Minutes of the Second Meeting of The PRISM Forum

18th and 18th June 1998
Eli Lilly
13 Hannover Square
London W1R, UK

Members

Diana Adams	Wyeth Ayerst Research
Robin Breckenridge (chairman)	F. Hoffmann-La Roche
Adrian Hampshire	British Biotech Limited
Chris Jones (secretary)	CERN and EBI
Staffan Linqvist	Astra Hässle AB
Sheldon Ort	Eli Lilly & Co
Bo Skoog	Pharmacia & Upjohn
Neil Stutchbury	Zeneca Pharmaceuticals
John Wise	Roche Discovery Welwyn
Paolo Zanella	European Bioinformatics Institute

Apologies

Hans-Heinrich Hausberg	Merck KGaA
Rene Ziegler	Novartis Pharma AG

Secretariat

Zahid Tharia	IBC
Jessica Robertson	IBC
Kavita Talreja	IBC

Day One

1. Organizational Remarks

The Chairman, Robin Breckenridge, thanked Sheldon Ort for providing the meeting location and facilities within Eli Lilly, London. He also thanked IBC for their continued logistical support. Robin welcomed as a new member Staffan Linqvist from Astra Hässle AB. He noted apologies from Rene Ziegler, Novartis and Hans-Heinrich Hausberg, Merck who had other pressing business engagements. Since the number of Roche attendees at the previous meting had been too high, Klaus Römer had kindly agreed to relinquish his membership.

Staffan Linqvist, who had been contacted as a potential new member by Bo Skoog, introduced himself, explaining that Astra had finally appointed a global IS/IT manager just the day before. In the future it might well be that this person would be the most appropriate member to participate in the group. However, in the meantime, he had felt it better for someone from Astra to attend rather than wait for this to be put in place.

2. Minutes of the Inaugural Meeting and Matters arising

The Minutes of the inaugural meeting were accepted with one change. At the bottom of page 5, point 9, "Theme for the June meeting" should state "Theme for the September meeting".

The major matter arising was that not all members had filled in the benchmarking questionnaire and those members that had made the effort were concerned that this would be hard to justify when reporting back to their management. **It was agreed that those who had not provided information would not receive the information from the other companies**.

There was strong agreement that other major pharmaceutical companies needed to be brought into the Forum. See the next point for a summary of actions on this matter.

There was a discussion concerning the name of the forum chosen at the last meeting, namely Parma. Amusing though the aetiology of the name might be, it was felt unsuitable in that it did not convey the role of the group in its name. A competition was launched for a new name. After serious and exhaustive discussion over dinner, Sheldon Ort proposed **"The PRISM Forum"**, where PRISM stands for "**Pharmaceutical Research Information Systems Management**". This name was unanimously adopted (the next day). In order to avoid propagating confusion the new name is used throughout these minutes.

The **Scope and Mission** draft statement, (appendix 1 of the previous minutes), was largely approved, although it was felt necessary to find some more specific "outcomes". The proposals made have been incorporated in the new scope and mission statement attached to these minutes.

The **Code of Conduct** written by Sheldon Ort was unanimously approved, with congratulations to Sheldon. It was proposed to incorporate this in the Scope and Mission statement and this has been done, (see Appendix 1 of these minutes).

Preliminary proposals were made for the **next meeting**. (See the end of these minutes.)

3. Membership

It was generally felt to be most important that other companies be brought into the PRISM Forum. The contacts agreed as actions at the first meeting had produced a new member from Astra, a contact at Jannsen (J&J), Michel Hoing, who was unable at the last minute to attend this meeting, and some interest from other companies who also could not attend this meeting. Philip Loftus of GlaxoWellcome had agreed to come or send someone to the next meeting, as had Ford Calhoun of Smithkline Beecham. It was felt important to contact Pfizer, Bristol Myers, RPR and MSD at least in addition to the above.

Contacts with other Companies that might join the Forum. The following contacts with other companies were agreed:
   1) Robin to contact Dan Klingler at Bristol Myers Sqibb

2) Diana to maintain contact with Tom Scarnecchia to give him feedback on the meeting and to inform him that the next meeting will be in the USA.
3) Neil to contact Trevor Devon, Pfizer
4) Robin to contact RPR
5) Robin to contact MSD
6) Robin to continue contact with Ford Calhoun, SB
7) Jessica to provide a name to Sheldon to contact at HMR

In addition, Robin will send a letter to the Research Directors in the companies, with copies to the PRISM Members.

Action: Stutchbury, Adams, Breckenridge, Robertson, Ort

There was a proposal to include Japanese representation which had some support in principle, but in practice it was felt by the majority that one should proceed in stages and that it was too early for such involvement.

4. Agenda of this Meeting

John Wise demonstrated his talent as a facilitator in a review of the agenda of this meeting. Those items listed in this discussion but which did not get discussed in detail have been added to Appendix 2, "Key Topics for discussion".

The members felt strongly that it would be useful to construct a "**Management Summary**" at the end of the meeting. This was done, and distributed immediately by e-mail. It is also attached as **Appendix 5** to these minutes.

5. Benchmark Comparisons

Seven companies presented benchmark information. Two of these companies, Astra and Zeneca, had not provided their information in machine-readable form but nonetheless made presentations and undertook to circulate this information in the format provided by the benchmark proforma.

The content of the presentations is deliberately not recorded here. The information and the comparisons were generally very interesting to the members. A "round the table" review demonstrated the benefit of such an activity and suggested some further comparisons that could be made.

It was agreed to try to obtain a better comparison of **the generic cost of providing a desktop computer to a scientist**, including LAN/WAN costs, e-mail, office environment, help desk, printers, file services/servers and including the amortisation/depreciation/leasing of the PC (indicate number of years).

Action: all

It was agreed to distribute the information in machine-readable form to those who had provided machine-readable input only. A period of one week was agreed as a delay in order to allow companies to update their information after their presentations, and to allow other companies to fill in the Benchmark template.

Action: Stutchbury, Linqvist, Jones

Sheldon and Diana agreed if possible to attempt a consolidation of the benchmarking information across the companies but did not commit to this.

Sheldon reminded people of a similar **benchmarking survey by KMR**. He felt it was a great deal of work and wondered who else from PRISM was involved. He was concerned that KMR's previous survey on project management had not necessarily provided the information one would want.

It was agreed that Neil and Sheldon would represent PRISM at the KMR meeting on August 4th in Germany. It was agreed that all members would inform PRISM whether or not they were going to this meeting.

Action: all

The benchmarking activity revealed that there were many organisational structures deployed in both Research & Development and IM/IT for R&D (depending on many factors including people and locations) but **managing data downstream was the key issue.**

It was universally recognised that the future success of the company was dependent on the ability to exploit historical & future data.

With the drive towards globalisation, and the need to embrace information from distributed research sites, all companies have implemented, or are implementing, **a data architecture** to allow global information sharing and are leveraging centrally controlled Research IM/IT resources to achieve this.

The Chairman proposed to focus the next meeting on this theme, and asked members **to consider to what extent they were prepared to reveal their data model at the November meeting?**

It is proposed that such a discussion take the same form as the benchmarking discussions.

In addition it was agreed that Sheldon and Robin would contact some vendors in data mining and visualisation to present at the next meeting. Such presentation should concentrate more on the state-of-the- art than on being a "sales pitch".

Action: Ort, Breckenridge

Neil proposed to circulate the ISBN of an excellent book on Data Visualisation.

Action: Stutchbury

The **Theme of the next meeting** was agreed as "Data Architecture, Data Mining and Visualisation".

Day Two

6. Role of IBC

Jessica Robertson presented IBC's proposal for their continuation of involvement with the PRISM Forum. IBC would like to continue to provide logistical support, documentation, funding for lunches and dinners. They had agreement that this support could be provided from the UK office or from the USA. If at some stage PRISM wished to use the marketing arm of IBC, e.g. for the Mission Statement, then that could no doubt be arranged.

IBC felt that it was a good opportunity for them to remain in close contact with the industry leaders in this field and to get a clear feeling for their needs.

Robin summarised the agreement of the meeting that the involvement of IBC was very helpful indeed, and in the notable absence of any other support extremely desirable. PRISM and IBC would nonetheless have to keep the situation under review. He thanked them for their continuing support.

7. Focus Groups

John Wise reported on the discussions between Diana Adams and himself on the possibility of setting up sub-groups of PRISM on specific topics. The proposal would be that several companies each assign a member of staff to discuss together, e.g. in the area of NCD IM/IT, and to report back to PRISM. This would be a means of promoting the development of new line managers by giving them a peer group within which to work.

There was a discussion of the need for clear terms of reference and clear deliverables versus the need for some freedom to form themselves into a peer group.

John acted as facilitator in drafting the Terms of Reference of such an initial group which would investigate the current and future informatics issues associated with drug safety and efficacy (see appendix 6) and report back to the next meeting. John and Diana agreed to distribute the draft Terms of Reference within two weeks.

Action: Adams, Wise

John Wise was appointed as the Chairman of this group and thus act as the liaison person with the PRISM Forum. IBC were asked to provide logistic support for the group. Members should be proposed by mid-July and a minimum of six companies was required. It was proposed to hold the first meeting in the USA during the second half of September 1998. There were suggestions to try to include some scientific users and some statisticians.

8. Wellcome Trust Genome Campus Inaugural Symposium

Chris Jones reported briefly on the above prestigious event, involving several Nobel Prize winners and other notable luminaries. It proved to be an excellent review of the current state of the science, from sequencing, genomes and genetics, through

bioinformatics and new technologies to an interesting coverage of the ethical and legal implications of genetics. The programme and abstracts can be found at: http://www.wellcome.ac.uk/

9. Staff Issues

There followed an interesting round table discussion of a number of staffing issues such as motivation, stability, and retention, and special issues such as the year 2000 problem. The members described the various incentive schemes in place to deal with these issues which, not surprisingly, varied considerably with the geographical location and the comparable job market in the surroundings.

10. Next Meeting

The next meeting was fixed for the **15th, 16th and 17th November 1998, in Roche Bioscience, Palo Alto, California**. The meeting will begin with a dinner on the evening of Sunday 15th November. The meeting may well last the full day on the 17th. It is foreseen to invite some vendors to give presentations.

The **Theme** of this third meeting was agreed as - **Data Architecture, Mining and Visualisation.** In addition there would be a continuation of the benchmarking activity and a report from the Focus Group on "Drug Safety and Efficacy". An outline of the proposed **Agenda** is attached to these minutes as **Appendix 4**.

The Scope and Mission Statement was then modified to reflect the decision that the PRISM Forum will normally meet twice a year, once in Europe and once in the USA.

11. Management Summary of this Meeting

A management summary of this meeting was agreed and distributed by e-mail for use by the members. This summary is included as appendix 5.

12. Closing Remarks

Robin Breckenridge thanked the members for contributing to a very successful, interesting and beneficial meeting. He felt that much progress had been made since the first meeting and the PRISM Forum was well on its way to being established as a most useful meeting. He reminded members of the need to follow up and involve other companies in order to increase the utility and to maximise the benefits.

Chris Jones
30 June 1998

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

Scope

- The initial scope of the PRISM Forum ranges from Discovery, through pre-Clinical Development.

Mission, Membership and Meetings

- The mission of the PRISM Forum is to:
    - share pre-competitive information and best practices of IM/IT supporting the research process.
    - define requirements for standards to support information exchange within the research process and feeding into Clinical Development
- The Forum is open only to senior Pharmaceutical Industry Research & Development IM/IT Managers
- It meets at least twice a year, normally once in Europe and once in the US

Code of Conduct

Meeting Participation

- Be accountable
- Operate with integrity
- Honor diversity of the participants
- Be willing to share pre-competitive information in a timely manner
- Strive for common understanding
- "Cabinet Solidarity"
- 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
- Establish best practices
- Improve vendor relationships. Requirements and standards will be published to, and discussed with the vendor community

Chairman and Secretary

- The Chairman and Secretary should be elected annually

Appendix 2
Flip Charts of initial round table on Key Topics (updated)

Infrastructure
- LAN/WAN
- Desktop
- Security
- Extranets e.g. (CROs)

Computer Systems Validation (CSV)

Library Infrastructure Systems
>   DB

Vendor Relationshops
>   Influence

Licensing

HPCN
- Visualisation
- Data mining

Intelligent Agents
- e.g. alerts

Share Benchmarking Information[B]

Compare/Contrast Organisation[B]

Electronic (Lab) Notebook
- How &how long we keep,
- How often need to change media in lifetime,
- Formats

Electronic Records
- Management of the archive
- Regulatory acceptance
- Patents acceptance
- E-MAIL
    - No privacy riders
    - Usage guidelines
    - Retention policies
    - (voice mail)

Service Management

Staff
- Devel., training & education
- Retention bonus
- Y2K, SAP

Personal Use of the Internet
- E-mail outside needs mgt. OK
- Some filtering of sites

Year 2000
- Laboratory equipment (all same suppliers)

Applic. Deployment/Dev/Sourcing

USERS[B]
- Committees, Priority lists, response desk

SOCIOLOGY
- Information Flow
- IM/IT embedded in Research thinking
- Staff

Charge Back
- Cost transparency
- Cost/profit centres

Management Information Systems
- Portfolio Systems
- Project Management Systems
- Resource Management Systems

TOPICS from SECOND meeting
- Emerging Technologies (CORBA. JAVA)
- Electronic Signatures
- Bioinfomatics
- Incyte
- Electronic Library
- Timely involvement of IT in business decisions

[B] These items were subsequently put into the Benchmarking Template discussions

Appendix 3
Future Topics of Interest in priority order

The topics listed in Appendix 3 were reviewed by a sub-group and five topics chosen. These were put in priority order, starting with the highest priority, and some sub-topics of interest were identified.

Vendor Relationships
- Common problems/interest
- Pressure on vendors
- Common standards/requirements
- Year 2000 problems
- Licensing

High Performance Computing – Data Mining – Visualisation
- Data Handling/Management/Warehousing
- Abstraction/Filtering/Storage requirements
- Inventory/Tools/Comparisons/Successes/Failures
- Future requirements

Application Development/Sourcing
- Buy/adapt/write
- In-house/Contract
- Common pre-competitive
- Inventory major areas

MIS - Project Management
- Portfolio/Project/Resource/Business Management
- Inventory process/decision/tools/success in practice/range of use
- Service management/service level agreements
- Overall IT Project management, with interfaces to corporate IT and users

Infrastructure
- Technical directions, h/w, s/w
- Requirements new/future by application area
- Guidelines/Standards
- LAN/WAN/Extranets/Security
- Desktop Environments/costs/support methods
- Help desks, etc.

Appendix 4
Proposed Agenda for the Third Meeting
Theme - Data Architecture, Mining and Visualisation

1. Minutes of the Second Meeting, action items and matters arising
2. Introductions and New Members
3. Benchmarking Information from New Members
4. Data Architectures
   - Scope, approach, plans, MODEL?
5. Presentations from Data Mining Vendors
6. Report from the Drug Safety and Efficacy Focus Group
7. Election of officers for 1999
8. Planning for Next Meeting

Appendix 5
Management Summary of the Second Meeting of
The PRISM Forum

1.   Overview

The group agreed to call itself the Pharma Research Information Systems Management Forum (The PRISM Forum)

Value has been derived from the first two exploratory meetings but the group recognised that value, on a long term basis, can only be achieved by expanding the membership of the group to embrace a wider representation of the pharmaceutical industry

2.   Benchmarking

The group observed that there were many organisational structures deployed in both Research & Development and IM/IT for R&D (depending on many factors including people and locations) but managing data downstream was the key issue.

2.1   Data Architecture

It was universally recognised that the future success of the company was dependent on the ability to exploit historical & future data.

With the drive towards globalisation, and the need to embrace information from distributed research sites, all companies have implemented, or are implementing, a data architecture to allow global information sharing and are leveraging centrally controlled Research IM/IT resources to achieve this.

Another business driver was the need for common data definitions rapidly to integrate information with other partners (e.g. academic organisations, 3rd part alliances, CROs)

There was universal agreement on the need to harmonise information systems and applications to support the data architecture as cost effectively as possible.

2.2   Resources

Investment in R&D IM/IT ranges from between 5% and 12% of R&D Budget.

All participating companies indicated that they are expending significant resources in developing applications to support the NDA process (reports from toxicology, drug metabolism and pharmacokinetics, and Pharmacy R&D) due to a lack of available off-the-shelf products

2.3   Staff

An open discussion took place on the issues associated with the acquisition, retention and motivation of personnel with appropriate skills to meet the changing needs of the research process supported by the IM/IT organisations.

A critical success factor for informatics activities was the tight integration of the scientific and informatics communities especially when new business alliances were being contemplated.

Appropriate staff with skills both in informatics and science are required to achieve the above.

2.4   Infrastructure

Infrastructure was either managed by corporate IS or was being migrated to Corporate IS.

3.   Focus Groups

The forum wished to determine whether its work might be enhanced by establishing short term subject matter expert groups. To investigate this, an initial group would investigate the current and future informatics issues associated with drug safety and efficacy (see appendix) and report back to the next meeting.

19 June 1998