

Minutes of the Inaugural PARMA Meeting

24th and 25th March 1998

EMBL-EBI

Wellcome Trust Genome Campus
Hinxton, Cambridge CB10 1SD, UK

Members

Dr. Diana Adams	Wyeth Ayerst Research
Dr. Robin Breckenridge (elected chairman)	F. Hoffmann-La Roche
Dr. Adrian Hampshire	British Biotech Limited
Dr. Hans-Heinrich Hausberg	Merck KGaA
Dr. Chris Jones (acting secretary)	CERN and EBI
Dr. Sheldon Ort	Eli Lilly & Co
Dr. Klaus Römer	Boehringer Mannheim GmbH
Dr. Bo Skoog	Pharmacia & Upjohn
Dr. Neil Stutchbury	Zeneca Pharmaceuticals
Mr. John Wise	Roche Discovery Welwyn
Prof. Paolo Zanella	European Bioinformatics Institute
Dr. Rene Ziegler	Novartis Pharma AG

Secretariat

Mr. Zahid Tharia, (for the start only)	IBC
Ms Jessica Robertson	IBC
Dr. Kavita Talreja	IBC

Day One

1. Organizational Remarks

Chris Jones welcomed the attendees to the conference centre of the Wellcome Trust Genome Campus. He noted that the original idea of organizing a meeting of heads of IT/IM in pharmaceutical R&D had first been discussed, (to the best of his knowledge), between Breckenridge, Ziegler, Zanella, Wise and Jones during an IBC conference. It was thus not inappropriate that IBC had kindly agreed to act as Secretariat for the organization of the meeting.

Jones noted that a similar meeting of heads of IT of major world particle physics laboratories had been launched by Zanella. This had proved a useful coordinating body. Jones had acted as organizing secretary for eight years, hence providing an opportunity for him to use this experience in helping to establish this new group.

2. Introductory Remarks

Professor Paolo Zanella, Head of the European Bioinformatics Institute explained the activities of the Wellcome Trust Genome Campus and its three constituent institutes:

- The Sanger Centre funded by the Wellcome Trust as a major genome sequencing laboratory on a world scale,

- The Human Genome Mapping Project Resource Centre, funded by the UK Medical Research Council,
- The European Bioinformatics Institute, EBI, an outstation of the European Molecular Biology Laboratory, EMBL.

The EBI had international status and had natural peer institutes in the NCBI in the States and the National Institute of Genetics in Japan. He described the three major parts of the EBI organization, namely Research, Services and the Industry Programme. The latter was funded roughly 1/3 by EMBL, 1/3 by the European Union and 1/3 by its Industry partners and affiliates. The work undertaken within the context of the Industry Programme was agreed by the contributing industry partners. It covered pre-competitive studies, workshops on new technologies such as JAVA and CORBA (as applied to bioinformatics), major conferences, industry liaison visits and other technology transfer activities. It was thus appropriate to stretch the definition of the EBI industry programme and to provide an attractive venue for this inaugural meeting. He wished the meeting every success.

Zanella's slides are available on request from the secretary:
(e-mail: Chris.Jones@cern.ch)

3. Round Table of Delegate Introductions

The delegates introduced themselves, expanding upon the summary information already provided in the meeting papers.

4. The Need for a Pharma IM Forum

Robin Breckenridge introduced this agenda item by noting the some of the ideas that had emerged in discussion with Rene Ziegler and which had led to the proposal to create such a forum:

- Leverage of pre-competitive discussion,
- Complex environment,
- IT not used sufficiently as a "strategic weapon",
- IT seen as part of the administration, too susceptible to up-sizing, down-sizing or otherwise getting kicked around,
- Many companies trying to sell IT products to the pharma industry, each trying to protect their proprietary (and hence non-standard) interfaces/formats etc.
- Could this group come up with standards?

Rene Ziegler agreed strongly with the above and added that they were all involved in the same generic process, even if each tackled it different ways. What could they learn from an exchange of knowledge and experience where this was pre-competitive and allowed? Could some working groups be set up to cover specific areas?

The table was then opened for a round table discussion. There was general strong support for the idea, and immediate proposals as to which information could be usefully exchanged and how to define valid comparisons. Examples proposed for exchange of information were:

- Percentage of the R&D budget going into IT

- Percentage of the equivalent for head count
- Cost per research worker seat
- Percentage of global IT spend in R&D

Delegates felt strongly that such a forum should be established, and that it was important to try to expand the group to include a number of major pharma companies absent at this inaugural meeting. It was noted that several companies had registered interest for this meeting but had been unable to attend because of clashes in their schedules.

After this preliminary discussion it was agreed to come back to the two last points in more detail. It was agreed to develop a template for the information to be exchanged.

5. The Mission and Scope of the IM Forum, Key Topics and *modus operandi*

John Wise acted as facilitator for a discussion session aimed at identifying:

- The Mission and Scope of the IM Forum
- The Key Topics for immediate consideration
- *Modus operandi* to pursue the objectives defined above.

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A wide ranging discussion led to the “flip-charts” summarized in appendix 3 of these minutes covering a number of key topics for consideration at future meetings.

The **preliminary conclusions of this discussion before the lunch break** were as follows:

- There is an accepted willingness to share information.
- A second meeting should be held in 3 months time,
- and a further meeting around September.
- There should eventually be sub-groups but be careful not to run too fast in the early days,
- it is more important to establish confidence in the forum first.
- It is accepted that certain important topics of concern are already handles well by other meetings and should not be treated in the forum, e.g. document management.
- It was agreed that the topics listed in appendix 1 should be put in priority order for treatment at future meetings.
- If a delegate cannot make a meeting, then it is acceptable to send a deputy.

The proposed **date of the next meeting was agreed as 17th, 18th, 19^h June 1998** with a meeting format modeled on this inaugural meeting:

- arrival on the evening of the 17th in time for dinner,
- meeting starting on the 18th and continuing until lunch on the 19th
- departure in the afternoon of the 19th.

Sheldon Ort offered to host the meeting at **Eli Lilly in London, near to Oxford Circus**.

Action: All

For the afternoon session it was agreed to split into two groups:

- One group to define the Benchmark Template to be completed as information to be exchanged.
- One group to put into priority order the key topics for consideration at future meetings, taking into account:
 - Areas not covered by other bodies
 - How to influence suppliers
 - Strategic areas

The meeting adjourned to lunch, followed by a visit to the Sanger Centre.

5.1 Report from the Benchmark Template Group

Rene Ziegler reported on the detailed template as constructed by this group and will write this up in detail for circulation by 1st May 1998.

Action: Ziegler

5.2 Report from the future Key Topics Group

Chris Jones reported on the priorities as seen by the group reviewing future key topics. Five topics were seen as of highest interest and developed in some more detail. See Appendix 4.

6. The Scope and Mission (continued)

John Wise acted as facilitator in a continuation of the round table session aimed at drafting a statement of scope and mission, charter, critical success factors and outcomes of the proposed forum. See the discussion of the next day.

7. End of Day One Summary

Breckenridge concluded by noting the willingness of everyone to contribute to such a Forum and the meeting adjourned to King's College, Cambridge for dinner.

Day Two

8. BioStandards - The Industry Programme of the EBI

Alan Robinson, in his role as Coordinator of the Industry Programme of the EBI, presented the organization and work of the EBI and in particular BioStandards, the name given to the Industry Programme when partial funding was obtained from the EU. There were opportunities for Pharmaceutical Companies to work together with the EBI either as direct partners in BioStandards or as Affiliates, the latter involving a lower level of financial commitment and providing less return.

The BioStandards currently work occupies about 15 full-time equivalents and covers e.g. development of prototypes of new software/application tools in bioinformatics, and comparisons of or investigations using existing tools. A major emphasis had been placed on running workshops of relevance to bioinformatics and some major conferences organized. Certain projects were funded directly by a sub-set of the

companies involved who benefited initially from a closer or earlier involvement in the outcome. Overall the funding of BioStandards came roughly in three equal parts from EMBL, the EU and from the industry partners.

Robinson's slides can be obtained on request from the secretary:
(e-mail: Chris.Jones@cern.ch).

9. Organizational Matters

Breckenridge introduced a number of organizational details that can be discussed or clarified during informal discussions.

1. **Role of IBC.** It was agreed that the Role of IBC in acting as a secretariat for the meeting had been very helpful and appreciated. IBC was asked to continue in that role for at least the next meeting. On the other hand people were concerned that IBC should not have access to some of the data being collected for rather natural reasons. IBC indicated that they were willing to continue even with this restriction and will make a proposal as to how they will participate.

Action: IBC

2. **Next Meeting.** The location and dates of the next meeting were confirmed as proposed earlier in these minutes at Eli Lilly near Oxford Circus. Similarly the meeting format with arrival on the evening of the 17th June in the evening. Exact details will be provided in time by Sheldon Ort and the secretary.

Action: Ort, Jones, IBC

3. **Meeting Funding.** The question of how exactly to fund the meeting was discussed. Should a common fund be created? It was decided to leave this question for the moment and arrange the next meeting in an *ad hoc* manner, as for this meeting.
4. **Name of the Forum.** Despite the excellence of the dinner in King's College no proposals for a clear and meaningful name/acronym for the forum were invented. On the other hand the inscription on the menu of the dinner, beginning with the word "Pharmaceutical" led to the proposal of the name PARMA. This was agreed as the name for the Forum from now on.
5. **Chairman.** It was agreed to elect the Chairman annually. By unanimous agreement Robin Breckenridge was proposed and elected as Chairman.
6. **Secretary.** It was agreed to elect the Secretary annually. Chris Jones was proposed and elected. Jones agreed to continue as secretary at least for the next meeting and then review this in the light of his commitments.
7. **Code of Conduct.** Sheldon Ort agreed to draft a "Code of Conduct", and this proposal is attached to these minutes as Appendix 2.
8. **Sub-Groups.** Diana Adams and John Wise undertake to examine how the work of the Forum could be enhanced through sub-groups.

Action: Adams, Wise

9. **Theme for June Meeting.** One theme for the September meeting of PARMA will be pre-Clinical Development IM/IT requirements with special emphasis on Toxicology / DMPK

Action: Adams, Wise

10. Contacts with other Companies that might join the Forum. The following contacts with other companies were agreed:

- 1) Neil to contact Philip Loftus, GlaxoWellcome
- 2) Neil to contact Trevor Devon, Pfizer
- 3) Bo to contact Astra through Stefan Lindquist
- 4) Diana to contact Tom Scarnecchia to give him feedback on the meeting
- 5) John will contact someone at SmithKline B

Once these five contacts have been made and feedback received, Robin will decide whether to activate the reserve list, which is:

- 6) Robin to contact MSD
- 7) Hans to contact HMR

Action: Stutchbury, Skoog, Adams, Wise, Breckenridge

The meeting then divided into two sub-groups:

- One group to work on the Scope, Mission and Charter in detail.
- One group to work on the agenda of the next meeting

9.1 Scope, Mission and Charter

The sub-group presented their draft of the statement of scope and mission, charter, critical success factors and outcomes of the proposed forum. After discussion, this proposal has been written up (see Appendix 1) by Wise for agreement at the next meeting.

9.2 Agenda of the Next Meeting

Hans-Heinrich Hausberg presented a proposal for the agenda of the next meeting. This is presented in Appendix 5. There was some debate as to the length of time required to cover the main item of the agenda, namely the review of the benchmarking information. On the other hand it is difficult to allocate less than 10/15 minutes per company.

10. Timing for Further Actions

- Distribution of the minutes, Easter
- Distribution of Benchmark Template, 1st May 1998
- Establish Membership of new Companies, 1st May 1998
- Deadline for receipt of information from Benchmarking, 1st June 1998
- Meeting, 17/18/19 June 1998

It was agreed that Breckenridge, Stutchbury and Jones would meet to collate the benchmarking information in early June, but that this information would not be distributed before the meeting.

Action: Breckenridge, Stutchbury, Jones

It was also agreed that a mechanism for the publication of PARMA information needs to be established.

11.Closing Remarks

Breckenridge closed the meeting with the following remarks:

- The meeting had accomplished a lot, which augers well for the future
- Open dialogue and trust were essential
- Confidentiality was essential as well
- Outside this meeting, remarks should be attributed to an anonymous company X only, this should be part of the code of conduct.

He thanked the members for a successful and enjoyable meeting.

Chris Jones
18 April 1998

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

Scope

- The scope of PARMA ranges from Discovery, through pre-Clinical Development and Clinical Development to Drug Regulatory Affairs

Mission

- The mission of PARMA is to:
 - share pre-competitive information on, and best practices of IM/IT supporting the research process. The initial focus will be in the areas of Discovery and pre-Clinical Development
 - define requirements for standards to support information exchange within the research process

Charter

- A willingness to share pre-competitive information in a timely manner
- Respecting confidentiality
- Meet approximately 3 times per year
- The forum is open only to senior Pharmaceutical Industry Research & Development IM/IT Managers
- Requirements and standards will be published to, and discussed with the vendor community

Critical Success Factors

- A mechanism for the open publishing of PARMA information needs to be established
- Benchmarking across companies needs to be accomplished

Outcomes

- Include enhanced peer contacts

Chairman and Secretary

- The Chairman and Secretary should be elected annually

Appendix 2 Code of Conduct (Proposal from Sheldon Ort)

Meeting Participation

- Be accountable
- Operate with integrity
- Honor diversity of the participants
- 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

Appendix 3

Flip Charts of initial round table on Key Topics

Infrastructure

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

Computer Systems Validation (CSV)

Library Infrastructure Systems

DB

Vendor Relationships

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

^B These items were subsequently put into the Benchmarking Template discussions

Appendix 4

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 5

Proposed Agenda for the Next Meeting

Meeting Day 1

- Introductions (30 mins)
 - Members old and new
- Review of Mission/Scope/Terms of Reference
- Review/presentation of Benchmark Information
 - Allowing 10/15 mins. per company this is ~4hours
- Issues arising
- Identify interesting trends for further analysis
- Comparison with other industries

Meeting Day 2

- IBC – proposal of participation
- Review Structure and Membership
- Review/prioritize future subjects
- Plan September Meeting