Management Summary of the Seventh Meeting of The PRISM Forum

hosted at the Lilly Corporate Center, Indianaoplis
17th to 19th October 2000

Meeting Theme:
"Data/Application and Information Architecture required for the Target Validation through Lead Optimisation Process"

1. The Seventh PRISM Forum Meeting

Eli Lilly hosted the seventh meeting of the PRISM Forum at their Corporate Center in Indianapolis. At the sixth PRISM it had been decided to make this a combined meeting of the main PRISM group and a Subject Matter Expert Group (SMEG) and to focus on the theme ***"Data/Application and Information Architecture required for the Target Validation through Lead Optimisation Process".*** Bristol Myers Squibb and Eli Lilly had agreed to drive the discussion on this main part of the meeting, starting from the requirements of the business process.

The meeting provided an opportunity to introduce new people to PRISM. Several members of the PRISM Forum were in the process of changing function and brought colleagues who could replace them in the future. The colleagues participating in the SMEG brought other welcome new faces to the Forum.

2. Company Information

It was not surprising that the Pharmaceutical Industry had continued to evolve since the previous meeting and hence members presented several notable changes in company organisations. Additionally there were useful discussions of certain current IT plans being deployed. As at previous PRISM meetings this information was received with great interest. It was apparent that there were similarities between companies in the issues under current focus. This led naturally to particularly beneficial comparisons of the approaches adopted. This activity continued to be of considerable value to members of PRISM.

Of particular interest were the multiple and varied implications for information management arising from the creation or "spinning-off" of independent companies. Pharmacia projected the creation of "Polaris Biotech", formally the metabolic disease research area, and Roche had announced a company, BASILEA Pharmaceutica, formed from the infectious diseases and dermatology research areas. It was observed that IM was unlikely to be consulted in advance of such "spin-offs" as to the implication for intellectual property and data management.

3. Meeting Theme:

"Data/Application and Information Architecture required for the Target Validation through Lead Optimisation Process"

The Members presented information on this theme prepared according to a proposal defined before the meeting. In particular BMS provided a valuable starting framework for the discussion, contrasting in particular the two extreme approaches of the use of a **Data Warehouse** or of **Integration Brokers.** There was general agreement that most companies were considering hybrid solutions, where both approaches had their places. The long popular idea of a unique "company-wide data model" was seen not to have been successful. It was considered better to group data into well-organised islands and provide integration technology to bring the islands together.

On the other hand, it was clear that this integration was not just a question of technology. It was essential to address the lack of common definitions of the terminology used without which the integration of data from different origins could be scientifically meaningless. This was far from trivial to achieve.

It was important to understand the different rates of change of technology and business process, and to reconcile these with the organisation skills required to support these changes.

The discussion included a consideration of how to deal with unstructured data such as text, (including forms such as annotation), and the technology available for classifying and/or structuring such data.

Peter Bares proposed to organise a SMEG on the theme of Integration Architectures in order to compare experiences with the technologies becoming available in this arena and this proposal was accepted.

Action: Peter Bares

4. The Use of a Warehouse for searching through Discovery Data

Matthias Trabandt presented an example of the use of a data warehouse for searching through discovery data within Novartis. This had originally been built upon a cheminformatics application, based on Daylight, with replication at each major site. A new version of this, currently in test, relied on network access to one central warehouse where the original Daylight search technology had been replaced by an Oracle cartridge from which an operational data set was derived. The client package had been written in Java. There were a number of questions upon which he sought the opinions and experience of the other members. This led to a useful exchange of experiences with the products of the different application vendors in this area.

Matthias was able to demonstrate the capability of the new application via an on-line connection with impressive results. Despite the modem connection the response to searches, e.g. for similar structures, was essentially immediate. Searches through over a

million compounds took slightly longer. Nonetheless Matthias was able to demonstrate the utility both of the search technology and the Java-based user interface.

5. The GRID

Chris Jones presented an update on the present activity around the GRID which continues to progress especially at the National Science and European Science funding levels. The particle physics DataGRID had been initially funded at 10 M Euros by the European Union whilst its American part had received $12 M from the DoE. In both cases there were clear indications that this was money to launch the activity and that there was further money available. The UK was about to release most substantial funding for E-Science activities including notably GRID developments in multiple sciences as part of the recent Comprehensive Spending Review. It was clear that any proposals for a GRID within the Life Sciences would be well received. There were discussions currently between EBI, EMBL and CERN that could lead to such a proposal.

A recent meeting at CERN with the EU Science Commissioner Busquin, the UK Minister for Science, Lord Sainsbury, the Head of the UK Office and Science and Technology, Taylor, the CERN Director General and Directors had discussed the importance of GRIDS for Science. It was important that Europe should play its part and not simply follow developments in the USA. Within Europe the UK wished to play a leading role. All sides agreed that it was essential to avoid diverging GRID developments in different sciences and countries. There were good arguments for a GRID Competency centre where the scientific requirements of different disciplines could be brought together around the same core GRID software and infrastructure. One such centre could possibly make sense at CERN as an extension of the mainline activity to build the particle physics DataGRID that is essential for the Large Hadron Collider experiments. It remained to be seen whether this idea could be developed into reality.

There were in addition an number of other National initiatives for GRIDs in the pipeline. Discussions with industry were taking place and trying to determine the model in which industry could participate. Clearly the “middleware” of the GRID was currently open source and based on Linux, a status that many people wished to defend. Therefore industry had to look for opportunities on top of that model. Finally discussions as how best to involve computer scientists alongside the scientists driving the requirements were very important.

6. PRISM Business Session

Given the probable change of function of a number of the original members the next meeting was considered an important crossroads in the future of the Forum. In this context Members reviewed the role and achievements of the PRISM Forum to date. In this process the Scope and Mission Statement was updated, see Appendix 1 attached. The themes of the seven meetings to date were noted as:

- Establishment of PRISM
- Benchmarking of R&D IT Organisations
- Data Mining and Visualisation
- Integration of Discovery and Pre-clinical data
- IT Leading Change

- Computer Systems Validation (Joint meeting with SMEG)
- Information Architecture for the Target Validation through Lead Optimisation process (Joint meeting with SMEG)

In addition there had been a very successful Subject Matter Expert Group (SMEG sub-group) meeting, on Safety and Efficacy.

The Members considered that the Forum had been notably successful and that they had derived considerable benefit for companies and themselves. An excellent level of trust had been created between the members, which permitted valuable exchange of ideas, and experiences. Some original fears that competitive information could be endangered had proved to be groundless.

It was decided to manage the next meeting intentionally as a transitional meeting and to ensure a good overlap of old and new members. It was also decided to make a further attempt to bring in new companies to compensate for mergers. A number of companies that had declared interest were discussed. "Polaris Biotech" was elected unanimously as a member of the PRISM Forum.

It was agreed to nominate normally one member per company. That person could bring another person specifically to cover the theme of the meeting. In targeting new companies or in exceptional cases it was proposed to approach more than one person at the company.

The members considered that the SMEG on CSV at the sixth PRISM Forum had produced valuable exchanges and contacts. It was agreed to encourage those SMEG members to continue the dialogue. Mark Chrzan was delegated by Lilly to assist John Wise in the process of organising a further meeting.

Action: Mark Chrzan, John Wise

There were two action items arising from this CSV SMEG. The first concerned the willingness of companies to share e.g. documentation and checklists as part of a process working towards harmonisation. All companies reported that they were supportive of this proposal and encouraged the CSV SMEG to continue in this direction. The second action item concerned a proposed letter from the CIOs with the aim of opening a dialogue with the regulatory authorities. Following the meeting Anders Graneli established contact with Claudio Spiguel in AstraZeneca, PhRMA Info. Mgmt. Liaison to the FDA. The letter from Spiguel to Graneli is attached as Appendix 2. The proposal for PRISM to work with PhRMA on this matter should be discussed at the next meeting. It was agreed to explore this route before going back to the CIOs.

Action: Mark Chrzan, John Wise

Diana Adams was unanimously proposed as PRISM Chairman for the year 2001. Given Diana's unavoidable absence at this meeting the appointment had to be conditional upon Diana's agreement. After the meeting Diana confirmed her acceptance.

The outgoing Chairman, Bo Skoog, was thanked for his excellent contribution and in particular for inviting PRISM to the Pharmacia Conference Facilities in Krusenberg Castle.

The PRISM Members once again thanked IBC for their greatly appreciated logistic support of the meeting, which IBC willingly agreed to continue for the proposed future.

Finally the PRISM Members expressed their profound gratitude to Jessica Robertson for all her personal contributions, which had been fundamental importance to the success of the Forum from its inception onwards, and wished her every possible success in her new career.

7. Next Meetings

The next meeting of the PRISM Forum will be hosted by Novartis, in **Vienna, Austria,** and held on the **7th to the 9th May 2001**.

The theme of this meeting was decided as:

Life-cycle management of alliances and partnerships within R&D including:

- *Data Exchange*
- *Assessment, Initiation, On-going Management and Closure*
- *Security Issues*

It was agreed to seek someone who could facilitate this discussion, this having been effective during the previous SMEG.

Action: Breckenridge, Graneli

The provisional dates for the following meeting are **22nd to 24th October 2001**, potentially in Boston, USA hosted by Beaufour-Ipsen.

Chris Jones
25 October 2000

Appendix 1 - Scope and Mission of The Pharmaceutical R&D Information Systems Management Forum - known as 'The PRISM Forum'

Scope

- The scope of the PRISM Forum covers the use of Information Technology to impact the R&D Processes of the Pharmaceutical Industry.

Mission, Membership and Meetings

- The mission of the PRISM Forum is to:
  - share pre-competitive information and best practices of IM/IT supporting the R&D process.
  - define requirements for standards to support information exchange across the R&D process.
- The PRISM Forum is open to individuals able to represent their companies with respect to the above scope of PRISM
- It meets twice a year, normally once in Europe and once in the USA

Code of Conduct

Meeting Participation

- Be accountable
- Operate with integrity
- Honour diversity of the participants
- Be willing to share pre-competitive information in a timely manner
- Strive for common understanding
- Loyalty to the absent
- If you choose to send a delegate to the meeting they hold your "proxy"

Information Confidentiality

- Information should only be shared prudently at your company and all company specific data must be masked
- Protect confidentiality and treat other company's information as you wish them to treat yours

Between Meeting Commitments

- Meet agreed upon commitments and deadlines
- Respond promptly to communications from other members

Outcomes

- Enhanced peer contacts and personal networking
- Determine best demonstrated practices and experiences
- Identify trends in the technology and business

Chairman and Secretary

- The Chairman and Secretary should be elected annually.

Revised 18 October 2000

Appendix 2
Correspondence on CSV from PhRMA

Anders,

First a bit of history to explain the PhRMA/FDA work and my role in it. In1998 Zeneca asked me to play an industry-wide role at PhRMA as IM Liaison to the FDA in the context of the FDA Modernization Act of 1997 which states that they will operate in a "paperless environment" by fiscal year 2002. I then formed the IMWG-Information Management Working Group, with primarily R&D IM Vice Presidents from the major Pharma companies and the FDA CIO, to oversee the investment and evolution of a common electronic environment that would approach "paperless" for both industry and the agency. In 1999, based in the success of our efforts, the PhRMA CIO Forum became part of the IMWG with several industry CIO's joining us, and the group then evolved to become IMPACC - Information Management Policy & Affairs Coordinating Committee, which is a standing committee in the Scientific & Regulatory Section of the PhRMA structure. I am the current chairperson of IMPACC, and our primary charter is to coordinate the formation of industry positions in the area of Information Management, and the systems and technology that support it. I am also a member as Industry liaison of the FDA IMAB-Information Management Advisory Board, which is chaired by the FDA CIO; the other members are the FDA Center Directors and their respective CIO's.

Sorry for the longish paragraph above, but I thought I would explain to you some of the acronyms that are likely to come up if the PRISM opportunity becomes a source of joint work. To that effect, I am sure you can infer from the above that the IMPACC plate is primarily taken with issues related to the FDA IM rolling 5-year Plan, as it relates to the evolution of the "paperless environment". Things like their implementation of a common IT infrastructure across the agency, a common interface/gateway for industry, performance measures, implementation of 21 CFR Part 11 (the electronic records and signatures rule), IM components of the evolution of PDUFA (Pharmaceutical Drugs User Fee Act), and the like. We also, nevertheless, sponsor the pursuit of broader items of impact to the industry in our area of expertise, primarily through spawning working groups of interested parties/people; items like IT Skills for the Future, and the Engagement of Minorities, and The Impact of the INTERNET on the Pharma Business. Your item on Computer Systems Validation strikes me as potentially one of these latter ones, so I would be glad to offer you and/or others from PRISM to come present to IMPACC seeking our support to spawn a working group with proper existing or new parties, the agency included, which could address the concerns that you raise. We have a meeting this coming week, but our agenda there is more than full... the next meeting is August 16-17, and again I would be happy to give you time in that agenda. Please let me know how you would like to proceed.

Thanks for your interest, and I look forward to meeting you in person when the opportunity presents itself.

Best regards. Claudio.

Dr. Claudio Spiguel
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Appendix 3

Members attending the 7th Meeting of the PRISM Forum

Sheldon Ort	Eli Lilly & Co	
Santae Kim	Eli Lilly & Co	
Anders Graneli	AstraZeneca	
Peter Bares	AstraZeneca	
Shawn Ramer	Bristol-Myers Squibb	
Jason Bronfeld	Bristol-Myers Squibb	
Ronald Behling	Bristol-Myers Squibb	
Matthias Trabandt	Novartis	
Bo Skoog	Pharmacia	Chairman
Robin Breckenridge	F. Hoffmann-La Roche	
Jessica Robertson	IBC	Logistics
Chris Jones	CERN	Secretary

Apologies

Diana Adams	Wyeth-Ayerst
John Wise	Beaufour-Ipsen
Frank Brown	R.E. Johnson
John Hearn	Glaxo Wellcome
Frank Harrison	Hoechst Marion Roussel
Seth Pinsky	Merck Research Laboratories
Richard Roberts	Pfizer Inc.
René Ziegler	Novartis