



## Dear ECRIN NEWS readers,

Many thanks to all who participated in the ECRIN Annual Meeting in Milan in May. The good weather, good cheer, and warm hospitality made for a successful meeting! We follow-up on some of the developments from the meeting in this issue of ECRIN NEWS.

Thanks to all those who voted for the new ECRIN logo! As announced at the ECRIN Annual Meeting, the designer of the winning logo is Pega Souri, ECRIN European Correspondent from Sweden. She was rewarded with champagne for her great design!



As you can see from this Issue, the new logo is in keeping with the EU colours, two shades of blue and a lemony yellow. The yellow figures may symbolise the stars in the EU flag, or the team of people behind ECRIN working together to support clinical research projects, or patients and investigators celebrating the results of a clinical trial. The blue building blocks could be the infrastructure and the projects, or the two groups compared in a trial, with one

showing more benefit than the other. What does the new logo say to you?

We have updated the ECRIN website with the new logo and a PDF-version is available for download on the ECRIN website ([ecrin.org](http://ecrin.org)). Please use the new logo when representing ECRIN from August 2009.

The Editorial Team

## ECRIN CALENDAR

### Launch of new ECRIN logo, August 2009

Our new logo can now be downloaded from the ECRIN website. Access through: Login - Document management – Intern - Miscellaneous.

### WP10 on Data centres

14th September 2009, Brussels

### WP3 on Financial plan

14th September 2009, Paris

### European Correspondent's Summer School 17th-19th September 2009, Mahon

European correspondents will be trained in the ECRIN quality assurance system and issues in the management of multinational clinical trials.

### Network Committee Meeting

19th September 2009, Barcelona

For further information about ECRIN,  
please see the website [www.ecrin.org](http://www.ecrin.org)

# ECRIN ANNUAL MEETING

ECRIN members, the Network Committee, the European correspondents, and members of the Scientific Board were all gathered at the Mario Negri Institute in sunny Milan the 19th and 20th May for this year's ECRIN Annual Meeting.

Plenary sessions included updates and discussion on the legal status of ECRIN, the e-learning tool, the activity of the Scientific Board, and the possible extension of ECRIN to Luxembourg, the Netherlands, Poland, Portugal, and Turkey. The meeting also included breakout sessions for each of the working parties (WP).

This was the first time for some of the WP members to meet in person, and everybody was very happy for the face-to-face meeting with the 'voices' from the telephone conferences.

The meeting was a great success thanks to your participation. Thank you to all the presenters and to the Mario Negri Institute for their organisation and hospitality. In 2010, ECRIN's Annual Meeting and ECRIN's celebration of International Clinical Trials' Day (ICTD) will be a two day meeting around the 20th of May, hosted in Stockholm, Sweden.



# INTERNATIONAL CLINICAL TRIALS' DAY 2009

ECRIN's celebration was held in Milan at the Mario Negri Institute on May 20th. Christian Gluud, DCRIN, chaired the session, Madame Françoise Meunier, EORTC Director General, presented 'Opportunities from and threats to randomised clinical trials' and Allan Tyndall, Professor and Head of the Department of Rheumatology in Basel, presented 'Randomised clinical trials assessing potential biotherapeutic interventions'. The presentations are available on the ECRIN website.<sup>1</sup>

We warmly thank all the speakers, contributors, and organisers to this event.

<sup>1</sup>[http://www.ecrin.org/index.php?option=com\\_content&task=view&id=69&Itemid=92](http://www.ecrin.org/index.php?option=com_content&task=view&id=69&Itemid=92)

ICTD 2009 was a truly global celebration marked in Europe, Australia, and Africa. The Mario Negri in Milan also hosted the Italian celebration of ICTD on May 20th. Paola Mosconi chaired the session and the fruitful discussion on the 'Promotion of public awareness of clinical research'. A highlight of the meeting was the video on 'Disease mongering'. The farce scenario was the promotion of a fake drug for the well-known and ubiquitous disease condition of laziness, which in its mild form can slow you from your bed on Monday morning, and in its severe form cause death!



The Cochrane Collaboration and Trials journal both celebrated the ICTD on their respective web pages. <http://www.cochrane.org/> and <http://www.trialsjournal.com/>

A Swedish celebration of ICTD was held in Stockholm's Kungsträdgården, hosted by SweCRIN. It was an all day event with short lectures, an outdoor fair, and live music and entertainment. ECRIN looks forward to celebrating ICTD in Stockholm on May 20th 2010.

Australia and New Zealand honoured contributors to clinical trials on ICTD. On May 20th, AccessCR published



its annual 'Clinical Trials Honour Roll'.<sup>2</sup> This honour roll recognises contributions to clinical research in Australia and New Zealand. This positive initiative is in the spirit of ICTD, celebrating all those who take part in clinical research for the advancement of clinical practice.

<sup>2</sup>[http://www.accesscr.com.au/2009\\_Clinical\\_Trials\\_Honour\\_Roll](http://www.accesscr.com.au/2009_Clinical_Trials_Honour_Roll)

EDCTP (European and Developing Countries Clinical Trials Partnership) expressed its support for ICTD and marked the day to highlight a new initiative; the AIDS, Tuberculosis and Malaria Clinical Trial Registry (ATMCTR) for trials conducted in Africa.<sup>3</sup> Trial registration is free and the new interface is easier to use, access, and navigate. ECRIN endorses all such efforts to promote clinical trial registration and promote transparency.

<sup>3</sup><http://www.edctp.org/Announcement.403+M5be906b5352.0.html>

# ECRIN SCIENTIFIC BOARD

Six pilot projects, with sponsors from different countries, have been submitted to the ECRIN Scientific Board for eligibility assessment. Presently, one trial has passed the ECRIN Scientific Board's eligibility phase and is currently undergoing assessment in the acceptance phase.

The current ECRIN Scientific Board assessment procedure is a two-step process with eligibility and acceptance phases. The procedures are currently undergoing revision which aims to simplify the eligibility phase for more efficient assessments.



## HYVET – 2008 TRIAL OF THE YEAR

The HYVET trial<sup>1</sup> (HYpertension in the Very Elderly Trial) has been voted the 2008 Trial of the Year by Project ImpACT (Important Achievements of Clinical Trials) and the Society for Clinical Trials.<sup>2</sup>

The HYVET trial was a randomised, double-blind, placebo-controlled multinational trial. HYVET involved 3,845 participants aged 80 years old or more with persistent hypertension. The experimental intervention was NATRILIX SR (a thiazide-like diuretic), with the addition of perindopril as needed, to reach a target blood pressure of 150/80 mm

Hg. The primary outcome measure was fatal or nonfatal stroke.

The final results showed a reduction of 30% ( $P=0.06$ ) in fatal or nonfatal stroke; 39% ( $P=0.046$ ) in stroke-related death; 21% ( $P=0.02$ ) in overall mortality; 64% ( $P<0.001$ ) in fatal and nonfatal heart failure; and 34% ( $P<0.001$ ) in cardiovascular events.

The HYVET trial is likely to impact on guidelines and clinical practice of hypertension in the elderly. The trial was especially relevant as this age group is the fastest growing population in the world.<sup>3</sup>

Professor Bulpitt, the coordinating investigator, said:

“The trial was entirely a collaborative effort. Our results clearly show that many patients aged 80 and over could benefit greatly from treatment.”



<sup>1</sup>Beckett NS, Peters R, Fletcher AE, et al. Treatment of hypertension in patients 80 years of age or older. *N Engl J Med* 2008;358:1887-98.

<sup>2</sup><http://www.hyvet.com/> (Accessed 1 July 2009)

<sup>3</sup>United Nations. World population ageing 1950-2050. IV. Demographic profile of the older population. <http://www.un.org/esa/population/publications/worldageing19502050/pdf/90chapteriv.pdf>.

## ECRIN CAMPUS

*"In times of profound change, the learners inherit the earth, while the learned find themselves beautifully equipped to deal with a world that no longer exists." Al Rogers.*

'ECRIN campus' is an e-learning tool developed in co-operation with HSet Foundation (Health Sciences e-Training) and provides web-based training to



support clinical research investigative teams in European countries. 'E-Learning', or online learning, is an accessible and cost effective training method for people involved in academic clinical research. ECRIN's e-learning tool is called ECRIN campus. ECRIN campus provides online content related to ECRIN standard operating procedures (SOPs), online learning activities as well as guidelines and templates. Topics are adverse event reporting, interaction with competent authorities, ethics, data management, monitoring, protocol development, and how to develop SOPs.

The users have the possibility to use ECRIN campus as a repository in order to get information about country-specific elements, differences and similarities amongst countries, and ECRIN SOPs. The content will be updated and edited frequently to keep the users up-to-date. The knowledge acquired can be applied to multinational clinical trials and thus, quality can be improved.

The pilot phase has started and a prototype has been created with content on interaction with ethics committee in multinational clinical trials.

## EDUCATION AND TRAINING

EMTRAIN (European Medicines Research and Training Network [www.emtrain.eu](http://www.emtrain.eu)) is a new research project selected for funding by the Innovative Medicines Initiative (IMI). IMI is a public-private partnership between the European Commission and the European Federation of Pharmaceutical Industries and Associations, and aims to improve the development of better medicines.<sup>1</sup>

The partners in EMTRAIN include the six European biomedical science research infrastructures: INSTRUCT (structural biology); ELIXIR (bioinformatics); INFRAFRONTIER (animal models); BBMRI (biobanks); EATRIS (translational research); and ECRIN (clinical research). EMTRAIN will fund and govern pharmaceutical medicine training and education programmes in the European Union. EMTRAIN will develop a platform for education and training covering the whole drug development process across Europe. One task of EMTRAIN will be to develop and implement a strategy for harmonisation and accreditation of Masters and PhD programmes in clinical research.<sup>2</sup> The first student should enter the EMTRAIN PhD programme in 2011, with an estimate of around 500 students in total. Entry into the EMTRAIN programme is independent of background. Michael Wolzt, leader of the ECRIN working group on Education and Training, is also the leader of the EMTRAIN project office, based in Vienna.

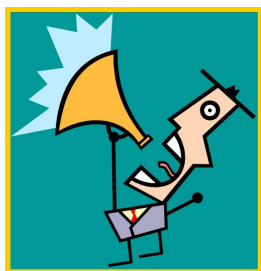
<sup>1</sup><http://www.emtrain.eu/public/news.htm>

<sup>2</sup><http://www.emtrain.eu/project/executive-summary.htm>

# ESFRI COMMUNICATION STRATEGY

The ESFRI BMS (European Strategy Forum on Research Infrastructures) biomedical sciences research infrastructures, ie, INSTRUCT (structural biology); ELIXIR (bioinformatics); INFRAFRONTIER (animal models); BBMRI (biobanks); EATRIS (translational research); and ECRIN (clinical research), share several aspects such as a need for bioinformatics or biobanking solutions. These infrastructures support the whole range of biomedical research from basic research to application of new diagnostics and medicines in patients. Since the six infrastructures listed above are in their preparatory phase and a further four have been included in the updated European roadmap, a unique momentum is being generated in the life sciences field, creating an outstanding opportunity for the advancement of European science and industry. This momentum, however, can only be fully developed if the infrastructures agree upon communication strategies to secure broad public and political support.

A communication strategy that considers both the content and the process of delivering these messages is needed. Such a strategy needs to be developed in collaboration between members of the various infrastructures as well as experts in communication, journalism, economy, social



and political sciences.

Kurt Zatloukal presented the need for such a strategy during the ECRIN Annual Meeting and is heading this initiative, for further information, please contact him at:

kurt.zatloukal@medunigraz.at

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## ECRIN in the NEWS

**Clinical Research in Hungary. Infrastructure, Organisation, Legislation and Framework. The Situation in 2008. György Blaskó and Gabriella Kardos. *Thérapie*, 2009; 64(1): 33-45.**



The current situation regarding clinical research regulatory frameworks in Hungary is described in this article. The piece follows from the extensive work carried during the ECRIN II TWG project.

The article comments that company-sponsored clinical trials is reasonably well regulated, but other types of clinical research (investigator initiated trials, trials of psychology, food supplements, devices, etc.) need further harmonisation. The article highlights that the present legislative and regulatory frameworks in Hungary are complicated and unique amongst other ECRIN countries. Organising clinical study centres into a functional Hungarian network will facilitate Hungary to conduct and participate in multinational studies in various research areas.

The quarterly ECRIN NEWS is written and edited by the ECRIN staff in the Copenhagen Trial Unit, Denmark, the UK Cancer Research Network, UK, and in the Medical University of Vienna, Austria. It is published in electronic form on the ECRIN website [www.ecrin.org](http://www.ecrin.org). Editorial staff are Christian Gluud, Chief Editor; Helen Howard, Editor; Johannes Pleiner, Editor; Diana Winter, Editor; Kate Whitfield, Managing Editor. Postal address: Copenhagen Trial Unit, Centre for Clinical Intervention Research, Dept 3344, Blegdamsvej 9, DK 2100, Copenhagen, Denmark. Tel. +45 3545 7169 or 68, Fax. +45 3545 7101, E-mail [kate.whitfield@ctu.rh.dk](mailto:kate.whitfield@ctu.rh.dk)