# Minutes of the Eighth Meeting of The PRISM Forum

**hosted by Novartis at Huesseren les Château, France**
**8th to 9th May 2001**

**Meeting Theme:**
*Lifecycle Management of Alliances and Partnerships within R&D*

- · *Data Exchange*
- · *Assessment, initiation, ongoing management and closure*
- · *Security Issue*

## 1. The Eighth PRISM Forum Meeting

Novartis hosted the eighth meeting of the PRISM Forum at Huesseren les Châteaux in the Alsace.

At the seventh PRISM it had been decided to overlap this meeting of the main PRISM group with a Subject Matter Expert Group (SMEG) Workshop. The theme of the PRISM Meeting was agreed as:
*Lifecycle Management of Alliances and Partnerships within R&D*
· · *Data Exchange*
· · *Assessment, initiation, ongoing management and closure*
· · *Security Issue*.
Robin Breckenridge, Roche and Anders Granelli, AstraZeneca agreed to prepare and facilitate this session.

The subject chosen for the SMEG Workshop was *Information Architecture and Integration.* Peter Bares of AstraZeneca agreed to lead this Workshop.

## 2. Welcome, Introductions and Actions arising

The new Chairperson Diana Adams welcomed the attendees and in particular the new members. She reviewed the agenda for the meeting given the overlap with the SMEG Workshop. All action items from the 8th meeting were complete except that the proposed further SMEG on CSV had not as yet taken place. The proposal to work with PhRMA in opening a dialogue with the regulatory authorities through C. Spiguel had not progressed since Spiguel had left the industry. It was agreed that in the meantime the issue had evolved and each company had found their own way of dealing with this.

## 3. Company Information

Members introduced themselves and their current functions. This led to a number of interesting detailed side discussions and comparisons across companies, e.g. the numbers of people nowadays employed as data architects.

Rene Ziegler described his new functions in Novartis, notably as head of Corporate IT Strategy, Architecture and Standards. This involved cross-sector activities in which Pharma processes and practices were tending to dominate and spread to other areas. He also reported in detail on the organisation of the Novartis Pharma IT Community.

John Wise noted the challenges of a medium-sized Pharmaceutical company moving from a family-owned business into a publicly quoted company in the 2003 timeframe. Current issues being addressed were the implementation of an electronic document management and publishing system to support e-submissions to the regulatory authorities and re-engineering of the pharmacovigilence database to become MedDRA compliant by 2002.

Bo Skoog gave an intriguing snapshot of the many original challenges arising in the spin-off of Biovitrum from Pharmacia. He was one of several members whose responsibilities had expanded to include more of the regulatory area. John Wise noted the difficulty of finding people with experience in quality assurance and computing in this regulatory area.

Giorgio Bolis presented the organisation of Schering Plough, a new member of the PRISM Forum, thus triggering in particular a discussion of how to quantify ROI for IT investments. This seemed a worthwhile topic for a future PRISM Theme.

Anders Graneli reported that within AstraZeneca the current organisation of R&D IS, which had been effective during the integration phase of the merger, was now under review in order to propose an operating model that would better serve the long term strategic needs of R&D. The outsourcing of the infrastructure services to IBM and the emerging partnership also had implications for the future organisation. AZ was also facing a major challenge in the next couple of years from the loss of patent protection of Losec/Prolosec and associated sales.

Merrie Wise of the recently merged GlaxoSmithKline, (attending PRISM for the first time), presented their new organisation of R&D. This was focussed on Centres of Excellence for Drug Discovery (CEDDs). This led to an important discussion of this organisational model and its consequences, e.g. the boundary between Discovery and GxP processes. In general there was a realisation of the business need to manage information rather than just the technology.

Sheldon Ort updated the forum on the overall IT organisation of Lilly. IT experts were employed in the IT organisation and assigned to Projects, thus belonging to both organisations and creating a positive exchange force. They had put in place a program to recruit 450 people last year in order to reduce the percentage of contract IT staff to 25% since the burden of turnover of contractors' staff was considered too great. They had recently rolled out Spotfire as a major common tool.

Diana Adams updated the Forum on the organisation of the Wyeth Research and Information Services Department. She covered the major initiatives for 2001, including the federation of a number of databases and a new Biobench.

## 4. Joint Session of PRISM and SMEG

***"Information Architecture and Integration"***

Peter Bares reported to the joint PRISM and SMEG members on the outcome of the 1.5 days of the SMEG Workshop. All eight companies had reported their strategies for integration. The workshop had determined the objectives and scientific requirements. They had reviewed the solutions available. A write-up of the SMEG would be assembled separately and distributed later.

The high level objective was seen as:
"To obtain the best return on investment, all information relevant to the process should be made available globally, in a clear accurate form, in an acceptably quick time frame, suitable for further analysis and decision making by the best tools."

This led to five support requirements:

- Data supports the decisions in a meaningful way
- Data standardised at an appropriate level to make integration meaningful
- There is a process for publishing data and tracking it
- Access to the data is controlled to ensure people see appropriate information
- Scientists receive reward and recognition for participating

Looking at Requirement 1: **"Knowing the data"**

- UML for Object definitions and relationships (common)
- XML for Data definitions (exploratory, some impl.)
- Repositories (emerging area, no commonality)
- More Pharma collaboration necessary for vendor pressure (OMG)

For Requirement 2: **"Knowing the terminology"**

- ICH, HL7, CDISC & other external initiatives important
- Public data formats not standardised (compound, sequence, med litt.)
- Internal vocabularies most important internally, needs careful scope to be externally standardised
- Proposal to create a PRISM sanctioned team to build business case using other industry experience
- Examples. Compound information, "Raw data"

For Requirement 3: **"Road maps" (process, decision points & info flows, user interfaces)"**

- Useful for understanding "the current picture" (before decision around integration)
- Part of the Discovery "Information environment"
- Analysing alliances
- Define the process for road map design

For Requirement 4: **"Process for data extraction, aggregation, publishing & tracking"**

- Definition of capture and aggregation (local - global) to repositories
- Ownership and approval procedures
- Lifecycle and retention

- Vendor understanding of Pharma R&D environment (annotation, data typers, etc) - general need
- When and how to publish is a company decision?
- General view of audit trails/tracking (ER:ES)
- Compliance pending if documentation derived

For Requirement 5: **"Consistent interface (user & data)"**

- Ability to apply different tools on same repository (open interface standards)
- Look and feel/Mac paradigm (interface consistency)
- Data source standards (XML) + presentation standard (XSL)
- Reduce # of query languages

Looking at historical lessons learnt around the choice of technical architecture:

- Oracle + terminal client -93
- Client server 93-95
- API era 95-00 (PL-SQL/ORACLE)
- Corba (3 tier client server, not mature enough)
- EJBs and true middleware 00-"for a while"

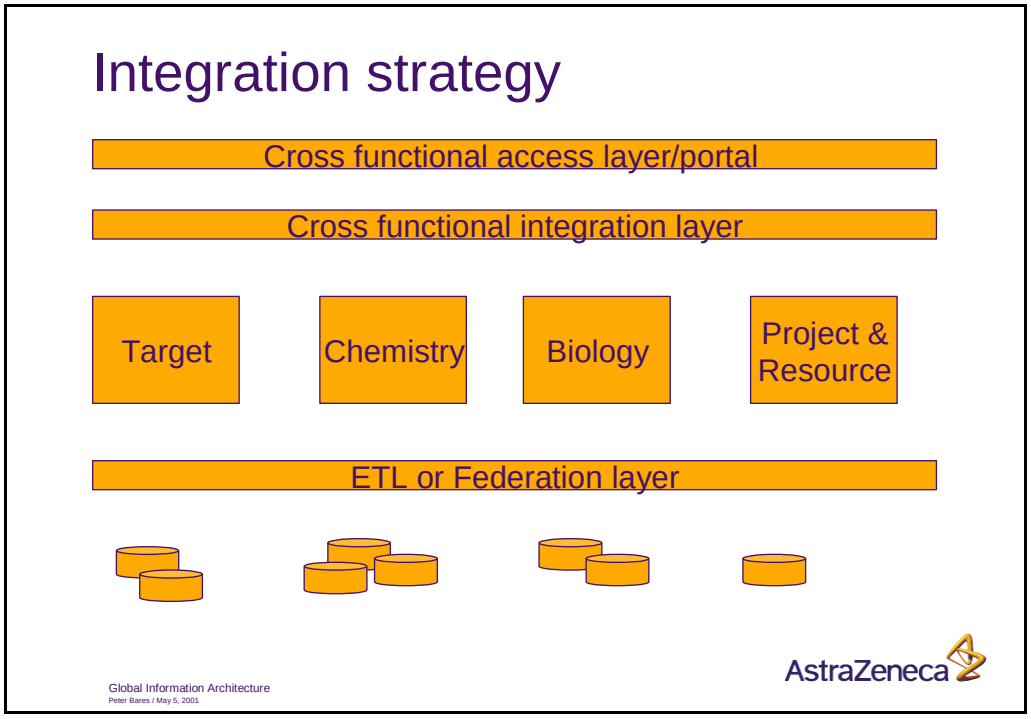
From which the following lessons had been learnt:

- All Pharma moving to OO architecture
- Architecture last 3-5 Years
- Tool sets change with them

There were a number of standards that seemed to be emerging for Pharma, (although this did not imply total consensus around the table):

| **Area** | **Product** |
|---|---|
| J2EE | WebLogic |
| ETL | PowerCentre |
| Source Code Repository | ClearCase |
| Directory | LDAP |
| Database | Oracle 8 |
| Modelling | UML |
| OS | NT, Solaris |
| Server HW | Intel, Sun |
| Message queuing | MQ*Series |
| Data Definitions | XML |
| System dev process | RUP |

The following diagram emerged as an Integration Strategy:




There were a number of $1M Questions:

- Aggregation (DataWarehouse) vs direct queries (EJB, federation)?
- Reduce operational systems from query load -> DataWarehouse
- Querying current data, less disk space -> EJB approach

Change management experience:

- Close partnership IS/Architecture
- City planning necessary (including plumbing)
- New skill sets (global project leaders, enterprise architects, information modellers)
- Strong sponsorship (Discovery Business, IS senior management)
- Proof of concept philosophy/benefits (Roche, Wyeth) vs “Big bang” (AZ)
- Change mgmt often undervalued
- Change readiness assessment
- Metrics not easy but valuable

Final ‘good to know’s”:

- Vision without action is hallucination” (GKS)
- Architects needs social competence (AZ)
- Think strategically, act tactically (GSK)
- Architecture needs to be part of an Application Portfolio - hard to motivate in isolation

One conclusion might be that both solutions had their place. It was probably sensible to consolidate like collections of data into data warehouses for reasons of efficiency but that in other areas there were just too many dissimilar databases (e.g. in bioinformatics or simply cross-sectorial) and it was necessary to put in place technology to federate the databases.

The PRISM Members thanked the SMEG, and in particular Peter Bares, for its report and valuable input. The topic had been sufficiently interesting that the PRISM members had attended the non-overlapping part of the SMEG Workshop and that had perhaps distorted the natural Workshop format and size. In this particular case it might have been better not to plan an overlap. On the other hand it would have been less of a problem had all companies been able to send representatives to both PRISM and SMEG. Overall it had been a very useful analysis and produced a valuable conclusion.

Breckenridge pointed out that discovery data had great importance to later stages in the development process and felt that PRISM should consider extending its scope to include people from development in such discussions.

## 5. Benchmark on Document Management

Rene Ziegler reported the results of a benchmarking questionnaire that he had submitted to the Forum. This surveyed which products were used for Document Management in different areas of the Pharma process. Rene agreed to make the full results available to the attending members.

**Action: Rene**

Lotus and/or Documentum were used by all companies and by large numbers of users. The use of Documentum had widened as its initially heavy user interface had been improved. The number of documents handled often exceeded 250 k. Most companies had global distributed servers and used replication. Beaufour Ipsen used the alternative solution of a single validated quality controlled environment and the Citrix software. All companies use Windows and Web interfaces. All companies used both attribute and full text search. Amongst the special features, 21 CFR Part 11 compliance and electronic signatures were partially and differently implemented across the companies. Data transfers between source documents and applications were planned by some but not implemented anywhere. According to achieve 21 CFR Part 11 compliance Nugenesis was being explored for the archiving of raw data by many partners.

Overall this was considered to be a most useful exercise, which would be completed with the addition information from those companies that had not yet replied. It was agreed that the questionnaire would benefit from clarification and review of the questions before circulation.

On a related topic, Ziegler was investigating the use of a consultancy company to conduct a must larger benchmark covering Pharma. He distributed an outline of the scope of the study. The merits and demerits of such a process were discussed and compared with the results of similar benchmarks in the past. Initial contacts by one consultancy contact at the CIO level had not been fully successfully received. Were there alternate approaches e.g. through PRISM? It was suggested that the CFOs should be convinced to approach the CIOs.

## 6. e-R&D

In response to a suggestion earlier in the meeting, members reviewed their company's activities in this area. Clearly the definition of e-R&D was none too precise at this stage. GSK and Wyeth both had initiatives in e-Clinical with interactions between investigators and the company. Lilly had a number of initiatives including spinning off a company with external discussion groups. They had a complementary organisation for sales and manufacturing. Novartis similarly had a number of initiatives in existing business units such as e-procurement. They also had e-Clinical activities. Roche had in addition some e-learning components for training.

Lilly had named technology mentors for senior executives, which seemed a positive step to a number of other companies. It was agreed to discuss this in more detail at the next meeting. BMS was active in e-training. Another initiative in several companies was an electronic solicitation of academic collaboration that included application for funding in certain areas. This led to a discussion of controlled software on desktops where companies had varied policies in research.

In general, the "e" implied re-engineering the process. A process turned into an e-system when it became an information process (possibly more efficient). At the same time one became more dependent on the electronic transactions.

## 7. Biowisdom

Jessica Roberston, founder member of the Forum, presented the products and services offered by the new company Biowisdom for whom she was now working. They provided free access to a number of integrated databases with more information or higher levels of services available for money They would broker access to other people's data. Biowisdom did not provide data themselves. They provided the ability to alert the end user to new information becoming available on the user's named targets. At this early stage of the company the focus was on bioinformatic databases but there were plans to add chemical databases this year.

Clearly there was an opportunity for Biowisdom to provide an additional marketing channel for these databases. Whilst a large Pharma could buy the major expensive databases "in-house", smaller companies might prefer the "pay by query" approach of Biowisdom. Similarly those providing smaller databases might not have the marketing strength to approach many Pharma companies. See www.biowisdom.com for more information. Jessica proposed in addition to provide accounts for each PRISM member to try the services.

**Action: Jessica**

## 8. Meeting Theme:

*"Lifecycle Management of Alliances and Partnerships within R&D*

- *Data Exchange*
- *Assessment, initiation, ongoing management and closure*
- *Security Issues"*

Robin Breckenridge introduced the main theme of the meeting as prepared by Anders Graneli and himself in order to trigger the discussion. Robin reviewed the drivers for change both in general in Healthcare and in particular in IT. An alternative to mergers that was perhaps more sustainable were alliances and partnerships. We were thus faced with the problem of providing seamless integrated information in a secure manner across "the extended enterprise". See Robin's presentation for further details.

**Action: Chris**

In the initial discussions it emerged that the relationships between the Pharmas and the CROs tended to be "many to many", and individual rather than global. Merrie Wise presented the GSK experience and practice in this area of alliances. Clearly time should be spent on careful definition of terms including security. A first major recommendation was that both sides should name an IT contact in both organisations. She noted some of the managerial issues of the exchange process, and the responsibilities in the closure process. "Should information obtained under such agreements be integrated with internally generated data?" Separate repositories reduced risk but also reduced availability. See Merrie's presentation for further information.

**Action: Chris**

In general it seems that not all aspects of the alliances with CROs were sufficiently managed, and some of these issues need to be addressed independently of, or before, the embarkation on a computerised integration of the resultant information.

The discussion returned to a favourite concern of PRISM, namely to which level one needed to audit the CROs and the practical details of assuring the regulatory responsibilities of the Pharma company vis a vis a contracted CRO. Was there a way of auditing CROs generally rather than independently by each Pharma? This was perhaps an issue for clinical and pre-clinical managements rather than PRISM.

John Wise proposed a further discussion bringing in an IT representative from a CRO for a future meeting.

## 9. The GRID

Chris Jones presented an update on the high activity around the GRID as the next stage in harnessing global distributed computing. The vision continued to gather support and funding. The EU had funded the particle physics DataGRID to the level of 10 MEuros over 3 years, whilst its American counterparts, GriPhyN and PPDG had received funding from the National Science Foundation and Department of Energy respectively. GRID proposals from other areas were seen as high profile activities within the EU Fifth Framework Program.

The DataGRID project contained two work packages relevant to subjects outside particle physics, namely Earth Observation Satellite data (ESA, Lecce) and Biology. The later was an initiative of the CNRS France and was in some senses a hasty placeholder within this first EU GRID proposal. Whilst there were 10 worthwhile small components to this work package, five of which concerned bioinfomatics, (including some micro-array work and some distributed BLAST experiments), and five closer to medical areas, this was not yet a real proposal for a strong life sciences GRID..

Alan Robinson at the EBI was coordinating a potential EU proposal, Bio-Enterprise, for a bioinformatic GRID with a number of European partners still to be finalised. The intention was that this GRID should be complementary to and sit logically on top of the activities of the DataGRID, rather than "re-invert the wheel". This proposal should focus instead on those GRID developments necessary to meet the requirements of the bioinfomatic community, e.g. the federation of many distributed heterogeneous databases. The intention was to raise awareness within this community and to assemble a firm proposal for submission in September 2001.

The UK Science Budget of November 2000 had provided entirely new money in three areas over and above the foreseen baseline budgets of the Research Councils. These three areas were "post-genomic research', "new technologies", and "E-Science", meaning GRIDS and scientists working in global teams. (E = enabled, enhanced, as well as electronic). The funding for E-Science across the Research Councils amounted to 98 +20 Million Pounds over 3 years starting April 2001. A new post of Director of E-Science, reporting directly to the Director of all Research Councils, had been appointed and funded with the aim of coordinating core GRID programmes, in order to attempt to ensure that the World would not have to face many different GRIDS in the future. There were a number of other National sources for GRID funding in the pipeline or approved (e.g. in Italy).

Even within particle physics the task of coordinating the various GRID activities across different Nations and funding sources was a daunting task. When the requirements of other sciences and industry were taken into account the task became even harder. Nonetheless there was great awareness of this problem at higher levels, as witnessed by the creation of the post of UK E-Science Director. It was less clear that this was understood at the level of those focussed on delivering a particular GRID.

The American and European GRID Forums had joined their standardisation activities with a first meeting in Amsterdam this year. There were 450 attendees with 250 turned away for lack of conference space. (see www.ggf1.nl). This was an important event with the first serious involvement of the IT industry.

There was also a healthy awareness that the middleware used by most people today in the first implementation of the GRID, namely the Globus package (www.globus.org) was but a starter set and there were many requirements for it to evolve. There was concern that the overall architecture for the GRID middleware should be reviewed by an appropriate expert team in the near future before it was too late for those GRIDS that had firm and difficult milestones to be met e.g. as in particle physics. It was not yet clear how this international coordination would be managed.

## 10. PRISM Business Session

The PRISM Members discussed a number of potential topics for future meetings. The results of this free discussion would be made available with the minutes.

**Action: Chris, John**

The theme of the next meeting was decided as *"ROI of IT investments"* Rene Ziegler and Robin Breckenridge agreed to be responsible for leading this theme session and for issuing guidelines to members in order that they could prepare consistent material for the meeting.

**Action: Robin, Rene**

The SMEG Workshop at the next meeting will cover *"Collaborative Technologies"* and Robin Breckenridge will either lead this SMEG or name a person to run the Workshop.

**Action: Robin**

As a additional agenda topic for the next meeting it was agreed to cover *"Executive IT Mentoring"* which would be introduced by Lilly.

**Action: Sheldon**

Anders Graneli agreed to conduct a survey on the subject of *"Project Management"* amongst members in order to determine the interest and suitability of this topic for future meeting.

**Action: Anders**

Looking again at the Scope and Mission of the PRISM Forum, the Members were happy to confirm the version modified at the previous meeting, and this Scope and Mission statement is copied again in Appendix 1 of these minutes. The Forum re-iterated the request that each company name one representative who would normally make an effort to attend the meetings, given the importance of the mutual trust and personal relationships to the success of the Forum. In the case that attendance was not possible then sending a representative was preferred to non-attendance. Each company was expected to send separate representatives to SMEG Workshops as appropriate.

In terms of contacting new members Sheldon agreed to contact Merck (Pinsky). Rene to contact Amgen, Giorgio would contact Abbott, and Diana would contact Pfizer (Roberts).

**Action: Sheldon, Rene, Giorgio, Diana**

It was agreed to clarify which information would be distributed to which lists. Minutes/Management Summaries of each meeting, as well as any presentations given for distribution would be made available **ONLY** to those people attending the meeting in question. The Agenda of the Meeting would be made available to a wider "potential attendance list". In the case of a new member expressing strong interest in attending a meeting the Management Summaries could be made available to them.

It was agreed that the responsibilities of the meeting host were to organise the logistical meeting arrangements in conjunction with IBC. Coordination of hotel and arrival arrangements should be the responsibility of IBC. The list of Members and SMEG attendees full names and contact details would be produced by IBC. A first agenda covering meeting logistics and dates should be distributed six weeks before the meeting by

IBC. The Chairperson and Secretary should agree and distribute the first detailed agenda a month before the meeting.

## 11. Next Meetings

The next meeting of the PRISM Forum will be hosted by Beaufour-Ipsen, in **Boston, USA,** and held on the **22nd to 24th October 2001**. The SMEG Workshop will assemble on the evening of Sunday 21st May 2001 and PRISM on the evening of Monday 22nd.

**Actions: John Wise, Chris, IBC, Robin, Diana**

For the Spring Meeting 2002 in Europe, Diana agreed to contact AstraZeneca in the first instance, with GSK as a backup possible. The **probable dates** for this meeting are the **14th to 16th May 2002**, with the SMEG Workshop assembling on the evening of Monday 13th May 2002 and PRISM on the evening of Tuesday 14th.

**Action: Diana**

Chris Jones
11th May 2001

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

## Scope

- The scope of the PRISM Forum covers the use of Information Technology to impact the R&D Processes of the Pharmaceutical Industry.

## Mission, Membership and Meetings

- The mission of the PRISM Forum is to:
  - share pre-competitive information and best practices of IM/IT supporting the R&D process.
  - define requirements for standards to support information exchange across the R&D process.
- The PRISM Forum is open to individuals able to represent their companies with respect to the above scope of PRISM
- It meets twice a year, normally once in Europe and once in the USA

## Code of Conduct

### Meeting Participation

- Be accountable
- Operate with integrity
- Honour diversity of the participants
- Be willing to share pre-competitive information in a timely manner
- Strive for common understanding
- 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
- Determine best demonstrated practices and experiences
- Identify trends in the technology and business

## Chairman and Secretary

- The Chairman and Secretary should be elected annually.

Revised 18 October 2000

# Appendix 2

## Members attending the 8th Meeting of the PRISM Forum

| | | |
|---|---|---|
| Diana Adams | Wyeth | Chairperson |
| Sheldon Ort | Eli Lilly & Co | |
| Anders Graneli | AstraZeneca | |
| Ronald Behling | Bristol-Myers Squibb | |
| Bo Skoog | Pharmacia | |
| Robin Breckenridge | Roche | |
| John Wise | Beaufour-Ipsen | |
| Merrie Wise | GlaxoSmithKline | |
| René Ziegler | Novartis | |
| Chris Jones | CERN | Secretary |
| Giorgio Bolis | Schering-Plough | |
| Katherine Rogers | IBC | Logistics |
| Nick Corbyn | IBC | |

**Apologies**

| | |
|---|---|
| Mark Cortelyou | R.E. Johnson, PRI |
| Richard Roberts | Pfizer Inc. |

**Invited**

| | |
|---|---|
| Jessica Robertson | Biowisdom |

## In addition, Participants in the SMEG at the 8th Meeting

Many of the PRISM Members attended the SMEG, in addition to the following participants:

| | | |
|---|---|---|
| Steve Gardner | Roche | |
| Stephan Laage | Roche | |
| Didier Richard | Beaufour-Ipsen | |
| Torsten Sejlitz | Pharmacia | |
| Dave Vanderbrooke | Wyeth | |
| Peter Smith | Wyeth | |
| Peter Bares | AstraZeneca | SMEG Organiser |
| Daniel Johansson | AstraZeneca | |
| Henry Law | AstraZeneca and IBM, | SMEG Facilitator |
| Wayne Faulkner | GlaxoSmithKline | |