Report from the First Meeting of the PRISM Forum Subject Matter Expert Group (SMEG) on Safety and Efficacy Information Management

Thursday 25th and Friday 26th March 1999
Roche
Nutley, New Jersey

Members

Ernie Bush	Roche, Nutley
John Coutant	Hoechst Marion Roussel
G. Michael Funk	Pharmacia &Upjohn
James D. Ginn	Eli Lilly & Co
Kevin Haszko	Roche, Nutley
Mark Ifshin	Zeneca
Chris Jones (secretary)	CERN
John Wise	Roche Discovery Welwyn
Richard Young	GlaxoWellcome

Apologies

Johan Gabrielsson	Astra Arcus AB
Thomas Karsch	Novartis
Ed Klotz	Wyeth-Ayerst

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1. Agenda of the Meeting and Chairman's Introduction

The Agenda is listed in **Appendix 1**.

The Chairman, John Wise, welcomed the members to Roche, Nutley and outlined the background to the meeting, including the origins of the PRISM Forum. He explained the thinking behind the formation of this particular sub-group, the PRISM-SMEG on Safety and Efficacy Informatics. He noted that a report from the group should be prepared for the meeting of the PRISM Forum in Geneva on April 22nd 1999.

2. Members' Introductions and Expected Outcomes

During the introductory session members were invited to identify their personal expectations for the outcomes of this meeting. These are listed in **Appendix 2**.

The construction of this list led to considerable useful discussion. At the end of the meeting it was felt that all issues had at least been visited and that about half of the issues had been well covered.

3. Description of major LIMS by company, discipline and site

Including discussion of:

- Strengths and weaknesses of product and vendor
- Value adding software tools

See the **Excel spreadsheets, distributed separately**, covering the members' responses in some detail, both for the LIMS themselves and for some associated software issues.

It was agreed that commercial LIMS were strong for in-life toxicology. Support and maintenance were considered good for two of the LIMS manufacturers but the third could only provide this important feature in America. The capability of providing bi-directional instrument interfacing was particularly important for the support of clinical pathology. There was a need for better statistical interpretation tools. In general, whilst commercially strong platforms could be purchased, all needed significant customisation.

4. Electronic Reporting

- All companies are attempting to deliver information from their LIMS to their CANDA environment.
- Levels of accomplishment ranged from "comfortable" to "lots of promise".
- Documentum clearly has the market niche in holding regulatory documentation and Core Dossier for providing the publishing functionality.
- See **Appendix 3**, which lists the solutions deployed in the various companies.

5. CSV

- Members of the meeting are not altogether satisfied that CSV is optimally organised within their companies.
- Within a company there were often several bodies contributing to CSV, leading to a spectrum of experiences. Whilst in some companies responsibilities were clearly defined, in others this was less than optimally organised
- It is possible to run GxP and non-GxP on the same server, but such servers must conform to GxP standards and there must be clear control.
- An account number/name and password is sufficient as an ID and to fulfil the requirements of electronic signature. Biometrics approaches to electronic signature should only used where there is an ergonomic advantage.
- Some companies had had their computing environment examined as part of an FDA audit. It seemed that inspectors were becoming more interested in this area.
- Mike Funk felt strongly that a "sane" (and perhaps common) approach should be developed towards handling electronic requests, archives, etc. without having to keep absolutely every piece of data for 30 years. He undertook to document his thoughts and make a proposal on this issue.

Action: Mike Funk

- Desktop Environment. Control or tracking of the desktop environment is probably necessary in future. Different solutions are being tried amongst companies present. Current MS tools

make it difficult to return a PC to a known state or maintain it in a known state. This could become a bigger problem if one company were to "raise the standards" applied in this area.

Recommendation (to PRISM):
Assign a working group to look further into the above issues of the validated Desktop Environment. Such a group needs to have expertise on both the technical and the business issues. It should include at least:

- An expert in regulatory compliance
- An expert in IT infrastructure/desktop delivery (e.g. Dave Foster/CERN)
- A user in the PCS area, e.g. John Coutant/HMR
- A QA expert.

Action: PRISM, April 1999

6. End User Support

There was an attempt to capture the ratio of support staff to end users, which demonstrated the difficulty of getting consistent comparisons. Examples were different structures for support staff, or different practices within companies as to whether users go first to the help desk or to the assigned responsible person for a particular system/LIMS.

Action: all members to supply these numbers

Comparisons of figures budgeted for informatics staff training revealed a general feeling that this should increase.

In general companies tend not to train new IT staff to support the business process they are trying to support but rather to take staff/scientists out of lab/process and train them for the IT support. This seems to be a one-way process. It was felt to be increasingly hard to keep enthusiastic young IT graduates in this area of GxP.

6. CROs

There was a full discussion on the issues related to the use of contract research organisations. These included for example, the form of transmission of the resultant reports or data, and the responsibilities of the CRO to archive their data.

If there are to be any more meetings of this PRISM-SMEG on Safety and Efficacy it was agreed that it would be useful to include one of the large CROs. Issues here include:

- Electronic data management
- Data transfer
- Data archiving
- Computer systems validation and desktop systems

Appendix 1 - Agenda

Day 1 - Building 123 Conference Room B

08:30 transport from the Sheraton Suites, Weehawken to Roche, Nutley

09:00 1 Welcome
review/modification of agenda
review and confirmation of S&E SMEG charter/goals

09:15 **2** **Brief delegate introductions** (no more than 3 slides and 10 minutes per delegate) suggested content to include:
- resume
- role & responsibility in parent organisation
- expected outcomes of this meeting

10:45 *Break*

11:00 3 Review, define and agree objectives of the meeting

12:00 *Lunch*

13:30 **4** **Description of major LIMS system by company, by discipline, by site - including discussion of**:
- Strengths & Weaknesses of product and vendor
- Value adding software tools

(Delegates to use slides and 10 minutes to illustrate the above points)

15:00 *Break*

15:15 5 CSV discussion
- validation strategies
- current FDA requirements
  - e.g. computerised equipment, e-rec & e-sig
- GLP needs vs GMP needs
- platform considerations for mixed GxP / non-GxP applications environments
- CSV of desktop computers in GxP Client / Server environments
- CSV issues for infrastructure - certified environments

18:00 Close of Day 1 and transport to the Sheraton Suites, Weehawken

19:30 SMEG Dinner, (Arthur's Landing, Weehawken) – rendezvous in hotel lobby at 19:15

Day 2 - Building 123 Conference Room B

08:30 transport from the Sheraton Suites, Weehawken to Roche, Nutley

09:00 **6** **End-user support** - help/response desk - numbers of users per IM/IT staff with reference to benchmarking information, discussion on:

- expenditure for support & maintenance vs development for:
  - infrastructure and applications
  - staff & users training programmes

10:30 Break

11:00 7 Safety & Efficacy

- study reporting, CANDA electronic submission
- knowledge management
- derived data sharing for predictive model building of activity/property from chemical structure/physico chemical properties

8 Contract Research Organisations

- electronic data interchange

9 Relevant emerging technologies

12:30 10 Structure of the report for the PRISM Forum, April 1999

13:00 Close of meeting & sandwich lunch

Appendix 2
Expectations for Outcomes of the SMEG Meeting

- Develop Contacts - Personal networking
- CSV
- Collaboration
- Benchmarking of Commercial Solutions
- Identification of Key Issues
- Systems for Managing Studies
- New Technology:
  - Predictive Modelling
  - Expert Systems
  - Data Mining
- Emerging Demands/Technologies, e.g.
  - Genomics
  - DNA Microarrays
- Sane Approach to Electronic Records
- Comparison of Organisational and Service Provision
- CRO Data Integration
- Guidelines for Electronic Submission

Appendix 3
Electronic Reporting

Solutions

Company		Solution
P&U	Infodata Systems: Compose e.e. LIMS report => PDF+>"WISDOM"	Documentum CD
Zeneca	ADONIS (requires RTF files)	Documentum
GW	Tox: PDF files, drag and drop Other: manual process Looking to automate, "SWIFT Project"	Documentum CD
HMR	Tox Reports	Documentum
EL	? Eureka Doc. VB scripting, MS Word and FTP	Documentum
Roche	Manual at presentProject on-going	Documentum CD