



## **Top Institute Pharma**

### **International Scientific Review Committee**

Report of the eighth meeting, April 16, 2010 (Leiden, The Netherlands)

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**Report of the eighth meeting of the International Scientific Review Committee (ISRC) on April 16, 2010, in Leiden, The Netherlands**

**Summary**

The ISRC convened for the eighth time on April 16 to discuss the scientific performance and plans of TI Pharma. On the day before the meeting, April 15 2010, the ISRC attended the TI Pharma Spring Meeting. In addition to a short evaluation of the Spring Meeting and a general status update, the Committee was briefed on the results of the Mid-Term Review and the follow-up activities planned by TI Pharma. The ISRC indicated its support for these activities.

The ISRC was also updated on the status of four projects. The Committee held discussions with the researchers and shared recommendations with the consortium.

## Introduction & agenda

On Friday 16 April 2010 the ISRC convened for the eighth 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, unable to attend the eighth meeting)
- Prof. dr. R. Laing (WHO, author of the Priority Medicines report)
- Prof. dr. L. Lesko (Food and Drug Administration, USA, unable to attend the eighth meeting)
- Dr. T. Wells (CSO, Medicines for Malaria Venture)
- Prof. dr. T.M. Jones, CBE (ex Wellcome Foundation, ex ABPI)

On the day before the meeting (Thursday 15 April), the ISRC members attended the TI Pharma Spring Meeting. On Friday 16 April the ISRC meeting was held at the TI Pharma office in Leiden, this meeting lasted until the end of the afternoon. The items discussed during this meeting were:

1. Reflection on the Spring meeting / TI Pharma general status update
2. Conclusions from Mid-Term Review & follow-up
3. Project presentation: Exploitation of toll-like receptors (TLR), Dr. Anja Garritsen
4. Project presentation: The Mondriaan project, Prof. Rick Grobbee
5. Project exit, lessons learned: Effective therapy in HIV infection, Dr. Rob Gruters
6. Project presentation: Escher – Science driven drug regulation, Prof. Bert Leufkens
7. Other remarks

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

A general overview was given of the current activities of TI Pharma. The ISRC was updated on the status of TI Pharma funding, recent events and plans for the future. Special attention was paid to the new projects that will start in the context of the 'joint call' together with CTMM and BMM. Two members of the ISRC were involved in the project review procedure for the joint call. The ISRC members involved noted that the procedure worked quite well.

Next, the 2010 Spring Meeting was discussed. About 450 persons attended. This year the setup was somewhat different from previous years. The ISRC appreciated the Spring Meeting and its setup with the workshops. The keynote lecture seemed to be well received by the participants. The ISRC suggested that next year it should be considered to have a booth with more information about TI Pharma Education & Training (E&T) opportunities, and to explore additional cross-links between the project consortia.

During discussions with PhD students the ISRC noticed that the E&T program was highly appreciated. The ISRC also noticed that more awareness about the ethical aspects of medical research (e.g. in the form of E&T opportunities) would be welcome.

## **2. Conclusions from Mid-Term Review & follow-up**

The conclusions and recommendations of the Mid-Term Review, as mentioned in the final report of the Mid-Term Review Committee, were discussed with the ISRC. The main follow-up activities of TI Pharma were also shared and discussed.

The follow-up activities planned by TI Pharma include an internal review of several procedures (e.g. for Education & Training and project agreements), organizing a number of workshops and setting up three working groups consisting of Principal Investigators.

### *Further quantifying performance indicators*

Two workshops will be organized together with the Innovative Medicines Initiative (IMI) on 3 June 2010 and in fall 2010 to come up with generally supported and 'authoritative' indicators to measure the performance and output of PPPs. At the moment such measures are still lacking, with these activities TI Pharma wants to contribute to the international discussion on this topic.

### *Enhancing cooperation with Principal Investigators*

Shortly after the publication of the final report of the Mid-Term Review Committee a meeting with all Principal Investigators was held (9 February 2010). This meeting was characterized by a positive and constructive attitude. The meeting yielded a number of ideas and suggestions for further improving TI Pharma.

Based on the discussions at the PI Meeting, three PI working groups are being set up. These working groups will focus on 'Human capital', 'Information exchange' (this includes the topic of how interactions between PIs from different projects and between PIs and the TI Pharma office can be further improved) and 'Value creation'. The working groups are asked to come up with concrete suggestions for TI Pharma. The working groups will submit their report to the TI Pharma management team in Q3 2010. Results will be discussed in an Executive Board Meeting afterwards.

### *Further defining the preconditions for active portfolio management*

One of the recommendations of the Mid-Term Review Committee was to create the preconditions for active portfolio management. This includes exploring the possibilities for TI Pharma in this area through an internal review of activities and involving the Principal Investigators through the working groups (see above). The activities will focus on building the portfolio (within the context of the open call procedure), developing the portfolio and project exits from the portfolio.

The ISRC supports these activities and is looking forward to learning more about the results which will be discussed in the next ISRC meeting in the fall of 2010.

## **3. Project presentation: Toll Like Receptors, Dr. Anja Garritsen**

The Principal Investigator of this project, accompanied by some of the senior researchers, discussed the current status of the project, the output so far, bottlenecks and success factors with the ISRC.

This consortium is the largest project in the portfolio, with many different partners. The ISRC noted that PI is doing an excellent job in managing such a broad and complex consortium. The ISRC recommends that ample attention should be given to finding the right balance between diversity in research topics and focused activities. More detailed ISRC recommendations were communicated directly to the researchers.

#### **4. Project presentation: Mondriaan: a Dutch 'population' laboratory , Prof. Rick Grobbee**

The Principal Investigator of the Mondriaan project, Prof. Grobbee held a presentation. In the presentation Prof. Grobbee focused on the challenges of linking anonymized data from various resources and organizations and safeguarding privacy. Through TI Pharma Mondriaan has gained a national identity that is beneficial for bringing parties together in this project.

The ISRC was very positive about the opportunities provided by the Mondriaan project. Especially where related to phase IV research. However, according to the ISRC, it is important to explore possible linkages and synergy between the Escher and the Mondriaan project. More detailed recommendations were given by the ISRC that were communicated directly to the researchers.

#### **5. Project exit, lessons learned: HIV project, Dr. Rob Gruters**

The project 'Effective therapy in HIV infection' has been finalized. The Principal Investigator shared his experiences from this TI Pharma project with the ISRC.

In general, the experience with TI Pharma and the other partners in the consortium were very positive. TI Pharma provided a unique way to support this project, finding another way to set up this consortium would have been hard.

The ISRC wants to congratulate the project team on the results and the potential of the work done on blood spots with particular reference to the pharmacokinetics of ARVs in children in developing countries. The ISRC hopes that ways can be found to develop the findings from this project into solutions that can be used in clinical practice.

#### **6. Project presentation: Escher – Science driven drug regulation, Prof. Bert Leufkens**

The Principal Investigator from the Escher project, Prof. Bert Leufkens, updated the ISRC on the project.

The ISRC underlines the importance of the Escher project, especially where it comes to creating a true scientific basis for drug regulation. Furthermore, the ISRC believes that it is very important to explore possible linkages and synergy between the Escher and the Mondriaan project. There are many opportunities here to conduct 'proof of concept' studies for Escher concepts in Mondriaan data. The ISRC recognizes that it is necessary for Mondriaan to be at a certain stage of completion before such studies can take place. More detailed recommendations were given by the ISRC that were communicated directly to the researchers.

#### **7. Other remarks**

The next ISRC meeting will be held on 1 October 2010 in the TI Pharma office in Leiden and will start at 9:00 AM.