



Transplantation Research Integration in Europe



TRIE Final Report

Period covered:	1st March 2007 to 28th February 2009
Date of preparation:	March 2009
Project Number:	LSHB-CT-2007-037540
Project acronym:	TRIE
Project title:	Transplantation Research Integration in Europe
Instrument:	SSA
Thematic Priority:	LSH-2005-3-4: Realising ERA objectives
Start date of project:	1 st March 2007
Duration:	24 months
Project coordinator name:	Professor Michel GOLDMAN
Project coordinator organisation name:	Institute for Medical Immunology, ULB
Revision:	V3

Recent developments in basic and translational immunology open new exciting perspectives for clinical cell and organ transplantation, including the development of novel immunosuppressive agents, new diagnostic tools and validation of biomarkers for the prediction of rejection as well as the induction of tolerance.

TRIE aimed to define a common approach for the European Transplantation Community, bringing together academia, clinicians, industry and patient organisations, to respond to specific questions that cannot be addressed independently but require scale of research across multiples centres and countries.

In a first phase, a dedicated Scientific Council was appointed to support TRIE partners identifying priority topics on themes common to cell and organ transplantation for which integration is critical and which will add value to the development of novel clinical therapies. This was followed by a large electronic survey among a selection of 370 key stakeholders from the Transplantation Community from which 115 responses have been collected from 16 EU countries, the USA and Canada. A high-level workshop was then organised to gather input from 60 leaders in the transplantation field (London, Jan.08).

On that basis, consensus was reached on the following three priority topics for further investigation:

- Topic 1. Biomarkers (donor & recipient) to define risk profiles and tailor pre/post-transplant therapies in haematopoietic stem cell and solid organ transplantation.
- Topic 2. Novel cell-based therapies for haematopoietic stem cell and solid organ transplantation.
- Topic 3. Innovative training programmes for physicians, surgeons, scientists and related health care staff involved in research on cell and solid organ transplantation.

The Transplantation Community agreed that progress on these topics necessitates a close collaboration with industry to ensure that patients are the final beneficiaries of research progress in this field. The Innovative Medicines Initiative Joint Undertaking (IMI JU) was identified as a potential instrument for leading industry-academic research in these priority topics.

Several initiatives followed in a second phase to progress on these 3 priority topics:

1. Validating the recommendations emerging from the London workshop with all stakeholder groups resulting in the preparation of a **Consensual Position Paper** entitled "*Integrating Transplantation Research in Europe: Pathways for a Public-Private Partnership*";
2. Ensuring the patient perspective was taken into account in this paper through undertaking a **European patient survey on transplantation research** past and future;
3. Further research and **specific recommendations were undertaken on priority topic 3** in a report prepared by R.RIEBEN from Bern University;
4. Engaging in **exploratory discussions with industry and EFPIA** on priority topics 1. and 2. regarding the potential for implementing the recommendations outlined in the consensual position paper;
5. Finally, to highlight the conclusions, recommendations and future perspectives emerging from the TRIE initiative, a **press conference and a high profile dissemination event** addressed by Commissioner Potocnik were organised in Brussels on 3rd November 2008.

In summary, the following recommendations were put forward by the TRIE consortium for future European initiatives in transplantation research:

[Tapez un texte]

Topic 1. Biomarkers (donor & recipient) to define risk profiles and tailor pre/post-transplant therapies in haematopoietic stem cell and solid organ transplantation.

Develop standardised tests and techniques to get an agreement among the Transplantation Community on valid biomarkers. Identify with industry clinical trials looking at biomarkers for both beneficial and detrimental immune reactivity using validated assays in multicentre studies. Set up uniform biobanking facilities and data collection procedures to compare patient data across countries. Develop biostatistics facilities and competencies to facilitate meaningful data analysis. Public-private partnership models can be envisaged to implement this topic since on the basis of clinical data collected by the industry, public funding should support the validation of biomarkers to progress on this field. Ethical and regulatory considerations will need to be addressed.

Topic 2. Novel cell-based therapies for haematopoietic stem cell and solid organ transplantation.

Standardisation of cell therapy protocols represent a critical challenge to improve regulatory issues and industrial investment in this field. This could be achieved through the standardisation of products being used in each lab in a first phase (compare cell lines, strengthen therapies). Markers of the products needs to be developed to this end. Cell therapy products could then be developed which could possibly have applications in solid organ transplantation. Involving industry is critical to guarantee that products will be translated into clinical application in a later phase.

Topic 3. Innovative training programmes for physicians, surgeons, scientists and related health care staff involved in research on cell and solid organ transplantation.

A coordinated network for training in transplantation research should be set up with identified training centres of high quality based on the needs of physicians, surgeons and scientists. In association with the scientific societies (ESOT, ESH-EBMT) and the industry, this network will contribute to integrate training needs in transplantation research (one-stop shop) and facilitate the transmission of developments in the pharmaceutical industry to the clinical setting and vice versa. A "Know How Manager" platform should be set up to promote scientific collaboration among the Transplantation Community (staff exchange, promotion of techniques, discussion on projects, etc.).

Several opportunities are currently being explored to ensure that these recommendations are followed up through concrete projects associating more closely scientists, clinicians and industry with the ultimate goal of benefiting the patients.

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<http://www.transplantation-research.eu>