



Biography of *Francesco Di Pisa*

Doctor with Honors in Statistical Sciences, *Alma mater* University of Rome "La Sapienza", he received a Master of Science degree in Mathematics, University of Kentucky-Lexington-USA, a two year fellowship from Consiglio Nazionale delle Ricerche (CNR-Comitato Nazionale Scienze Matematiche), Rome-Italy, and a postdoc fellowship in Functional Analysis at SISSA (ISAS-International School for Advanced Studies) in Trieste, Italy.

His outstanding, internationally recognized [1, 2], activity is dedicated to Laboratory Informatics, Data Intelligence, Discovery and Analysis in the fields of biology, medicine, immunology, physics and chemistry; in particular to the Design of Experiments and Complex Systems, the Development of Procedures and the Support of Activities related to laboratory outcomes and experimental results, biological assay and testing in Research and Preclinical studies, Development, Manufacturing and Quality Control.

His mission is to provide transparent and based-on-data-evidence support to Research and Development in the aforementioned areas and in Scientific Computing by means of statistical, mathematical, engineering and information science methods, and to foster a better understanding of basic validated procedures, data intelligence management, computerized data analysis systems and originally developed methodologies.

Formerly *Senior Scientist*, he covered several positions in Industry: Software designer at *Olivetti* (OSAI Allen Badley-Ivrea-Torino-Italy), Researcher at *CSELT* (Centro Studi e Laboratori Telecomunicazioni-Telecom-Torino-Italy), Analyst and responsible of ERP Systems at *CCPMA* (Consorzio Cooperative-Grosseto-Italy). In 1985 he joined the *Sclavo Research Center* in Siena as Responsible of scientific computing and bioinformatics; then as Scientist at *Biocine SpA Research Centre* in Siena; as Senior Scientist & Head of Biostatistics Laboratory of Process Development Department of *Chiron SpA* Siena; and Head of the Biostatistics Unit of Technology Development and member of the Animal Ethical Committee at *Novartis Vaccines and Diagnostics* in Siena.

Professor for more than fifteen years of *Database* and *Information Systems* at the School of Informatics and at the Department of Information Engineering of the University of Siena, he is member of the Scienze Medico-Legali research group of the University of Siena for contributions in the fields of Mathematics & Biostatistics, Informatics, Databases and Knowledge applied to Medicine and Law, and formerly member of the Center for Research in Tumor Eye Diseases (CRISATO), Ophthalmology and Neurosurgery Sciences Department, University of Siena. He has been also Scientific Consultant

in mathematical and computational methods for X-Ray Powder Diffractometry (XRPD) Pattern Analysis at the Earth Sciences Department of the University of Pisa.

Patent holder (Brev.Inv.Italia 68155 A/84, 19/11/84) of "Computerized Device for inert gas saturation control in human body tissues". Silver Medal Prize for *Quality of the Invention* at the 13th International Invention Exhibition, Geneva CH, 1985.

Inventor of "Image processing System for Single Radial ImmunoDiffusion (SRID) Assay". Patent - Novartis Vaccines (European & US Patent Office), 2006.

He is member of the American Statistical Association (ASA), the Institute of Electrical and Electronics Engineers (IEEE & Computer Society), the American Association of Artificial Intelligence (AAAI) and the Association for Computing Machinery (ACM & SIGBIO, SIGCHI, SIGART).

Fields of Interest & Research

Applications to Science and Technology of: High Performance Computational Systems, Intelligent User Interfaces; Statistical Systems, Biostatistics & Discovery, Computability and Complexity of Statistical & Mathematical methods in Physics, Chemistry, Biology and Medicine; Declarative Specification Languages, Cognitive Database Semantics and Knowledge Modelling, Agent Theory; Bioinformatics & Molecular Computing, Data Mining & Learning, Web Marking Knowledge, Applied Logic and Programming for Knowledge Base Representation; Numerical Mathematics Methods & Software for Approximation, Pattern Recognition & Imaging; Validation & Verification of Intelligent Systems.

Email fdipisa@dii.unisi.it
fdipisa@gmail.com

mob +393296171926

[1] Laboratory Data Management Conference 2009 brochure, Munich - DE

[2] Smart Lab 2009 Conference brochure, London - UK

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Tuesday 16 and Wednesday 17 June 2009, Munich, Germany

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Francesco Di Pisa, Head of Biostatistics, Technology Development, NOVARTIS VACCINES DIAGNOSTICS



Dr. Jan Hauss, Head, Central Analytics Informatics, MERCK



Wolfgang G. Hoeck, Senior Manager, Therapeutic Area Systems, Research and Development Informatics, AMGEN



Armin Ollig, Director, Information Technologies, BIOFRONTERA



Teodor Wagner, Head Laboratory Informatics Support Team, F. HOFFMANN-LA ROCHE



Dr. Johannes Floeckner, Head of Information Systems R&D, ALMIRALL S.A.



Gerhard Noelken, Business IT Lead for Development Science and Technology in WW Pharmaceutical Science, PFIZER



Daniel Caparrós, Head of Information Technology, AETERNA ZENTARIS



Manfred Goebel, Senior European Technical Development Applications Analyst, MUNDIPHARMA



Giorgio Gatti, IS-Specialist, Research Systems, BOEHRINGER INGELHEIM ITALIA S.P.A.



Dean Flanders, Head of Informatics, NOVARTIS



Dr. Klaus Klinder, Senior Associate Director, Drug Discovery Support, Group Drug Metabolism and Pharmacokinetics, BOEHRINGER INGELHEIM GMBH

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Programme Day One

Tuesday 16 June 2009

08:30 *Registration*

09:00 **Opening remarks from the Chair**

Francesco Di Pisa, Head of Biostatistics, Technology Development, NOVARTIS VACCINES AND DIAGNOSTICS

AN INNOVATIVE APPROACH: THE CHANGING FACE OF LABORATORY INFORMATICS

09:10 **Keynote presentation: Maximising data intelligence from R&D to manufacturing**

- Data intelligence in the context of laboratory data management
- Discovering the semantic basis of information and knowledge modelling
- Harmonising science, research, technology and regulations
- Assessing data validity, quality, compliance and costs
- The human factor: behaviour, learning and awareness of control
- Approaching computational intelligence: complexity and cognition
- Computer-human interaction: the intelligent user interface
- Epilogue: e-lab perspectives and challenges

Francesco Di Pisa, Senior Scientist, Head of Biostatistics, Technology Development, NOVARTIS VACCINES AND DIAGNOSTICS

LIMS AND ELNs IN FOCUS: IMPROVING THE INTERFACE

09:40 **Benefiting from real-time data management: improving R&D performance with Laboratory Information Management Systems (LIMS)**

- Finding common user requirement specifications for pharmaceutical research in multiple sites
- Installing and customising LIMS for use in a research area
- Validation of LIMS in a controlled environment
- Maintaining a running system in an area that is continuously changing
- The future outlook for LIMS in Mundipharma Research

Manfred Goebel, Senior European Technical Development Applications Analyst, MUNDIPHARMA RESEARCH

10:10 **Increasing the efficiency of laboratory data management by moving towards the ELN 2.0**

- Lessons learned from the first ELN
- Expectations of a new ELN: biology integration
- Choosing a new system
- Integration into an existing data infrastructure
- Preparing data for migration

Daniel Caparrós, Head of Information Technology, AETERNA ZENTARIS

10:40 *Morning refreshments*

11:10 **Improving quality management capabilities: incorporating ELN software into a system for recording GMP criteria for clinical trial APIs**

- Introducing an ELN-based system for rapid technology transfer of chemical processes from process R&D laboratories into GMP multi-kilo pilot plants
- Replacing long-established paper and wet ink signature-based control systems with electronic records and signatures
- Overcoming resistance to change from paper to electronic systems in an environment that is highly controlled by both internal and external regulators
- Requiring much less documentation than previous paper-based systems
- Gaining broad acceptance for an ELN-based system by putting improved quality management and efficiency criteria as key requirements for a new system
- Providing more immediate operational transparency with information captured in a single ELN notebook

- Understanding how to use an electronic system in compliance with external and internal regulatory guidance
- A collaborative cross-functional team developed the system with representation from process chemistry (R&D), development manufacture (pilot plant) and QA

John Leonard, Principal Scientist, Process R&D, ASTRAZENECA

11:40 **Food industry case study: Custom web-based solution for laboratory data centralisation and management**

- 100% web for convenient handling
- No software to install on computer
- Limited deployment costs: install once - use anywhere
- Designed for the specific needs of the laboratories
- Web interface with intuitive operations
- User-specific configurations

Frederic Raymond, Managing Scientist, Microarray Facility, NESTLE RESEARCH CENTRE

12:10 **Case study: Implementing a new flexible LIMS and ELN system for complex research studies**

- Needs analysis business reference group
- Market analysis: how to have a good selection process
- Pilot evaluation
- Implementation: challenges to face and overcome
- Integration in the research data and knowledge environment
- Lessons learned

Didier Laureys, Principal Scientist, Informatics, UCB PHARMA S.A

12:40 *Lunch*

13:40 **Agribusiness case study: Design and implementation of a geographically distributed research logistics infrastructure**

- Considerations when designing a distributed and expandable research logistic architecture
- Bridging the gap between the scientist and the robot
- Innovative approaches to exception handling to cope with 'real life' situations
- Leveraging a single architecture to meet diverse needs

Martin Rice, Lead Information Domain Specialist, SYNGENTA

ENSURING IP PROTECTION AND COMPLIANCE – EFFECTIVE COLLABORATION BETWEEN LABS AND LAWYERS

14:10 **Walking the tightrope between scientists and lawyers**

- Bridging the chasm between scientists and lawyers whilst keeping them both productive and harmonious
- How to work with scientists and IT to ensure adequate and consistent IP protection
- Responding to the challenge of long-term compliance and availability of electronic recordkeeping processes
- The increasing move to computerised working and collaboration within the lab is changing the IP protection landscape

Simon Coles, Co-Founder and CTO, AMPHORA RESEARCH SYSTEMS

14:40 **Outlining the legal framework for laboratory data management – what is needed to comply?**

- What is the discovery/disclosure process?
- Why should this affect laboratory practice and data management?
- Disclosure in UK litigation - obligations and timing
- Disclosure in mainland Europe and the impact of the IP enforcement directive
- Conclusions

Brian Cordery, Partner, BRISTOWS

EFFECTIVE TRAINING METHODS TO ACCELERATE USER ACCEPTANCE

15:10 Improving user adoption of data management systems

- User adoption processes
- Assessing the reasons for user resistance
- People/problem focus – how to overcome challenges
- Effective training methodologies

Dean Flanders, Head of Informatics, NOVARTIS

15:40 Afternoon refreshments

16:10 Can a LIMS vendor fully validate its software?

- Can a LIMS vendor validate its software or is this a conflict of interest?
- How change in industry governance and practices changes the approach to implementation and validation
- How to address predictable ongoing TCO (Total Cost of Ownership)

Peter J. Boogaard, Director LIMS Product Management and LIMS Global Marketing, APPLIED BIOSYSTEMS INTERNATIONAL

IMPROVING INTEROPERABILITY AND STANDARDISATION ACROSS THE ORGANISATION

16:40 Case study: Expanding an integrated discovery informatics platform: leveraging laboratory informatics and business processes to drive efficiency

- Outlining the integrated data solutions within Almirall S.A.
- Connecting data management systems with decision-making processes
- Implementing a tracking tool into the integrated infrastructure in order to enhance efficiency
- Reflecting internal discovery processes with the Almirall discovery portal
- Managing, sharing, mining and visualising data and knowledge using this web-based solution
- Defining research programmes
- Tracking progress during lead optimisation

Dr Johannes Floeckner, Head of Information Systems R&D, ALMIRALL S.A.

17:10 Case study: Introducing BIRMA (Boehringer Ingelheim Reagent Management Application): a logistics application to improve access and information-sharing throughout the laboratories

- Standardising and harmonising systems and data with a SOA (Service Oriented Architecture)
- Increasing productivity, information access and sharing of data using one platform
- Improving efficiency and reducing cost by streamlining processes
- Integrating the different laboratory systems (e.g. barcode scanners, balances and storage robots)
- Comparing the key benefits of off-the-shelf systems versus custom-built challenges
- Managing regulatory submission and providing risk, safety phrases and hazard class information

Giorgio Gatti, IS-Specialist, Research Systems, BOEHRINGER INGELHEIM ITALIA S.P.A.

17:40 Closing remarks from the Chair

17:50 Close of Day One

08:30 Registration

09:00 Opening remarks from the Chair

Gerhard Noelken, Business IT Lead for Development Science and Technology in WW Pharmaceutical Science, PFIZER

09:10 Roundtable morning sessions

Delegates will be able to attend three one-hour roundtable discussion groups from a selection of key topics. Each session will be chaired by an industry expert who will facilitate an exchange of opinions, essential experiences and learning related to a current aspect of laboratory data management.

Roundtable 1

Discussing the growing need for increased automation of R&D processes

Understanding the role of electronic laboratory data management systems and their contribution to increasing efficiency and reducing the costs of R&D processes

Francesco Di Pisa, Head of Biostatistics, Technology Development, NOVARTIS VACCINES AND DIAGNOSTICS

Roundtable 2

Discussing long-term archiving technologies: keeping data for 65 years - a challenge or “mission impossible”?

Debating techniques to keep data media independent and data formats agnostic to the architecture they are on and an example design of a long-term archive

Dr Jan Hauss, Head Central Analytics Informatics, MERCK

Roundtable 3

Overcoming regulatory concerns regarding electronic records and signatures

Discussing strategies to ensure that electronic records and signatures are trustworthy, reliable and compatible

John Leonard, Principal Scientist, Process R&D, ASTRAZENECA

Roundtable 4

Discussing interoperability between different software, technologies and platforms

Discussion will focus on the technical challenges of integrating different data management systems into one easy to use platform

Gerhard Noelken, Business IT Lead for Development Science and Technology in WW Pharmaceutical Science, PFIZER

Roundtable 5

Utilising the latest visualisation tools and techniques

Discussing available tools to visualise data and how compatible they will be with future technologies

Wolfgang G. Hoeck, Senior Manager, Therapeutic Area Systems, Research and Development Informatics, AMGEN

12:30 Lunch

OPTIMISING LABORATORY WORKFLOW SOLUTIONS

13:30 Keynote presentation: Optimising inter-laboratory workflow solutions to accelerate proceedings within pharmaceutical research

- Moving from a spreadsheet to a datasmart approach
- Planning and ordering of in-vitro ADME experiments in research
- Improving data-mining of experiment status and final results
- The alignment of data processing and analysis across different labs and various types of assays
- Data retrieval and visualisation

Dr Klaus Klinder, Senior Associate Director, Drug Discovery Support, Group Drug Metabolism and Pharmacokinetics, BOEHRINGER INGELHEIM

IMPROVING INTERFACES BETWEEN LAB DATA MANAGEMENT SYSTEMS

14:00 Case study: Imaging systems - thoughts about data flow and integration

- Expansion of imaging instruments and software
- Impact of automatic image analysis
- How to manage, store and search through the large amount of data generated by the imaging systems
- Diversity of requirements for data flow and integration
- Finding the optimum level of data integration

Teodor Wagner, Head Laboratory Informatics Support, F. HOFFMANN-LA ROCHE

14:30 Interactive visual data analytics – understanding the meaning of your data

- Interactive visual data analytics - what is it, what is it not?
- The scientific context - target identification and validation in oncology
- Omics data challenges in oncology
- Registration systems: uniquely identifying what you are working with
- Data mapping – the essence of bringing data together
- Expectations from an interactive visual data analytics platform
- Taxonomies, ontologies and data networks
- Visual text analytics - learning from what others have already done

Wolfgang G. Hoeck, Senior Manager, Therapeutic Area Systems, Research and Development Informatics, AMGEN

15:00 Developing the platform of the future: improving the interface between LIMS and ELNs to drive data management efficiency

- Integration: how it used to be
- Integration: how it is today
- Integration: how it should be
- Why we keep our data
- How we keep our data
- Data formats do matter

Dr Jan Hauss, Head, Central Analytics Informatics, MERCK

15:30 Afternoon refreshments

16:00 Enhancing data analysis and decision support: from data to knowledge

- Defining scientific objectives and observations
- Outlining data generation and plausibility analysis
- Discussing data integration and data analysis
- Introducing our decision support solution

Brunhilde Markus, Analyst and Software Developer, INTERVET INNOVATION GMBH

16:30 Project eNotebooks: integrating information and knowledge across research departments

- Requirement: sharing information and knowledge to drive decision making
- Issue: one size does not fit all
- Discussing the proliferation of information silos
- Issue: collaboration all too readily takes place in Outlook
- Utilising enterprise social computing tools to create project-centric workspaces and enable a culture of collaboration

Ben Gardner, Sandwich Research Informatics Client Engagement Manager, PFIZER

17:00 Enterprise information integration: merging the LIMS

- Replication versus uniform information representation
- Architecture of tightly and loosely integrated systems
- Implications on efficient software development
- Case study: data mining and plausibility analysis

Armin Ollig, Director Information Technology, BIOFRONTERA

17:30 Closing remarks from the Chair and close of conference

POST-CONFERENCE WORKSHOP

The integrated laboratory of the future

Led by: John Trigg, Founder, PHASEFOUR INFORMATICS LIMITED

About the workshop:

This workshop will explore an integrated approach to data, information and knowledge management in the laboratory, taking into account changing business and scientific demand and the relentless progress of information technology.

Workshop agenda:

09:00 *Delegate registration and coffee*

09:30 **Workshop welcome and introduction**

09:45 **Session 1: The current laboratory landscape**

- The history of the electronic/paperless lab
- What have we got already; what is missing?
- Integration issues and other constraints

10:30 **Session 2: Change Agents**

- Business objectives
- Scientific objectives
- Workplace culture

11:00 *Coffee Break*

11:30 **Session 3: Emerging Technologies**

- Software as a service
- Mobility
- Web 2.0

12:00 **Session 4: Skills and Culture**

- The laboratory/IT relationship
- Technology adoption
- Knowledge and skills of laboratory and IT workers

12:30 **Session 5: Bringing it all together**

- Building the right infrastructure
- Making the right technology choices
- Implementing the right processes
- Conclusions

13:00 *Close of workshop*

About your workshop leader:

John Trigg is the founder of phaseFour Informatics Limited and has over 25 years' experience working in laboratory data, information and knowledge management. He has authored a number of publications, including a guide book for ELNs and has presented papers and run workshops at conferences in Europe, USA and Australia. He was the recipient of the 2000 International LIMS Award.

About phaseFour Informatics:

phaseFour Informatics Limited is an independent consultancy, based in the UK, that provides consultancy services for laboratory integration. A specific emphasis is placed on the strategic choice and successful deployment of laboratory systems to meet business, technical and cultural requirements and to enhance data, information and knowledge management practices in the laboratory.

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About the conference:

In the current economic environment, streamlining laboratory data management processes is key to maximising the time of the R&D department and speeding time to market for new products. Ensuring that research information is easy to input and access by multiple departments can give your organisation the competitive edge by improving productivity, quality and decision making throughout the development phase.

However, moving towards a paperless lab has its challenges. With multiple systems in place, integrating everything into one user-friendly platform cannot happen overnight. Coping with the regulatory requirements, choosing whether to custom-build or buy systems off the shelf and managing the transition are all key issues when implementing an integrated data-management approach.

VIEvents' **Laboratory Data Management** conference, being held on 16 and 17 June 2009 in Munich, Germany, will bring experts from the pharmaceutical and biotech industry together to discuss practical strategies for improving your data management processes. From managing the ELNs and LIMS interface and effective data mining techniques, to interoperability, standardisation and archiving, this event will provide you with the latest approaches to driving lab efficiency and enhancing knowledge across the organisation.

Who should attend?

Senior representatives from biotech and pharmaceutical companies working within the following areas:

- Informatics/ Information
- Bioinformatics
- R&D
- Information Management
- Research IT
- Data Management
- Research Informatics
- Quality Assurance
- R&D IT
- Quality Control
- R&D Informatics
- Research Scientists
- R&D Computing
- Laboratory Compliance
- Information Discovery
- Chief Technology Officers
- Discovery Informatics
- Chief Scientific Officers
- Information Knowledge Management
- Chief Medical Officers

Why you should attend?

- Network with your laboratory data management peers from pharmaceutical and biotech companies
- Learn how to improve productivity, quality and decision making throughout the development phase
- Discuss the latest key issues from laboratory data management with industry experts during the roundtable morning
- Learn more about the interoperability of different laboratory data management systems
- Discuss the current legal aspects of laboratory data management

Booking Form

Laboratory Data Management, Tuesday 16 and Wednesday 17 June 2009, Munich, Germany

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- Register online at www.vibeevents.com/pharma/laboratorydata Tel +44 (0)20 7753 4268
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Data Management & Discovery

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- **Bring your data to life: Utilise the latest visualisation tools and techniques :** Join **Actelion's** workshop and leave with the knowledge and skills that will allow you to make the most of your data

Informatics Strategy

- **Streamline the time it takes for your company's product to get to market:** **Wyeth** reveals how they are exploiting an integrated data management platform that brings together **ELNs, LIMS** and **data warehouses** to provide them with the competitive edge
- **Create an environment of innovation, collaboration and knowledge sharing on a global level:** By connecting laboratory, data management systems and ERP, **Syngenta** demonstrates how you can harness the **business intelligence** within your systems to drive organisational growth

Speakers include:

- **James Clark**, Director, Global IT GSC/GQO, **Schering Plough**
- **Graham Mullier**, Head of Information Connection R&D IS, **Syngenta**
- **Frederik Bocklandt**, Global Program Manager IM Projects Quality, **Johnson & Johnson**
- **Jim King**, Senior Consultant, Business Systems and Processes, **Wyeth Research**
- **Mats Sundgren**, Principal Scientist, Information Strategy, Global Clinical Development, **AstraZeneca R&D**
- **Flemming Simonsen**, Senior Director - Global QA, G(IT)P, **Ferring Pharmaceuticals**
- **Jerry Lanfear**, Head of Data Support and Management, **Pfizer Global Research and Development**
- **Francesco Di Pisa**, Senior Scientist, Head Biostatistics, **Novartis Vaccines**
- **Joelle Delfour**, R&D and Scientific Systems Manager, **Total Petrochemicals Research**
- **John Trigg**, Director, **phaseFour Informatics**
- **Slava Budin-Jones**, IT Director, **GlaxoSmithKline**
- **Johannes Floeckner**, Head R&D IS, **Almirall**
- **Michael Schmidt**, Director, **Lodestone Management Consultants AG**
- **Dean Flanders**, Head of Informatics, **Novartis Research Foundation**
- **David De Roure**, Professor of Computer Science, **University of Southampton**
- **Simon Wood PhD**, Executive Director Marketing and Education, **STARLIMS Corporation**
- **Dr. Thomas Kandl**, Head Scientific Systems, **Roche**
- **Mollie Shields Uehling**, President and CEO, **SAFE-BioPharma Association**
- **Modest von Korff**, Senior Scientist, Research Informatics, **Actelion Ltd**
- **Ken Rapp**, President & CEO, **VelQuest Corporation**
- **Charlie Sodano**, Director, **eOrganizedWorld**
- **Jorg Ochsmann**, Bioinformatics & Data management, **KWS SAAT AG**
- **Hector Sanchez**, Senior Director R&D IT, **UCB**
- **Mark Beggs**, Programme Director, **Wyeth Research**



Lodestone



Waters



Freephone: 0800 652 2363 or +44 (0)20 7368 9300



Fax: +44 (0)20 7368 9301



Email: enquire@iqpc.co.uk

www.smartlab.co.uk



