Minutes of the Sixth Meeting of The PRISM Forum

10th and 11th May 2000
hosted by Pharmacia at
Krusenberg Hergård, Uppsala

Members

Rene Ziegler	Novartis Pharma AG
Robin Breckenridge	F. Hoffmann-La Roche
Anders Graneli	AstraZeneca
Chris Jones (secretary)	CERN
Robert Herouet Ort	Eli Lilly & Co
Shawn Ramer	Bristol-Myers Squibb
Bo Skoog (chairman)	Pharmacia
John Wise	Beafour Ipsen

Apologies

Sheldon Ort (sent deputy)	Eli Lilly & Co
Diana Adams (send SMEG representative)	Wyeth Ayerst Research
Frank Brown	J&J, PRI
Neil Stutchbury (sent deputy)	AstraZeneca
Frank Harrison	Hoechst Marion Roussel
John Hearn (sent SMEG representative)	GlaxoWellcome
Richard Roberts	Pfizer Inc

Logistics

Jessica Robertson	IBC
Katherine Rogers	IBC

Day One

1. Chairman's Remarks and PRISM Forum Membership

The new Chairman, Bo Skoog, welcomed the members to the magnificent conference facilities of the Krusenberg Castle near Uppsala and its 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.

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 8th, with the main meeting on the 9th and the 10th, whilst the PRISM Forum will assemble on the evening of the 9th for a meeting on the 10th and 11th.

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.

Joint Meeting with PRISM SMEG on CSV

In his role as Chairman of the PRISM Subject Matter Expert Group meeting on Computer Systems Validation John Wise introduced the members of the SMEG and in particular Mark Chrzan from Eli Lilly who had volunteered to present the discussions and conclusions of the SMEG. (These will be available in detail as part of the SMEG report.)

Mark began by reviewing the reasons why CSV had to be taken seriously. Clearly many of these were related to the demands of the regulatory authorities, but there was an over-riding consideration of desire to produce safe drugs of high quality.

The team had constructed a "Dream CSV environment" as an ideal target and described its properties and component parts.

Mark covered the aspects of ISO 9001 and its importance as a global standard. Two companies present had been certified for ISO 9001 but not all.

The group had the constructed a list of components of a CSV Policy. It was pointed out that this list did not explicitly cover the often-neglected operational support considerations. They had in addition listed some of the templates and tools that should be available and the requirements, for example in the area of glossaries.

21 CFR Part 11 had been in place since 20th August 1997. All companies agreed they had a policy, implicit or explicit, to ensure that new products conformed. However an action plan was necessary to create an inventory of applications, (perhaps building on Y2K efforts), determine their compliance and priority for remediation as necessary. The time-scale for completing this was estimated as five to seven years, but starting from August 1997!

A disaster recovery policy had to be in place and from the point of view of the FDA it was seen as how well a company could recover efficiently from e.g. an accident leading to a potentially dangerous batch of a drug in circulation.

A defined training program and training records were essential but there were a surprising number of wider consequences to consider, for example the large number of people who should have at least minimal GxP training simply because at some stage they came into contact with GxP data. If the HR system were used to support GxP training records the company could be asked to validate its HR system. This led to a rich and useful discussion of the full PRISM group.

There were growing requirements for software version control, perhaps operating system version control, and this could extent to validation of desktop systems or even hardware. This continued into a discussion of other controls on infrastructure in general

The interesting question of responsibilities for CSV in relation to CROs and other third parties was discussed. As a consequence there were arguments for using a small number of well-recognised CROs.

The main conclusions was that this was the cost of doing business and that each company had to work at implementing CSV as correctly and efficiently as possible.

Questions to PRISM:

- Is it possible to share CSV documentation?
- Can we collaborate on 3rd party assessments?
    - E.g. share a checklist?
    - E.g. share the results of a vendor audit?
- Is there any competitive gain from sharing individual company efforts?

The PRISM Members were sympathetic about such initiatives to at least share best practices even where full harmonisation was pragmatically unlikely because of policies already in place. It was noted that mergers provided further opportunities for harmonisation. It was agreed that PRISM members, in conjunction with their SMEG representatives, would take this matter back to their companies and discuss whether it was considered worthwhile to participate in such a process. The PRISM members are required to reply to the PRISM Chairman by the 16th June 2000.

Action: Prism and SMEG Members

On behalf of the PRISM Members the Chairman thanked the SMEG members and in particular the chairman for their excellent insightful work and constructive proposals. He noted that this second SMEG, as the first, had more than proved the utility of such exercises.

Resuming the main PRISM Meeting

The Chairman noted that the session exchanging latest organisational information amongst the members had been difficult to plan in advance and had in practice taken the whole morning. It was ……useful.

Dialogue with the drug regulatory authorities

Bo Skoog reported as requested on his discussion with his CIO on the interaction between the PISA organisation and the FDA. This seems not to have progressed and members questioned whether the CIOs where sufficiently aware of importance of the issues at stake. In particular there has been considerable change arising through the spread of IT in the regulatory area and perhaps the CIOs are not fully aware of these new issues.

Some form of discussion with the CIOs seemed desirable in order to increase their awareness. In contrast to many other issues in front of PRISM where members are responsible and able to act, this particular issue of how to open up a dialogue with the FDA requires intervention at another level such as that of the CIO.

The question is how to do this. Maybe we invite the host CIO for an hour at each PRISM or we provide words to be presented by one of us to some forum of CIO's. Do they have suitable forum. There is a Hever meeting of heads of R&D. We don't know.

Agree to prepare suitable documentation to be given by each member to his CIO.

Agree to invite host CIO to each meeting as a method of improving contact between PRISM and CIOs.

Staffing Issues

This issue was discussed at the previous meeting. The conclusion was that the trained staff required e.g. in bioinformatics were not available today and that the courses now starting in universities would need say four years to produce candidates.

Jessica Robertson presented the possibilities of distance based learning, as offered by IBC. It was agreed to investigate a presentation on this at the next meeting.

Action: Jessica Robertson

John Wise proposed that if members felt that there was a skills shortage in the pharma industry then there was a responsibility to press the universities to produce one year courses, MSc or diploma. Areas to be treated within the context of pharma could be project management, communication skills, the constraints of the regulatory domain, and business process.

Future of Electronic Library Services

This session was driven by John Wise, renowned for his clearly analysed views on this subject. He began by characterising some of the features of the classic paper library and of librarians. He then reviewed several systems providing e-mail alerts in various forms in a modern digital library and noted that this involved considerable change that was challenging the librarians. Within BI they had considered using the services of an information aggregator in order to supply the required range of electronic journals at an advantageous price. This led to other advantageous such as a standardised interface. Companies offering these services were e.g. EBSCO, RoweCom, SWETs, OVID, Blackwells, Adonis, OCLC and certainly some others. This indeed seemed a sensible way to modernise and save money.

It was generally felt that this was a considerable change in the role of the classic librarian but that a new form of librarian was emerging closer to an information scientist that performed quite complex intelligent information searches in order to alert scientists of new information available in their area of interest. There followed a discussion of the future role of the librarian. Shawn Ramer noted that the volume of electronic information available had increased so dramatically recently that simple searches were often ineffective. This reduced the capability of the scientist to find information and provided an opportunity for class of information scientist trained in more complex searching techniques. Jessica Robertson noted that this was coming closer to the task of searching patent databases for IPR issues. Should such people be attached directly to project teams? Was it possible to convert all librarians to this new role? Experience seemed to indicate that not all of them could make this change and these people continued to look after the classic paper library or the archive.

Bo Skoog demonstrated the facilities of the Pharmacia Global Information Network. Scientists had considerable flexibility to define areas of interest. This was built on software technology for building portals from Plumtree. This seemed to be an excellent facility. Pharmacia also used an information aggregator. In order to support this portal there were four people per therapeutic area. There was a perceived shortage of people with these skills on the open market but that, given appropriate status, some scientists were taking up this work.

Rene Ziegler asked whether there were security issues in leaving a search trail through these portals in a way similar to searching for a sequence. Shawn noted that there potentially some issues of loss of IPR as well. It was concluded that in the end this came down to a contract of confidentiality with the information supplier.

The Grid

Chris Jones presented an update of the GRID activities world-wide. This has clearly come a very long way since last October. GLOBUS etc.

Feasibility of a SMEG on Data/Application Architecture

Shawn Ramer and Sheldon Ort held a meeting to determine the feasibility of a SMEG on the subject of Data/Application Architecture. The discussion focussed on IT support for lead discovery and optimisation. They analysed in some detail the probable content of such a meeting, and found that there were many items other than just architecture to consider, e.g. business process overview, key decision points, information required to support decisions, agree on common language for architecture components, description of programs and projects, solutions: make/buy/partner, metrics and demonstration of business value, other approaches and advanced technologies.

They recommended:

- At October meeting expand participants to enable discussion of above topics
- Determine appropriate SMEG topics for follow-up
- Determine October pre-work needs

It was proposed to take two full days for the next PRISM Meeting, namely Tuesday 17th and Wednesday 18th October 2000 in Indianapolis hosted by Ely Lilly. Clearly this study would occupy the major part of these two days, with potentially a half-day break out of a sub group whilst PRISM conducted its normal meeting. This agenda would imply that people arrive on Monday 16th October and not plan to leave on the Wednesday evening. Sheldon Ort and Shawn Ramer volunteered to put together the agenda of the meeting with the Chairman Bo Skoog. This implied some work also to prepare a list of deliverables and to identify a generic business model if possible.

The likely consequence of such a combined meeting was seen to be the initiation of several SMEGs. This was seen as a thoroughly desirable direction for PRISM, providing that each SMEG had a facilitator/sponsor from PRISM prepared to drive the group.

Business Session

Management summary

Next Meeting see above

Programme Issues

Is there anything to learn from inviting speakers from other industries such as aerospace, auto industry, financial? Answer yes in principle if we can fit them into the program.

Action: Jessica and Rene

John Wise will investigate getting a CRO to talk at a future meeting with emphasis on computing in the regulatory domain.

Action: John Wise

Membership Issues

The question was raised whether Biotech should be invited to join the Forum. It was felt that one needed to understand better what advantages this would bring companies s? Need to understand better what we would get out of this?

Next Meetings

The next meeting will be held Indianapolis from 17th to 18th October 2000, arriving on October 16th in the evening. The meeting will be two full days this time.

The meeting in Spring 2001 is proposed for May in the Alsace hosted by Novartis. Rene Ziegler will propose dates.

Action: Rene Ziegler

Draft memo for CIO on
Opportunities for dialogue with the drug regulatory authorities

The PRISM Forum is a group of experienced Pharmaceutical R&D IM/IT managers from different companies who meet twice a year to share pre-competitive information and best practices of IM/IT supporting the R&D process.

In several meetings a recurrent theme of computer system validation led to the establishment of two specialist sub-groups. Both meetings were productive and illuminating, generating concrete action items that are being pursued. In addition, an opportunity was identified for opening a dialogue with the drug regulatory authorities. This dialogue would aim at shaping the future environment for computer systems validation. The assessment of this group is that this opportunity goes beyond the scope of the members and that this dialogue would be better initiated at the CIO (or equivalent) level.

The PRISM Forum considers this issue of considerable importance to the industry and therefore raises this to your attention for your active consideration and feedback. .

Members of the Subject Matter Expert Group on Computer Systems Validation

Jill Collins	Wyeth-Ayerst Research
Robin Breckenridge (part time)	F. Hoffmann-La Roche
Brian Corfield	AstraZeneca
Frank Hémont	Beaufour Ipsen
Mark D Chrzan	Eli Lilly & Co
Shawn Ramer (part time)	Bristol-Myers Squibb
Per Hallin	Pharmacia
John Wise (SMEG Chairman)	Beaufour Ipsen
Jane Duesterberg	Bristol-Myers Squibb
Carl Richards (consultant)	FCG
Steve Williamson	GlaxoWellcome