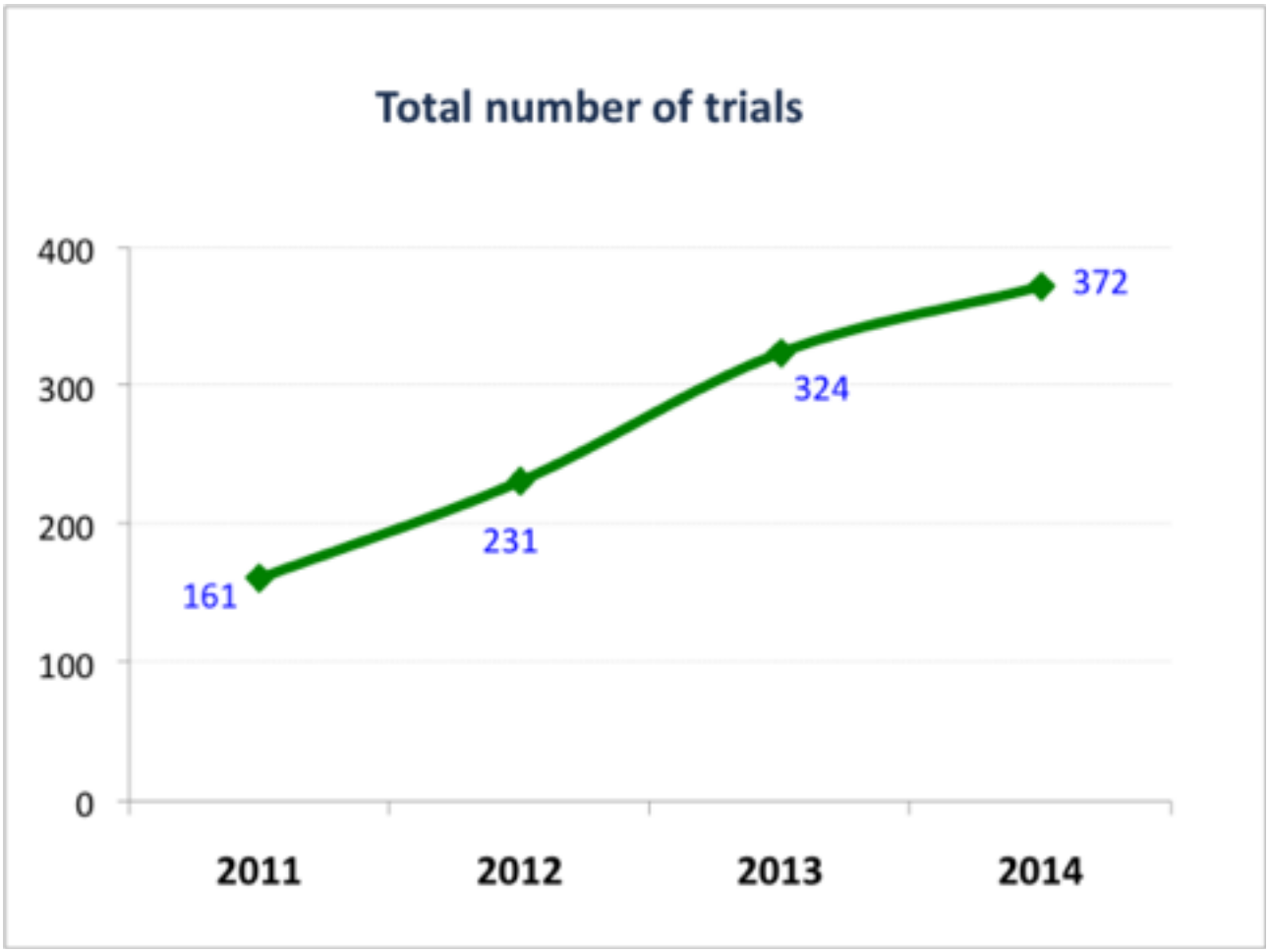
Trends in cell therapy clinical trials 2011 – 2014

by ALEXEY BERSENEV *on* FEBRUARY 14, 2015 · 0 COMMENTS
in ANNUAL REPORTS

Today I'm sharing some of my data for the last 4 years. This is a snapshot of trends in cell therapy trials from 2011 to 2014. This year, I'm planning to make few posts on cell therapy trends. I'd like to analyze some trends in mesenchymal stromal cells, adipose tissue-derived cells, industry versus academia and, finally, get to results of the trials. Some of these posts we will find on StemCellAssays.

Total number of trials

Total number of cell therapy trials, registered in international databases, continue to grow from year to year. From 2011 to 2014 a total number of trials increase more than 2 times. In 2014, every day cell therapy trial got registered in database. Please note that "registered" is not necessarily "new".

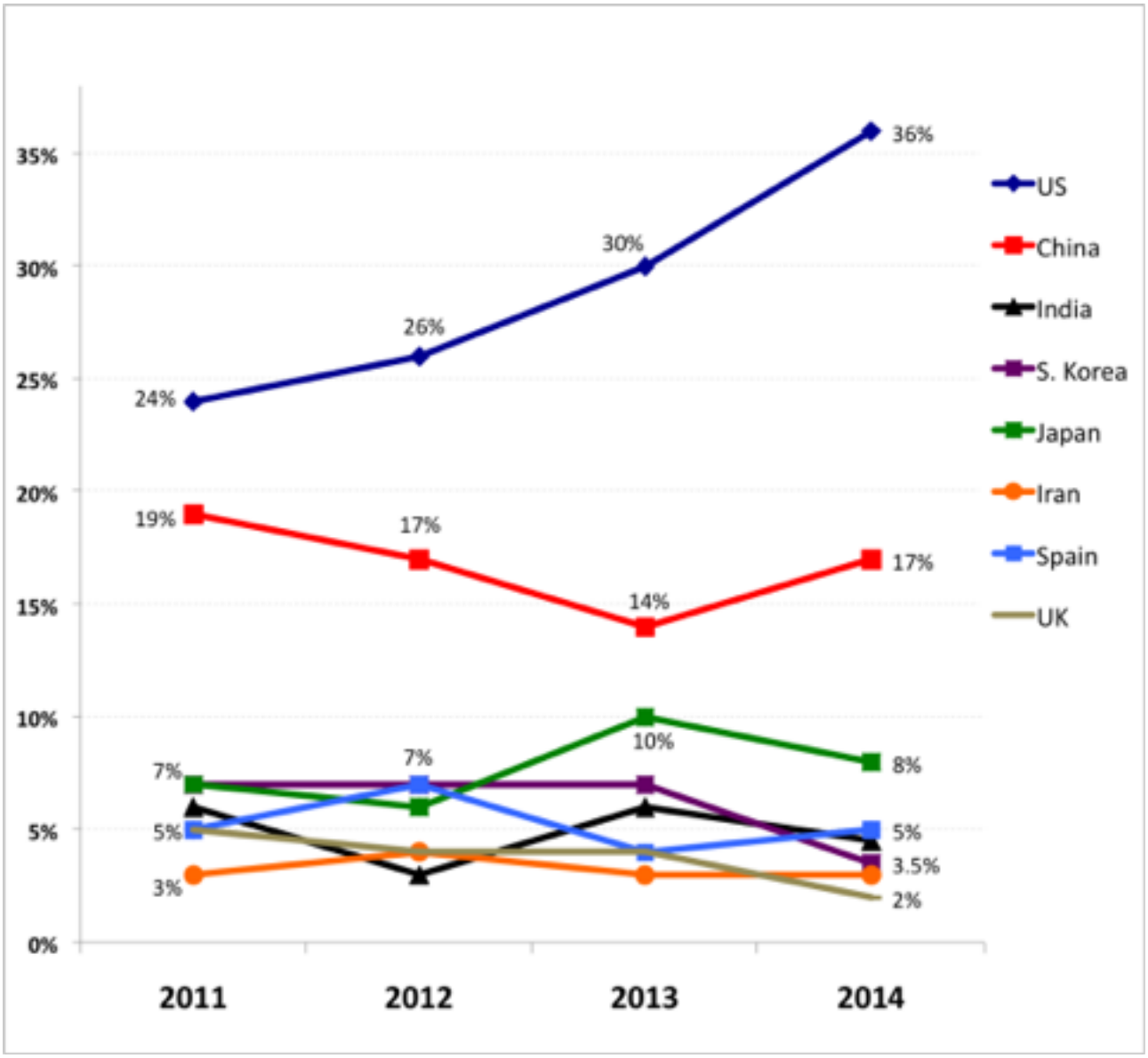


About 75% of all databases cell therapy listings posted on US-based **NCT registry** (ClinicalTrials.gov). The contribution of NCT database remains constant over the years, with range of 71-79% from all cell therapy trials, registered worldwide.

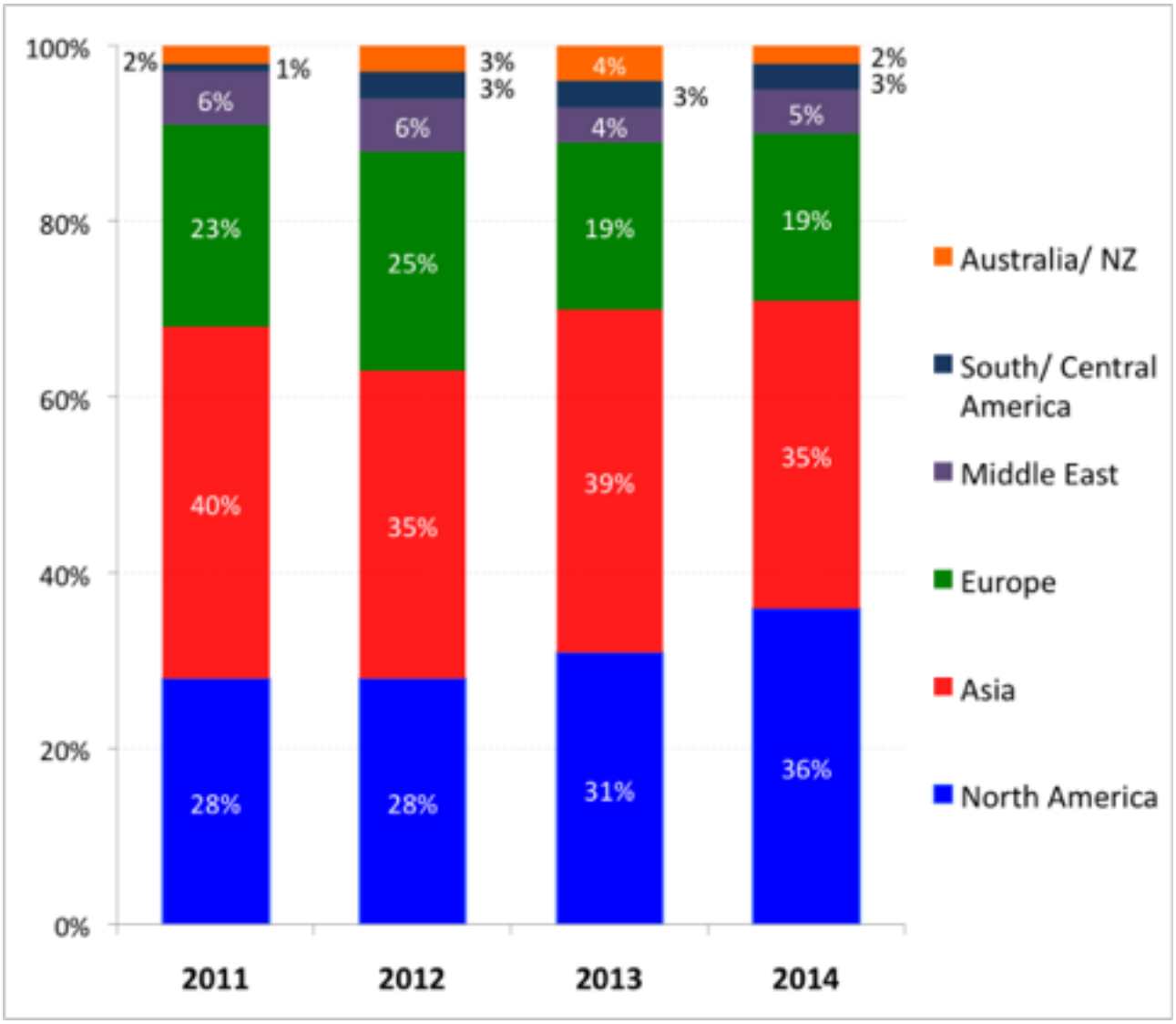
Demographics

Similarly to the previous 2 years, US and China dominated all other countries in number of cell therapy trials in 2013. The US trend is keep going up, but China's trend is getting flattened. Japan, South Korea and UK went down in 2014.

This graph shows a value of the most representative countries as % of total trials number.

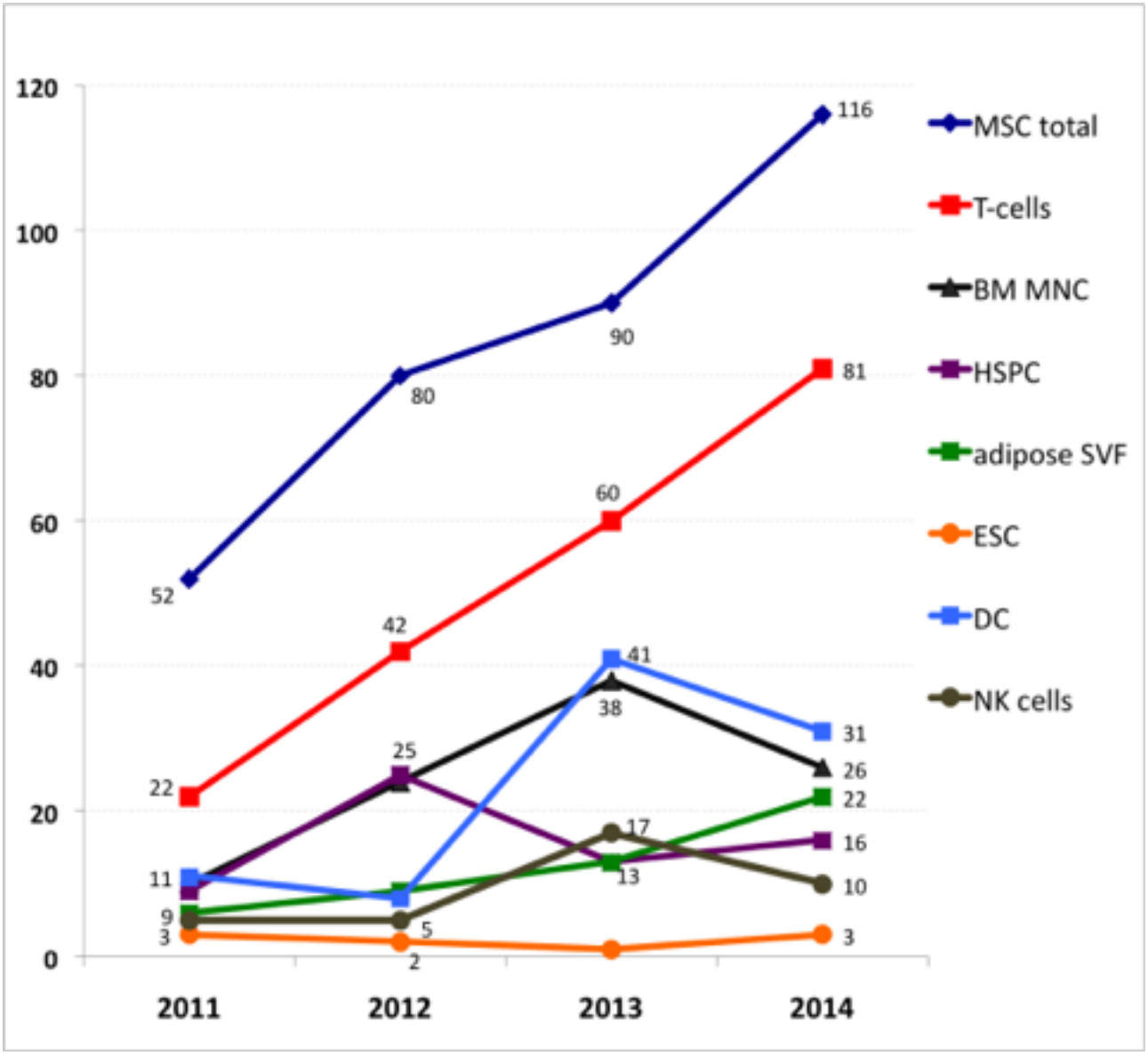


There is no big difference from year to year in contribution by regions of listed cell therapy trials. However, the value of North America (read USA) steady increased from 28% to 36%.


100%
80%
60%
40%
20%
0%
2%
1%
6%
23%
40%
28%
3%
3%
6%
25%
35%
28%
4%
3%
4%
19%
39%
31%
2%
3%
5%
19%
35%
36%
2011
2012
2013
2014
Australia/ NZ
South/ Central America
Middle East
Europe
Asia
North America

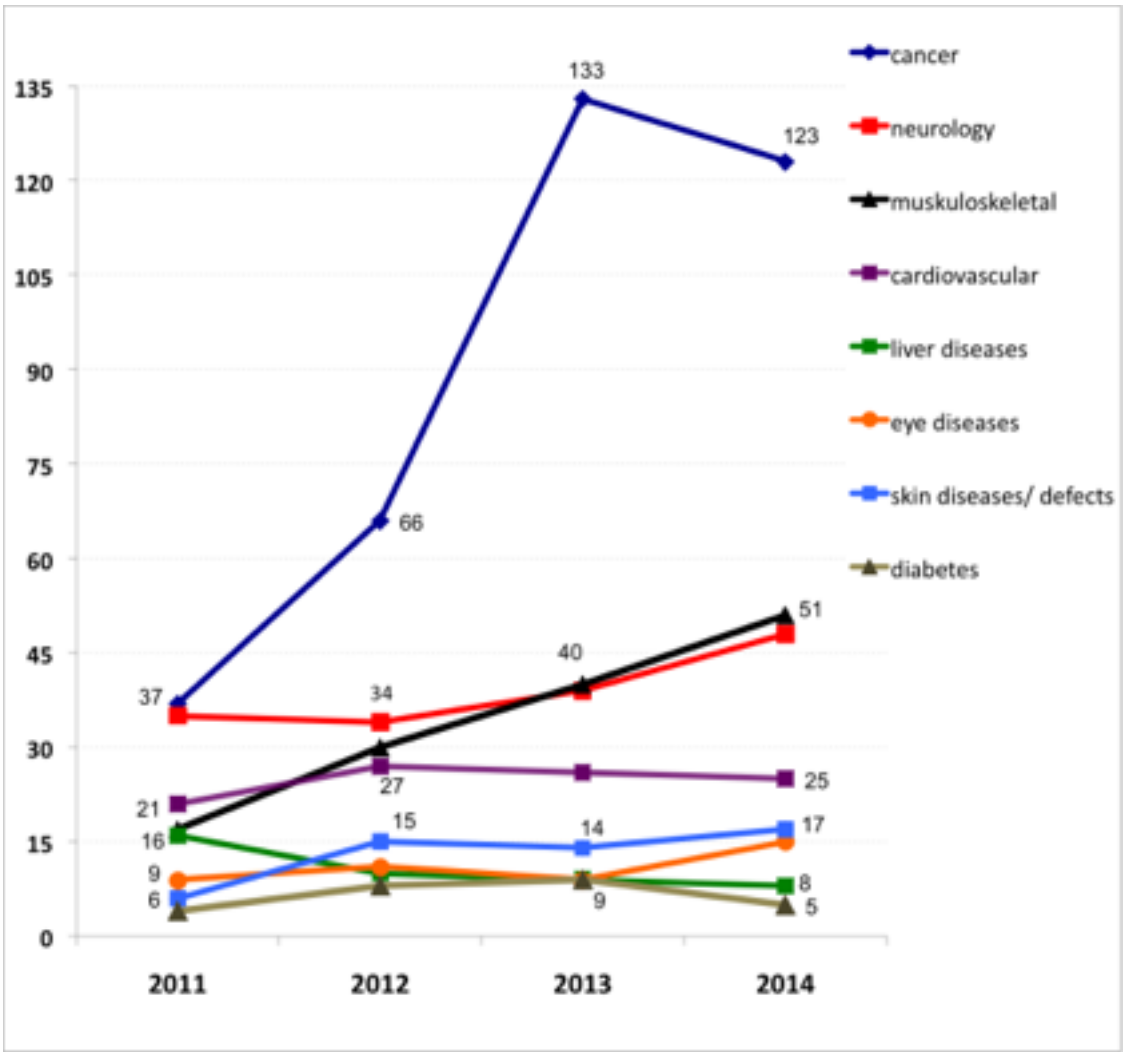
Cell types

The positive trend for 2 “major advancers” – mesenchymal stromal cells (MSC) and T-cells is continued. T-cell curve looks especially impressive. MSC trials continue to surpass all other cell types in 2014. Another steady growing cell type is adipose-derived cells – very good positive trend. It seem like field lost interest to bone marrow mononuclear cells (BM MNC) and dendritic cells (DC) in 2014. Yet another decliner is NK cells. Embryonic stem cell trials are coming back! Three ESC trials were registered in 2014.



Indications

Malignancies is the most frequent indication for cell therapy trials. It skyrocketed in the last 3 years (increase about twice every year) with some decline in 2014. Of course, it coupled with interest to cellular immunotherapy and strictly correlates with use of immune cells (T-cells, DC, NK cells…). Interest to cell therapy in cardiovascular medicine remains pretty much flat. Muskoloskeletal diseases have a prominent positive trend. Yet another "advancer" of 2014 is neurology. Interest to cell therapy for liver diseases seem to be decreasing.



It was a snapshot of dataset analysis for the last 4 years. I've picked only few trends to demonstrate that the data could be "sliced and diced" in many different ways. Stay tuned for some other interesting results and trends!

How to cite:

Bersenev Alexey. Trends in cell therapy clinical trials 2011 – 2014. CellTrials blog. February 14, 2015. Available: http://celltrials.info/2015/02/14/trends-2014/