Minutes of the Fifth Meeting of The PRISM Forum

2nd and 3rd November 1999 Wyeth Ayerst Research Princeton NJ

Members

Wyeth Ayerst Research F. Hoffmann-La Roche AstraZeneca CERN Eli Lilly & Co Bristol-Myers Squibb Pharmacia & Upjohn Roche Discovery Welwyn

Apologies

J&J, PRI AstraZeneca Hoechst Marion Roussel GlaxoWellcome Pfizer Inc Novartis Pharma AG

Logistics IBC

Day One

1. Chairman's Remarks and PRISM Forum Membership

The Chairman, Sheldon Ort, welcomed the members to Wyeth Ayerst in Princeton and thanked Diana Adams for the provision of the facilities and for acting as local host.

He welcomed Anders Granelli back as deputy for Neil Stutchbury, unable to attend. John Wise was welcomed in his new role as Head of R&D Informatics for Beaufour-Ipsen International.

Finally Sheldon noted the apologies from those members unable to attend this time (see above). Although the group was getting slightly smaller through mergers he felt that the core membership was working well and members trusted each other such that this led to useful exchanges both during and outside the meetings.

Diana Adams Robin Breckenridge Anders Graneli Chris Jones (secretary) Sheldon Ort (chairman) Shawn Ramer Bo Skoog John Wise

Frank Brown Neil Stutchbury Frank Harrison John Hearn Richard Roberts Rene Ziegler

Jessica Robertson

2. Minutes of the Last Meeting , Actions arising, and Agenda of this meeting

The minutes of the last meeting were accepted with no changes. The action list was reviewed. Clearly one had to be realistic about how much members were able to do as homework between meetings and benchmarking activities seemed low on the priority list. Members all agreed that this kind of activity was best handled during the meetings themselves.

3. PRISM 5 Meeting

In view of the new activities of the Secretary, the main body of the meeting is reported in the attached Management Summary that was distributed after the meeting. Apologies!

4. Next Meetings

It was agreed to hold the next meeting near Stockholm at a facility available to Pharmacia who will host the meeting in **the week beginning the 8th May 2000**. A PRISM SMEG will be run in association with the meeting.

The SMEG will start on the evening of the 8^{th} , with the main meeting on the 9^{th} and the 10^{th} , whilst the PRISM Forum will assemble on the evening of the 9^{th} for a meeting on the 10^{th} and 11^{th} .

The proposed dates for the subsequent meeting, PRISM 7, were **the week of the 16th October 2000**, with potentially a SMEG on the 17th and 18th and the main PRISM on the 18th and 19th.

5. Business Issues

Bo Skoog was appointed the Chairman for the year 2000, and Chris Jones agreed to continue as Secretary. The out-going Chairman, Sheldon Ort was thanked for his sterling efforts in keeping the group focussed and effective. Sheldon emphasised that he found the group to be trustful and very useful.

The assistance of IBC was again considered invaluable and Jessica was thanked in particular. It was agreed that IBC could also participate in the SMEG Groups.

It was decided that the presence of eight companies was to be considered as necessary for a normal PRISM meting and six companies attending for a PRISM SMEG.

It was agreed that members would send deputies if at all possible when they were unable to attend.

Management Summary of the Fifth Meeting of The PRISM Forum

1. Membership and Company Information

At its fifth meeting, the PRISM Forum welcomed Beaufour Ipsen as a new member. The comparison of the informatics issues facing this medium sized international company with those experienced in the larger Pharma companies led to much valuable discussion. The presentation of a methodology to review and balance with available resources the portfolio of IT projects that had been requested by the user community led to an excellent exchange of such methodologies amongst the companies and a discussion of the relative merits.

Several established members presented new organisational information of interest. See the apendix at the end of this summary for the list of companies that attended this fifth meeting.

2. Priorities for the year 2000

Members had been invited by the Chairman before the meeting to prepare a presentation of their priority areas in next year's planning. The resulting open discussion identified clear common themes and initiatives across the pharma discovery value chain as well as a number of new ideas and products. This led to a selection of possible topics to be revisited usefully at future meetings. Many companies are focussing their attention on mathematical modelling and simulation, and supporting generation/lead optimisation processes. As a general trend it was noted that informatics organisations were beginning to support business processes rather than provide point solutions.

3. Theme Discussion: "IT Leading Change"

Shawn Ramer and Robin Breckenridge led the theme discussion of the meeting on the subject of "Informatics Leading Change". An extended and interesting discussion demonstrated the relevance of this theme to the members, and the difficulty of demonstrating that major success comes about simply through the application of IT alone.

Two broad aspects of informatics leading change were discussed: the technology driving the changes in the business, and the role of the informatics organisations in participating in the business issues and hence enabling change. Simply implementing new technology does not necessarily change business process. Co-evolutionary processes are necessary. In many cases it is the opportunity provided by many technologies maturing together that leads to an opportunity for successful change. In addition, the business functions have not embraced the need for changes to their processes and organisation sufficiently to benefit from the introduction of new technologies.

The discussion highlighted the particular difficulty caused by change in the regulatory area where change is an anathema and there are many issues inadequately clarified. It was clear that clarity of thinking needed to be applied when differentiating between those pre-clinical development activities that could be exploited for the benefit of discovery (e.g. screening for toxicological, DMPK, stability data) and those activities that were dealing in the acquisition of GxP data to support regulatory submissions. Innovation needed actively to be exploited for the former but

cost-conscious, cost effective change needed to be carefully managed for the latter due to the profound overhead of computer systems validation.

It was widely agreed that informatics departments had to get closer to the functions. They needed to have an integrated rather than just an aligned strategy. Importantly, science management needed to be more aware of how best to derive maximum benefits from technological advances and become more capable of co-ordinating and managing change across geographically dispersed research centres.

4. The Grids – a blueprint for a new computing architecture

Chris Jones presented an idea that has very quickly attracted significant attention and support especially in the USA. The book entitled "The Grid, a blueprint for a new computer architecture", describes a common vision of how to move forward in distributed computing in distributed organisations. "Grids" have attracted funding of the order of \$100M per year contributed from NSF, NASA, DoE and other USA agencies. Since many real issues in distributed computing cannot be resolved by individual organisations, many people welcome such a common vision.

Much of the "middleware" that is required in order to implement the grids is the same or similar across multiple scientific areas, be they particle physics, astrophysics or bioinformatics, and indeed may be applied to any distributed enterprise. The idea of multi-disciplinary development is attractive to central funding agencies. A forum, similar in organisation to the Internet Engineering Task Force, (engendering discussion and creating consensus with its RFCs), has been established as a way of developing the necessary non-proprietary standards, see www.gridforum.org. There are many parallels between the seed funding (from governments and other leading organisations) of the IP Internet in 1987/8 and the current phase of the grids.

5. Company Benchmark Information

The group continued its benchmarking activities, comparing organisational information across the companies. It was decided to change approach and in future to treat the benchmarking as an interactive exercise during the meeting. Members not prepared to contribute would be asked to leave the room for this session.

6. Subject Matter Expert Groups

The subject matter expert group, SMEG, organised by John Wise on safety and efficacy in NCD had been successful. It had produced useful comparative information on the information technologies in use and some of the accompanying issues. In particular, it was seen as a useful training exercise but it required more than zero effort to organise the SMEG.

The meeting considered that it would be very useful to organise another SMEG in parallel with the next PRISM meeting. The responsibility for organising the SMEG on the subject of Computer Systems Validation will be held jointly by Anders Granelli and John Wise. Sheldon Ort and Shawn Ramer will investigate the practicality of a SMEG on Data Architectures for a future meeting.

Several companies presented initiatives that they were taking to organise courses at various levels at a number of universities as ways of attacking the shortage of appropriately skilled informatics staff for the pharmaceutical industry. IBC is also involved in some initiatives for Distance Learning Modules. See Appendix 2 at the end of this summary.

7. Business Issues

Bo Skoog was appointed the Chairman for the year 2000, and Chris Jones agreed to continue as Secretary. The out-going Chairman, Sheldon Ort was thanked for his sterling efforts in keeping the group focussed and effective.

It was decided that the presence of eight companies was to be considered as necessary for a normal PRISM meting and six companies attending for a PRISM SMEG.

8. Agenda Items for the Next Meeting

- Chairman's Remarks
- Minutes of Fifth Meeting, Action Items and Matters Arising
- Possibilities for **Dialogue with the drug regulatory authorities**
- All companies update on **Priorities for the Year 2000**
- Issues arising out of the **Company Benchmarking**
- SMEG findings on "Computer System Validation" to be presented to PRISM group and discussion to follow
- Presentation on the "Future of Electronic Library Services"
- Update on "The Data Grid" CJ
 - Feedback from viability of **SMEG Data/Application Architecture** SO/SR

9. Next Meetings

Pharmacia and Upjohn near Stockholm, Sweden will host the next meeting in the week beginning the 8th May 2000. A PRISM SMEG will be run in association with the meeting.

The SMEG will start on the evening of the 8^{th} , with the main meeting on the 9^{th} and the 10^{th} , whilst the PRISM Forum will assemble on the evening of the 9^{th} for a meeting on the 10^{th} and 11^{th} .

23 March 2018 Chris Jones

Appendix 1 Companies attending the fifth meeting of the PRISM Forum

- AstraZeneca
- Beaufour Ipsen
- F. Hoffmann-La Roche
- Eli Lilly &Co

- Pharmacia & Upjohn
- Wyeth Ayerst Pharmaceuticals
- Bristol-Myers Squibb

Companies unable to attend

- Glaxo Wellcome
- Hoechst Marion Roussel
- Novartis
- Pfizer
- R.W. Johnson Pharmaceutical Research Institute

Appendix 2 Educational Program Initiatives

• S.Ort

–Indianna University / Perdue University Integrated Masters and/or Doctorate in Scientific Computing

- J.Wise -Bath University, Masters Degree and/or Diploma in Informatics in the Pharmaceutical Industry
- Jessica Robertson

– IBC

- -distance learning programme
- -continuing education programme points allocated
- S.Ramer
 - Bioinformatics, Ray Oakes St Johns University in New York
- C. Jones– good web reference for bioinformatics courses: <u>http://www.techfak.uni-bielefeld.de/bcd/ForAll/Econom/study.html</u> –Geneva University – Informatics for Life Scientists –UCSD http://matisse.ucsd.edu/itp-bioinfo