

EDITORIAL

Dear readers,

This is it! You now have your hands on the first *Newsletter* of the Sylvia Lawry Centre for Multiple Sclerosis Research in Munich. The research centre formed in February 2001 is developing in leaps and bounds. The next few pages will give you an initial outline of the objectives of the Centre and of the paths leading us towards these objectives. A **short glossary on Page 2** offers a brief summary of the institutions involved in the project. Personnel recruiting and the purchase of the necessary hardware and software for the first year have for the most part already been completed. Initial data from clinical trials have arrived at the Centre and are already being processed there. The collection of further data is in full swing. You can convince yourself of the progress our team has made by visiting the website www.slcmsr.org that we launched in April (**Page 3**). Use of the Internet as an information and communications platform is a vital mainstay in the daily work of the Centre. Security, discretion and careful handling of the sensitive data collected here is guaranteed by a circumspect **IT and security concept** described in further detail on **Page 3**. In an **interview on Page 4**, we asked Prof. Dr. Ian McDonald, Head of the Scientific Oversight Committee, about his views regarding the work to be performed at the Centre. Here you will also find some important dates and short updates on what is currently happening at the Sylvia Lawry Centre for Multiple Sclerosis Research (SLCMSR).

Albrecht Neiß
Prof. Dr. Albrecht Neiß
Scientific Director

Sylvia Lawry Centre founded in Munich

Multiple Sclerosis Research breaks new ground

In February 2001 the Sylvia Lawry Centre for Multiple Sclerosis Research (SLCMSR) was founded at the Technical University of Munich. The new research centre is to become a major hub for international MS research.

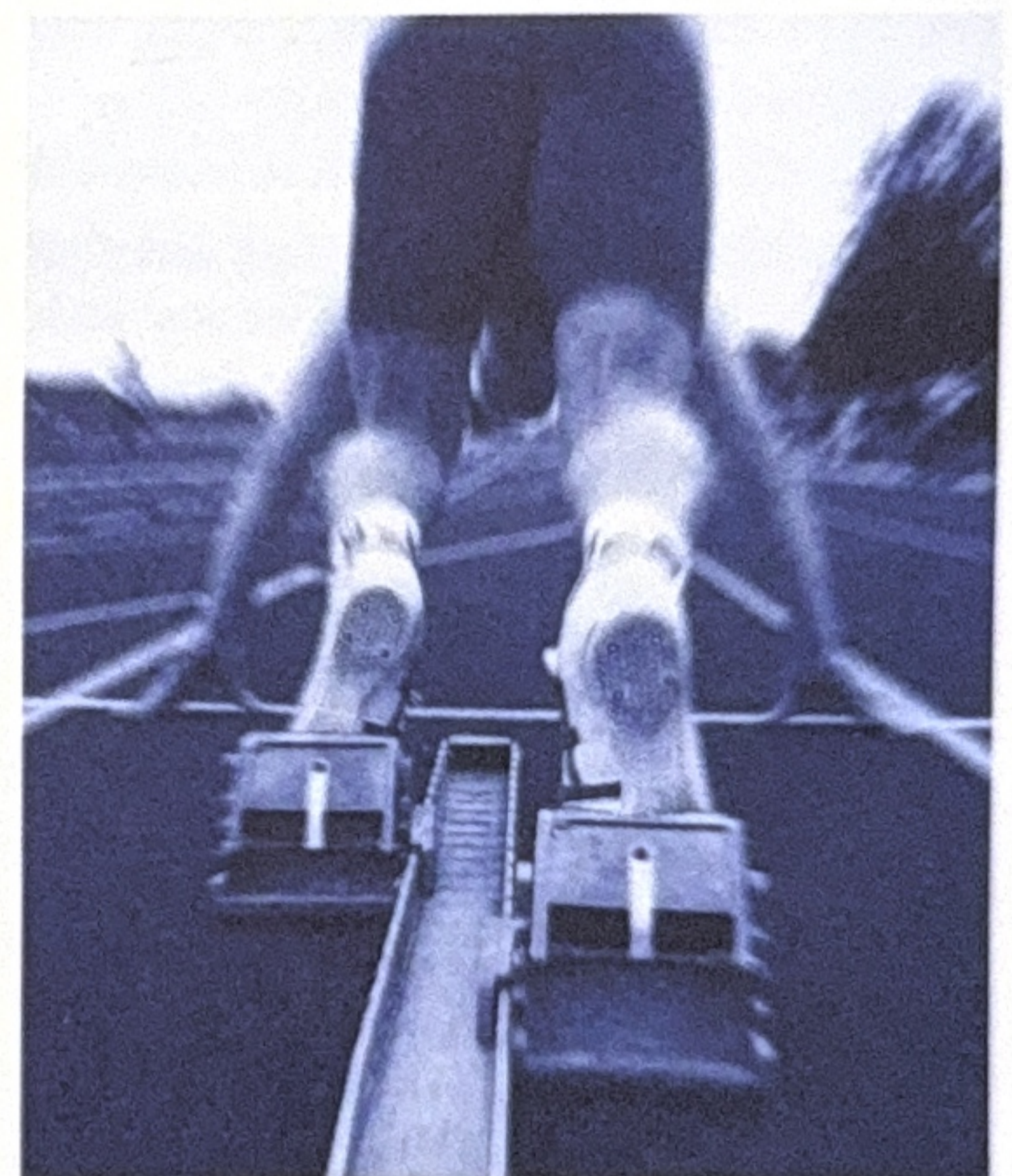
By using innovative statistical methods and state-of-the-art information technology coupled with medical expertise, the Centre supports research into the causes of multiple sclerosis and performs vital groundwork for the development of new therapies.

The Multiple Sclerosis International Federation (MSIF) laid the cornerstone to the Sylvia Lawry Centre, both in developing the initial concept and in acquiring the necessary funding. In April 2000 the MSIF published in the magazine *Nature* an invitation to tender for the establishment of an international MS trials, research and resource centre. With their proposal the German scientists managed to hold their own in the face of strong competition from Europe and the USA, and now a team of staff from the Institute for Medical Statistics and Epidemiology (IMSE), under Professor Albrecht Neiß and the spin-off company Trium Analysis Online GmbH, are responsible for developing the Centre.

New methods

The development of new forms of treatment for MS patients is becoming increasingly cost-intensive and time-consuming. The Sylvia Lawry Centre has set itself the goal of seeking methods to reduce the time and money spent on such trials.

While in the past conventional clinical efficacy trials of new drugs used placebos as reference drugs, pseudo medicines are now no longer acceptable on ethical grounds, because effective therapies for MS patients are already available. This



means that in future tests, new medicinal products have to be compared with a product, whose efficacy has already been proven. More and more patients are therefore needed to test the superiority of a new type of medication, which in turn dramatically increases the duration and cost of the trials.

It is at this disheartening point for MS patients that the scientists of the Sylvia Lawry Centre come on the scene. They are concentrating on two main goals: to reduce the number of patients and to shorten the observation time in the clinical trials. The calculation of "virtual" placebo patients from a vast pool of data is preparing the way for this development.

"Virtual" placebo patients

The Sylvia Lawry Centre will set up a new design for clinical trials. As a result, placebo-controlled trials can in future



The Location of the Sylvia Lawry Centre at the Klinikum rechts der Isar at the Technical University of Munich.

national Multiple Sclerosis registers kept by academic institutions will be stored there. Such an extensive collection of data from clinical trials is currently unparalleled in medical research. With the help of this database, the scientists in the Sylvia Lawry Centre can calculate comparative data for use in new clinical trials. This should make the development of therapies for MS patients faster, safer and less costly in future. By bringing together the three fields computer science, mathematics and medicine, the Sylvia Lawry Centre is following a new forward-pointing avenue that could have exemplary effect for many areas of medicine. ■

▶ still be carried out, although with "virtual" mathematically generated placebo patients rather than "real" patients.

Statistics at its best

The basis for calculating virtual placebo patients and the development of new assessment criteria are mathematical models describing the course of the disease afflicting MS patients. The research centre is currently creating a database that will bring together the data from all major clinical trials conducted worldwide by the pharmaceutical industry and academic centres. In addition, all the major inter-

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GLOSSARY

What is: MSIF, IMSE, Trium and SLCMSR?

SLCMSR: Sylvia Lawry, the person, after whom the Munich research centre is named, was one of the great pioneers championing the cause of MS patients. With a small advertisement in the NY Times, she launched her impassioned fight against the disease in 1945. She was the initiator and longterm chairwoman of the American MS Society and founder of MSIF.

▶ www.slcmsr.org

MSIF: The Multiple Sclerosis International Federation is the international umbrella organisation of 39 national MS societies. Working in worldwide partnership with Member MS Societies and the international research community, the MSIF is at the forefront of the global campaign to end multiple sclerosis and its devastating consequences.

▶ www.msif.org

IMSE: The Institute for Medical Statistics and Epidemiology is part of the

Klinikum rechts der Isar of the Technical University of Munich. Its assignments include supporting medical research with statistical methods and advanced information technology. Numerous international trials are conducted at the IMSE. The research projects of the IMSE mainly involve the development and testing of new statistical methods in response to clinical problems, e.g. the evaluation of new therapies or identification of prognosis factors.

▶ www.imse.med.tum.de

Trium: The spin-off company Trium Analysis Online GmbH was formed in 1999 by Dr. Martin Daumer and Michael Scholz. Trium combines three key competences: medicine, mathematics and information technology. The company is engaged in a number of medical research projects involving time-critical and safety-relevant data processing.

▶ www.trium.de

PERSON



Prof. Dr. Albrecht Neiß

Scientific Director

Prof. Dr. Albrecht Neiß was born in 1938, studied mathematics at the Technical University of Munich and obtained his doctor's degree at the University of Hanover. He first worked for four years in clinical research for the pharmaceutical company Byk-Gulden, before moving to the Institute for Medical Statistics and Epidemiology (IMSE) of the Technical University of Munich in 1970.

After a period of research at the University of California, Berkeley, Neiß then followed a call to University of Innsbruck, where he directed the Institute of Biostatistics from 1985 onwards. In 1993 he returned to his home university in Munich and was appointed Director of the Institute for Medical Statistics and Epidemiology at the Klinikum rechts der Isar.

Prof. Neiß works among other things as an expert assessor for the German Research Community (DFG), the German Federal Ministry of Education and Research (BMBF), the German Cancer Society and the German Aerospace Centre (DLR). In addition, he is a member of the Executive Board of the Collaborative Research Centre "Discreet Structures" (SFB 386) and the Commission issuing the "Medical Informatics" Certificate of the German Society for Medical Informatics, Biometry and Epidemiology.

In the course of his long scientific career, Prof. Neiß has built up excellent contacts with numerous international research groups as well as with the pharmaceutical industry. Through his many years of experience in the development of innovative clinical trials and as a member of monitoring and advisory boards of a wide variety of international research projects, Prof. Neiß ideally meets the prerequisites for heading the research team at the Sylvia Lawry Centre.

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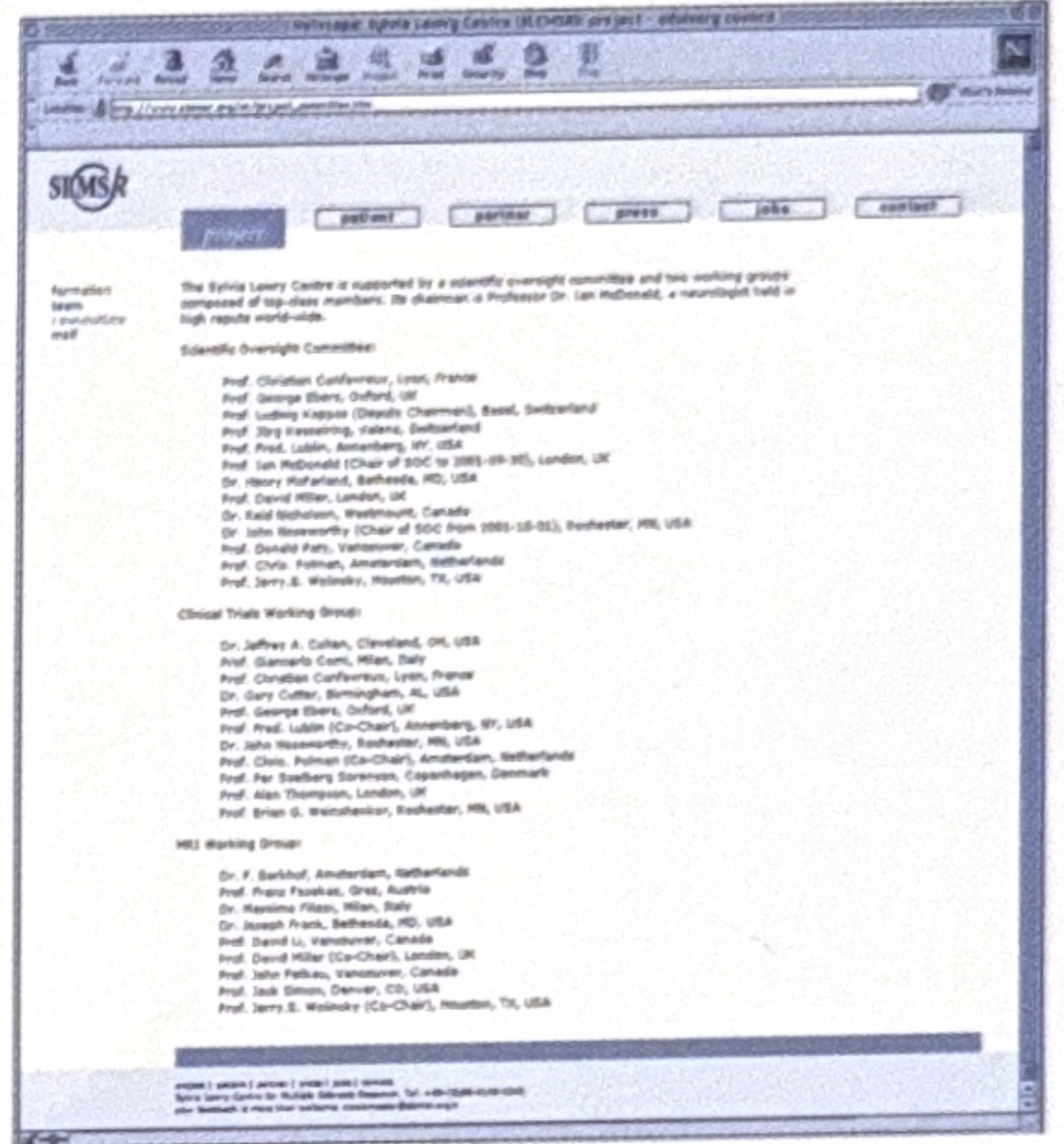
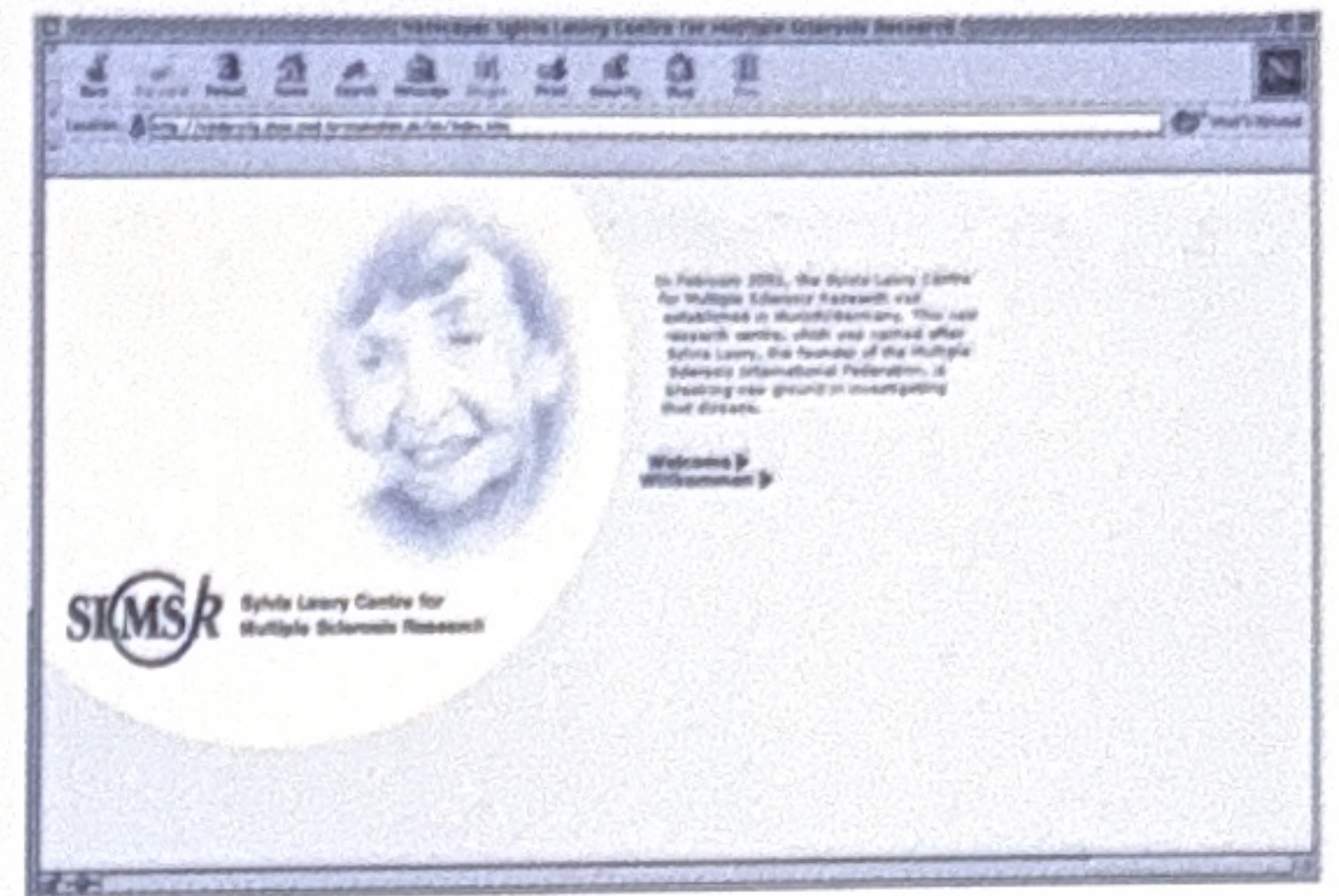
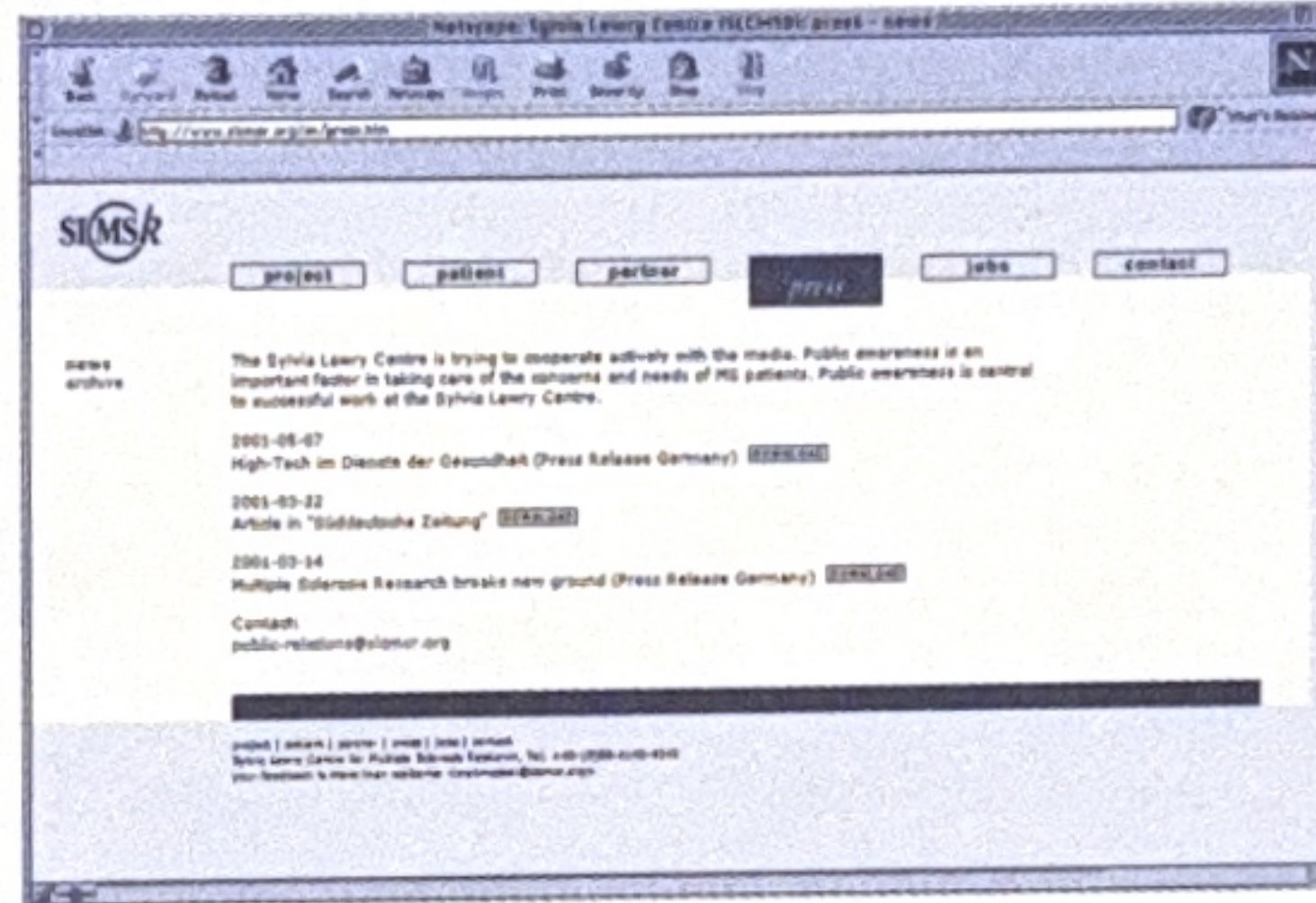
The Sylvia Lawry Centre online

Since April the Sylvia Lawry Centre can be accessed in the World Wide Web. Under the address www.slcmr.org the Web pages offer all the latest information about the research centre.

The Internet is a major component in the IT concept of the Sylvia Lawry Centre and serves both as an information and a communications platform. As a first step, it is now possible for anyone in the world to quickly and reliably find the latest news from the Munich research centre. Basic information about the team, the scientific environment and the research methods can be accessed here. In addition, contact addresses, press releases and photographic material are also available.

Links to the MSIF and the national MS societies connect up with the direct contact persons for patients. Up until the launch of the great Online Communica-

tions Forum for patients, scientists and pharmaceutical companies scheduled to take place early in 2002, the Web pages will mainly supply informative news in summary form. It is worth paying a visit to the homepage of the Sylvia Lawry Centre!



The Sylvia Lawry Centre is represented in the internet at www.slcmr.org.

IT concept

Data security and advanced communication

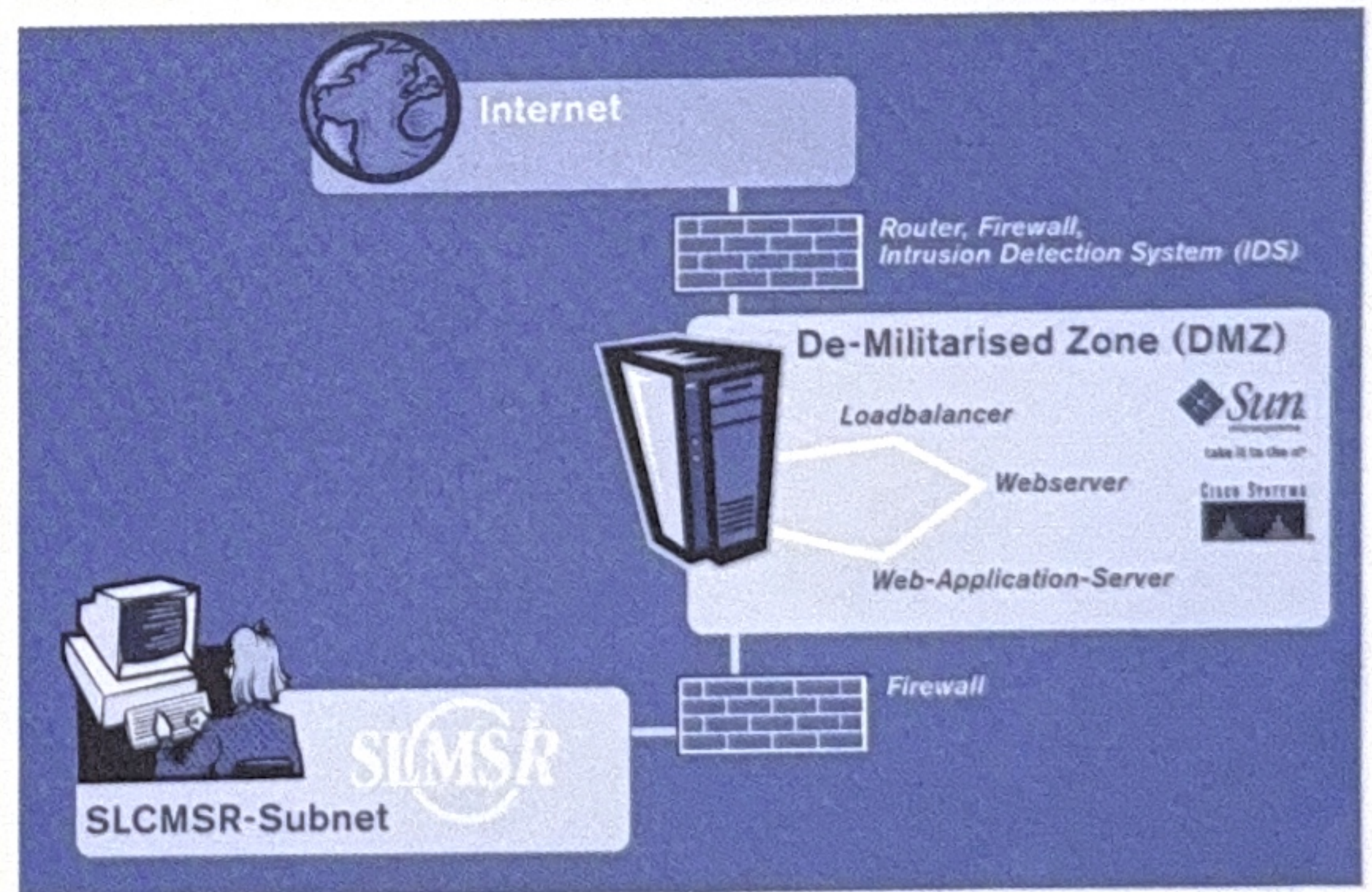
The IT concept of the Sylvia Lawry Centre is made up of a number of different components that we shall present to you here as appropriate. Apart from the hardware and software, under which the various Internet and Intranet applications run, it is mainly the security concept that is of overriding importance. In the first contribution, we shall briefly outline the network topology and its relevant components.

The Internet service provider of the Sylvia Lawry Centre is the Leibniz Computer Centre located in the Bavarian Science Academy, which operates an Internet node of the German Research Network for universities in the Greater Munich Area. The services it offers are Internet services in the "traditional sense" without any restrictions or limitations. The current 200 Mbps bandwidth of the Internet link can in the meantime also be increased to Gigabit speeds.

The key Internet services (E-mail, WWW, Active Content Applications, Data Warehouse) of the Centre run on SUN Enterprise and SUN Netra servers provided with generous support from SUN Microsystems. These central computers cope with the Centre's information and communications needs and are

The security design and network topology of the Sylvia Lawry Centre for Multiple Sclerosis Research.

located in a special sector (a so-called DMZ - De-Militarised Zone). To set up and operate the DMZ and to effectively manage the workload across the servers, CISCO components are used. CISCO also provided generous expert advice on the security concept of the centre. A high-security machine-room of Grade II on the security scale (protection against fire and water, air-conditioning, redundant power supply, rigorous access controls), where patients' data from the Klinikum rechts der Isar are processed, serves as the location. It is being developed and operated by THYSSSEN Health Care Services,



which not only offered valuable support in the conceptual phase but also assists the Centre with its routine assignments.

The actual research work of the Centre, i.e. its work with the data of placebo and natural history patients, is carried out in an Intranet of its own. This sub-network is completely sealed off and offers no direct possibility of transferring data outside the network (e.g. floppy disk, CD-ROM, Internet, telephone). Access is restricted purely to authorised members of the Centre's staff.

We shall provide a detailed overview of the security concept of the Centre in the next Newsletter.

"Better treatment for MS"

Sylvia Lawry Centre: *Prof. Ian McDonald, you are chairman of the Scientific Oversight Committee of the Sylvia Lawry Centre for Multiple Sclerosis Research in Munich, Germany. You were one of the main initiators of this Centre, which was founded in February 2001. What are your expectations regarding the work of the Sylvia Lawry Centre?*

Ian McDonald: The main initial expectation is to develop new ways of assessing effectiveness of treatments for MS. This will be done by bringing in very large amounts of data derived from population based trials which already exist and the data from placebo arms of clinical trials that were carried out in the nineties. This will be done by analysing this data statistically, to identify combinations of features which predict the rate of progression of the disease.

SLCMSR: *Why did the MSIF choose the Munich bid under numerous competitors?*

Ian McDonald: The standard was very high and the reason was, that the Munich application had the highest level of technical sophistication and the most secure way of transferring data. The proposals for mathematical modelling were impressive. They already had experience in designing

new approaches for testing effectiveness of treatment, which had been accepted by the United States Food and Drug Administration (FDA). The Sylvia Lawry Centre would be at a single university site which would provide a framework for training the next generation of investigators for MS.

SLCMSR: *What is the role of the Scientific Oversight Committee of the Sylvia Lawry Centre? And how is the quality of the scientific work guaranteed?*

Ian McDonald: The role is to set the scientific policy and to determine priorities in research. The quality of scientific work will be guaranteed by monitoring the progress of the Centre and by having publications in peer reviewed scientific journals

SLCMSR: *The aim of the Centre is to support clinical research into MS for the benefit of the patients. What concrete benefits will patients have to expect from the work done at the Sylvia Lawry Centre?*

Ian McDonald: Briefly: They will have better treatments for MS and these will be developed sooner than would otherwise be possible. ■

EVENTS

● 25 January 2001

Workshop on "Developments in Multiple Sclerosis", Munich.
Invited speakers: Prof. Dr. Ludwig Kappos, Prof. Dr. Jürg Kesselring, Prof. Dr. Ian McDonald

● 26 January 2001

Signing of the agreement between MSIF, TUM/IMSE and Trium to found the Sylvia Lawry Centre, Munich.

● 1 February 2001

Official start of the project.

● 9 March 2001

Scientific Oversight Committee (SOC) Meeting, Munich. Appointment of Prof. Dr. John Noseworthy, Mayo-Clinic as successor of Prof. Dr. Ian McDonald as chairman of the SOC beginning September, 30. Appointment of Prof. Dr. Ludwig Kappos as deputy chairman and medical adviser.

● 23 April 2001

Presentation at MSIF Board Meeting, London.

● 31 May 2001

Presentation at ICODIMS Meeting, Fort Worth, TX.

● 23 & 24 June 2001

Booth at Life Science Live Exhibition, Munich.



The Parliamentary State Secretary Wolf-Michael Catenhusen (left) visited the booth of the centre. Having explained

the mission of the centre by Dr. M. Daumer (right), he elucidated possible supports by the German Ministry of Education, Science, Research and Technology for the Centre.

● 25 June 2001

Inaugural Meeting for SLCMSR e.V., Munich.

● 30 July 2001

The "Amtsgericht Munich" officially registered the SLCMSR e.V. and the local tax office issued the non-profit-status certificate.

INAUGURAL MEETING



Professor Dr. Albrecht Neiß, Director of IMSE, Technical University of Munich

On June 25, 2001, less than half a year after the project was officially launched, all steps were taken for registering the Centre as a non-profit-organization in Munich. The seven founder members are as follows (from left to right):

General Mike Dugan, *Managing Director of NMSS, a former general of the US Air Force*

Christine Purdy, *Managing Director of the MSIF*

Professor Dr. Jürg Kesselring, *Chairman of the International Medical Advisory Board of the MSIF*

Professor Dr. Ian McDonald, *Chairman of the Scientific Oversight Committee*
Dr. Martin Daumer, *IMSE, Technical University of Munich/Trium Analysis Online*
George Ernest Loudon, *Treasurer of the MSIF*

At the inaugural meeting, Professor Neiß was unanimously elected Chairman of the Executive Board. In accordance with its statutes, this non-profit-organization is committed on a long-term basis to promoting science and research in medicine and natural sciences, in particular in relation to multiple sclerosis.

Imprint

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