biomarker candidates for drug-induced injury of the kidney, the liver and the vascular system and established a generic strategy to qualify biomarkers[4], whereas the eTOX consortium (http://www.e-tox.net/consortium.html), which includes four IT solution SMEs, developed an innovative multi-scale modeling strategy allowing the *in silico* prediction of drug effects on the heart using electrocardiogram simulations[5]. In parallel, four education and training projects are running, covering different areas of pharmaceutical sciences, including pharmacovigilance, of direct relevance to industry and regulatory authorities. Therefore, the alarmist and negative description of IMI reported in this journal does not reflect reality.

In an era where biopharmaceutical companies rely more and more on noncompetitive research and open collaboration to develop new models for drug development, IMI offers unique opportunities for academic groups and SMEs interested in translating results of their endeavors into innovative therapies. The update of the IMI Scientific Research Agenda has just been completed and will result in a series of even more ambitious projects based on sharing of data and know-how to address major unmet medical needs.

The currently running 4th Call for Proposals (**Table 1**) already contains two 'Think Big' projects with a transformational potential: the first aims at developing a European framework for patient-level health information, which will be exploited for investigations on major diseases in adult and pediatric populations; the second will focus on the use of induced pluripotent stem cells derived from patients as innovative tools for drug discovery and safety assessment. The budget of each project will be around €50 ($70) million, with equal contributions from the European Commission and companies in EFPIA (the European Federation of Pharmaceutical Industries and Associations), the latter in the form of in-kind contributions.

More than ever, the European Commission and EFPIA are determined to stimulate industry, including SMEs, and academia to collaborate on large-scale 'game changing' IMI projects to foster scientific talents and strengthen the ecosystem of pharmaceutical research across the European Union, for the ultimate benefit of patients.

COMPETING FINANCIAL INTERESTS
The authors declare competing financial interests: details accompany the full-text HTML version of the paper at http://www.nature.com/nbt/index.html.

Rudolf Strohmeier[1,2], Ruxandra Draghia-Akli[1,2], Andrzej Rys[1,2], Pedro Ortun Silvan[1,2], Theodius Lennon[1,2], Carlo Incerti[2,3], Richard Bergström[2,3], Salahdine Chibout[2,3], Roch Doliveux[2,3] & Peter Hongaard Andersen[2,3]

[1]*European Commission, Brussels, Belgium.* [2]*Innovative Medicines Initiative (IMI), Brussels, Belgium.* [3]*European Federation of Pharmaceutical Industries and Associations, Brussels, Belgium. Correspondence should be addressed to Michel Goldman, Executive Director, Innovative Medicines Initiative (IMI), Brussels, Belgium. e-mail: michel.goldman@imi.europa.eu*

1. Sinha, G. *Nat. Biotechnol.* **29**, 473 (2011).
2. Editorial. *Nat. Biotechnol.* **29**, 551 (2011).
3. Abbott, A. *Nature* **468**, 158–159 (2010).
4. Matheis, K.J. *et al. Drug Discov. Today* (in press).
5. Obiol-Pardo, C., Gomis-Tena, J., Ferran Sanz, F., Saiz, F. & Pastor, M. *J. Chem. Inf. Model.* **51**, 483–492 (2011).

***Nature Biotechnology* replies:**

We continue to urge the IMI governing board to do more to engage SMEs in setting the agendas for IMI projects. Success in recruiting SMEs into projects is different from providing SMEs with a voice at the table that can contribute to setting the innovation agenda. We recognize this is difficult—for one thing, people at SMEs very often don't have time to devote employees to outside projects, such as IMI. Our editorial attempted to highlight the problem that the innovative agenda of EFPIA members may not be as broad as the innovative agenda put forward by less established and smaller companies who seek to disrupt conventional approaches. For example, it is clear that cells derived from human induced pluripotent stem cells offer considerable potential in drug discovery screens and safety assessment, and this has been demonstrated by the investment by the pharmaceutical industry in these approaches in recent years. But what about the potential of such products as experimental therapies in themselves? Clearly, a focus for many SMEs and academic groups but not a major focus for many major pharmaceutical companies. Perhaps IMI could play a role in moving such unconventional approaches forward, especially if the funding and expertise from EU and EFPIA could be used to help SMEs focus their efforts to address the formidable manufacturing, regulatory and reimbursement issues that cell therapies face before reaching the market.

Biosimilars—why terminology matters

To the Editor:

As members of the Biosimilar Medicinal Products Working Party (BMWP) at the European Medicines Agency (EMA; London), we would like to draw readers' attention to problems arising from imprecise usage of the term biosimilar (similar biological medicinal product) in the literature. We have repeatedly noticed misinterpretations of the biosimilar concept as well as inconsistent use of terminology and are concerned about potential implications of this, such as negative perception and impaired acceptance of biosimilars among prescribing physicians and patients. Here we outline the scientific principles underlying the biosimilar concept in the European Union (EU; Brussels). We also address problems in terminology in the context of global emergence of copy biologicals (including 'true' biosimilars) and 'biobetters', and the potential for unjustified concerns about the efficacy and safety of biosimilars in their stricter sense.

The recent expiry of data protection or patents for the first biopharmaceuticals has opened up the possibility of developing biological products similar to these original products and to rely for licensing, in part, on the extensive knowledge gained with the originator products. Although copy versions of original biopharmaceuticals are already available in different parts of the world, there are no consistent worldwide requirements for their registration.

In Europe, the EMA's Committee for Medicinal Products for Human Use (CHMP) is responsible for the scientific assessment of human medicines that follow the European 'centralized procedure of marketing authorization'. According to this legislation, all recombinant proteins must undergo this route for licensing[1]. As most biosimilars are recombinant proteins, they usually have to follow this centralized route.

According to the EU, a biosimilar medicinal product is a copy version of an already authorized biological medicinal product (the reference product) with demonstrated similarity in physicochemical characteristics, efficacy and safety, based on