



Top Institute Pharma

International Scientific Review Committee

Report of the sixth meeting, April 23-24, 2009 (Utrecht & Leiden, The Netherlands)

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Report of the sixth meeting of the International Scientific Review Committee (ISRC) on April 23-24, 2009, in Utrecht & Leiden, The Netherlands

Summary

The ISRC convened for the sixth time on April 23-24, 2009 to attend the TI Pharma Spring Meeting and to discuss the scientific performance and plans of TI Pharma. In addition to a short evaluation of the Spring Meeting and a general status update, the ISRC was informed of developments in the Education & Training area, a recently submitted FES proposal and the planned Mid-term Review of the Institute. On all these items the ISRC gave its input. The ISRC meeting concluded with an extensive discussion with two PIs of TI Pharma projects.

The ISRC appreciated the Education & Training program and the extension of the portfolio with new courses; the three new activities have significant relevance for translating basic science into industrial practice. Moreover, the committee is satisfied with the fact that 44 projects are underway. The coming Mid-Term Review should give an indication of the impact of TI Pharma. To evaluate a unique public-private initiative such as TI Pharma, this Mid-term Review should be designed following a holistic approach. Overall, the ISRC was pleased with the progress that has been made and hopes that its constructive comments will be taken into consideration and acted upon.

Introduction & agenda

On Thursday 23 April and Friday 24 April 2009 the ISRC convened for the sixth time.

The members of the ISRC are:

Prof. dr. E.J. Ruitenbergh (chair, Professor of International Public Health, Free University Amsterdam, ex RIVM and Sanquin)

Prof. dr. A.T. Florence (former Dean of the London School of Pharmacy)

Prof. dr. P. Krosgard Larsen (President of the Carlsberg Foundation and professor at the University of Copenhagen)

Prof. dr. R. Laing (WHO, author of the Priority Medicines report)

Prof. dr. L. Lesko (Food and Drug Administration, USA, unable to attend the sixth meeting)

Prof. dr. R. Metternich (Merck Research, USA, unable to attend the sixth meeting)

Prof. dr. T.M. Jones, CBE (ex Wellcome Foundation, ex ABPI)

The sixth ISRC meeting consisted of two parts. On the first day (Thursday 23 April) the ISRC members attended the TI Pharma Spring Meeting. On the second day (Friday 24 April) a meeting was held at the TI Pharma office in Leiden, this meeting lasted until the end of the afternoon. The report below refers to the meeting on the second day. The items discussed during this meeting were:

1. Reflection on the Spring meeting / TI Pharma general status update
2. Education & Training
3. The 2009 FES proposal
4. The Mid-term Review
5. A presentation by the PIs of the projects 'Sustainable orphan drug development through registries and monitoring' (Project T6-208) & 'Effective therapy in HIV infection' (Project T4-212)

1. Reflection on the Spring meeting / TI Pharma general status update

At the start of the meeting, the ISRC briefly reflected on the TI Pharma Spring Meeting of the previous day. Overall, the meeting was highly appreciated, and was a step forward compared to the 2008 meeting. Some suggestions for further improvement were: a clearer set-up of the poster sessions, a re-assessment of the large number of parallel sessions (could be less with more focus on synergies and cross-talk between activities in the research program). Furthermore, it may be interesting to consider the optimal length of the meeting, given the large number of participants.

A general overview was given of the activities of TI Pharma. To underline the ambitions of TI Pharma, the mission of the institute has been adjusted to reflect European collaboration. At the moment, 44 project consortia are active in TI Pharma, two of which were highlighted in more detail in presentations later during the ISRC meeting.

TI Pharma has not been as successful as it had hoped with regard to their submissions to IMI. The ISRC is disappointed that the TI Pharma IMI projects have not been selected. The ISRC supports TI Pharma's efforts to reassess its focus with regard to IMI.

Another important activity for the coming months is the joint call between CTMM, BMM and TI Pharma entitled 'Imaging guided and targeted drug delivery', the details of which are being finalized. For the review committee of the joint call two ISRC members are

invited. It is decided that Prof. Florence and Prof. Jones will take on this role. The call will open in June 2009.

The ISRC was pleased with the 'dashboard' that is used to monitor the progress of projects based on the submitted 'Progress Reports'. It is good to see that such an extensive reporting system is set up and used. Furthermore, the ISRC noted that the social relevance of the projects is an important measure that is part of the Progress Reports and which should feature prominently in future assessments of TI Pharma. The ISRC suggested that TI Pharma should strive to improve the overall quality of reporting (using 'best practices') and explore means by which this can be achieved.

As a final point, the ISRC members were invited to participate in the upcoming Dutch-Danish workshop 'Modeling and simulation approaches in drug discovery and development' which will be held on 24 November 2009 in Leiden, the same workshop will be held on 19 November 2009 in Copenhagen.

2. Education & Training

An overview of developments in the Education & Training sphere was given. It was welcomed by the ISRC that the 'On top' curriculum is now reaching a large number of the PhD-students and postdocs. The ISRC recognizes the problems in involving postdocs, and notes with approval that participation in the courses is now part of the new project agreements. There was general agreement that participation in Education & Training should also be a part of the project evaluations in future assessments and Progress Reports.

The ISRC also pointed to opportunities that lie in organizing (parts of) the drug discovery and drug development simulations for companies. This could be an interesting route for further exploration. However, it should be noted that organizing the courses involves significant resources and that the added value of the courses also lies in the public-private character of both faculty and participants.

In the coming year the Business & Entrepreneurial Skills course will also be offered in collaboration with CTMM (and possibly other partners). As a result, the number of times per year that this course is organized will be increased.

Three new activities have been added to the portfolio based on discussions with the Education & Training Committee: project management, intellectual property and an 'industrial day' about career opportunities in the industry. The project management course was held for the first time in April 2009; feedback from participants was very positive. Also, there was significant interest for this course. 13 places were available, there were 40 applicants. Whether the course will be organized for a second time this year is currently under consideration.

Attention is drawn to courses in ethics as a possible important gap in the curriculum for researchers in The Netherlands, TI Pharma will look into this. It was mentioned that in many academic research institutes ethics courses are already part of the curriculum for researchers.

The ISRC appreciated the Education & Training program and the extension of the portfolio; the three new activities have significant relevance for translating basic science into industrial practice. In particular the intellectual property course reappraises the

balance between industrial exploitation and the responsibility involved for the public ownership of new information.

3. The FES 2009 proposal

An update is given on the FES proposal that was submitted to the Dutch government on 1 March 2009.

Overall, the ISRC was positive about the application, in which the Dutch life sciences and health sector presents a single, coherent proposal for future activities. The ISRC extensively discussed the consolidation of the TI Pharma research program matrix. The ISRC was of the opinion that the format and focus of the TI Pharma research program should be designed in such a way that it is as complementary as possible to all other initiatives in the life sciences and that it remains linked to development such as nutraceuticals and the polypill (examples from the cardiovascular field).

The ISRC reiterates that the second tendering procedure through open calls, as is done by TI Pharma and other top institutes, is a good method for assuring scientific quality through a competitive process.

4. The Mid-term review

The initial plans for the TI Pharma Mid-term Review of the Institute are discussed.

The ISRC is of the opinion that the Mid-term Review procedure to evaluate a unique public-private initiative such as TI Pharma should be designed considering a holistic approach. This includes the governance, interactions between the projects, the program management, Education & Training and the contribution of TI Pharma to the climate for (bio)pharmaceutical research in The Netherlands. Furthermore, the procedure for the Mid-Term Review should be discussed with stakeholders such as the Dutch Government.

To ensure an independent review procedure, a construction is proposed by the ISRC in which the Executive Board selects a Mid-Term Review Committee of independent international experts (not including members of the ISRC) that would conduct a review based on various inputs, such as project data (both qualitative and quantitative), information on the operations of the TI Pharma office and interviews with stakeholders (among which could be the ISRC members). The committee could be supported by an independent secretary. The review procedure will be detailed by the TI Pharma office in the coming weeks and submitted for approval to the Executive Board.

The ISRC will meet on 22-24 November 2009 to conduct a full review of the portfolio based on the July 2009 Progress Reports.

5. A presentation by the PIs of the projects 'Sustainable orphan drug development through registries and monitoring' (Project T6-208) & 'Effective therapy in HIV infection' (Project T4-212)

Project T6-208 has recently started, so the discussion focused on the design of the project and how best use can be made of the TI Pharma infrastructure.

T4-212 is a project that is nearing completion and thus was able to present the most important results of the work conducted. The ISRC was impressed by the scientific output of T4-212 and hoped that the project could be built upon further in future research. The ISRC also took note of the possible clinical implications for drug adherence for patients using ARVs (e.g. children), especially in resource limited settings.

During the wrap-up of the meeting, the ISRC members remarked that they were pleased with the progress that had been made and hoped that its constructive comments will be taken into consideration and acted upon. The combination of the Spring Meeting and the ISRC meeting was seen as very valuable as it gave the ISRC members an excellent overview of the status of the Top Institute.