ECCO NEWS 2007

EUROPEAN CROHN'S & COLITIS ORGANIZATION 3 2007 VOLUME 2

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  Reports from three Workshops
- Report from DDW in Washington
- ECCO launches New Official Journal

ECCO NEWS

The Quarterly Publication of ECCO
European Crohn's & Colitis Organization

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LETTER FROM THE PRESIDENT

President
MIQUEL GASSULL
Badalona, Spain

Dear Colleagues,

Once again I use the opportunity of ECCO NEWS to inform you about the activities, decisions and projects of ECCO since my last letter.

After the success of our second congress in Innsbruck last winter, the Governing Board has regularly being holding telephone conferences to decide upon subjects that can not wait until our summer meeting in July.

Important decisions include the organisation of the individual membership, the role of the national representatives' council, the election of ECCO officers, approval of the final program for the 3rd congress, reorganisation and position of Young ECCO within ECCO, organisation of a workshop on Opportunistic Infections on IBD and the launching of the first issue of the Journal of Crohn's and Colitis.

The two first issues are very much linked. The Governing Board has designed a strategy where both the National Societies and also the individual members of a given country can be represented within the ECCO organisation and how an individual member can stand for a position in ECCO Committees and Board. This system will be proposed to the next National Representatives Assembly for its approval. If it is the case, all ECCO members and those who have expressed their intention of becoming ECCO members by filling out the form provided during our congress in Innsbruck, will be properly informed. Our secretariat has designed a form which all of you interested to be informed about ECCO's individual membership can use. It can be also be obtained through our secretariat via e.mail *(ecco@vereint.com)* or through the ECCO website front page *(www.ecco-ibd.eu)* which I invite you to visit.

The final program of our 3rd Congress that will be held in Lyon, France on February 28–March 1 was completed. The traditional structure of lectures will be approached in a different way, that is: each subject will be approached or interpreted in a translational way by both a basic scientist and a clinical scientist. This may help to provide a more complete approach to IBD. In addition, a whole morning will be devoted to Live-Endoscopy demonstrations with discussion of the cases and findings presented both in terms of diagnosis and therapy. I am sure that the third ECCO congress will be of great interest to the entire IBD community, in which also papers can be submitted; the 10 most highly qualified will be presented orally and the remaining accepted as posters. Prizes will be awarded to the best presentations both as oral or poster papers. As usual, ECCO Fellowships and Grants will be awarded during the congress. Information about registration and deadline for submissions can be found at *www.ecco-ibd.eu*
We are very glad to meet all of you there, since we are sure you will enjoy both the content of the program and the ECCO environment also in the social gatherings.

Young ECCO (YECCO) has became one of the most active initiatives within ECCO. In this sense, the Governing Board wants to incorporate this highly dynamic group into tasks of responsibility in the ECCO Committees. Therefore, the following has been agreed upon:

- All individual ECCO members up to 35 years of age will be considered Young ECCO members.
- Young ECCO will have a Chair and a Vice-Chair, that will report to the ECCO Governing Board.
- Two Young ECCO members will be elected, on the basis of their *CV*, to serve as full members, one in the Scientific Committee and one in the Educational Committee. In this way they can gain expertise in ECCO organisational mechanisms.
- Young ECCO members will cooperate in the educational activities such as the ECCO School and ECCO workshops.

Therefore, Young ECCO members will be fully involved in the scientific and educational activities of our society.

The forthcoming 14th and 15th of December ECCO has organised a workshop in Nice on Opportunistic Infections in IBD. This workshop will gather and discuss the

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results of the previous work of different taskforces including clinicians, microbiologists and basic scientists, who will analyse the available evidence on each of the clinical situations. The aim is to present the results during our next congress in Lyon, and produce, if possible, guidelines for the prevention and management of these serious complications in IBD.

Finally it is my pleasure to announce that in September the first issue of the *Journal of Crohn's and Colitis (JCC)* will be launched. *JCC* is the official journal of ECCO and its aim is to disseminate the knowledge on clinical and basic science and innovative methods related to IBD. *JCC* will publish original articles, review papers, editorials, leading articles, view points, innovative methodology and letters to the editor; all material published is peer-reviewed. *JCC* has a very potent Associate Editors team, Consensus and Guidelines (one of the relevant ECCO activities) Editors and a wide truly International Advisory Editorial Board (global representation), which will assure the quality of the contents of each issue. Although *JCC* is the official ECCO journal, it is in fact an international journal, open to anyone in the world interested or working in Inflammatory Bowel Disease. The editors look very much forward to your submissions and also your new ideas, criticisms (positive!) and ways of improving this important activity of our society. All ECCO registered members will receive, as part of their membership, a subscription to the Journal of Crohn's and Colitis. Of course, anyone can subscribe to the journal through the Elsevier Journals Customer Service *(elsols@elsevier.com)*

I hope this letter has been able to provide enough interesting information about ECCO activities to be able to stimulate all of you interested in IBD to become ECCO members.

MIQUEL GASSULL
M.D., Ph.D.
President

New website address

Please note our new address – **www.ecco-ibd.eu**

Here you can find useful information about many details concerning ECCO. It's easy to navigate via menus which can be found to the left and at the top of the page. E-mail links to the Governing Board are provided.
The website also contains many other links, both internal and external. Documentation for ECCO projects can be downloaded and links to partner organizations can also be found here.
In order to keep yourself updated – don't forget to add **www.ecco-ibd.eu** to your Favourites!

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ECCO

EFCCA (European Federation of Crohn and Colitis Associations) and IBDIS (Inflammatory Bowel Disease Information System)

latest news about clinical trials in IBD – New Online listing at the EFCCA-Website supported by trials.ibdis.net

London, June.
The executive committee of EFCCA and Nikolaus F. Pedarnig from UNIDATA GEODESIGN met in London, UK and committed themselves to cooperate.

UNIDATA supports the EFCCA-website with current information about **clinical trials in IBD** in all European Countries including Israel.

IBD Patients benefit from the new tool as a reliable source of information.

Pharmaceutical industries and clinical sites now have a one-stop-shop to increase patient recruitment for clinical trials. Via **www.efcca.org** and **trials.ibdis.net** ethics committee approved postings of all IBD trials can be found.

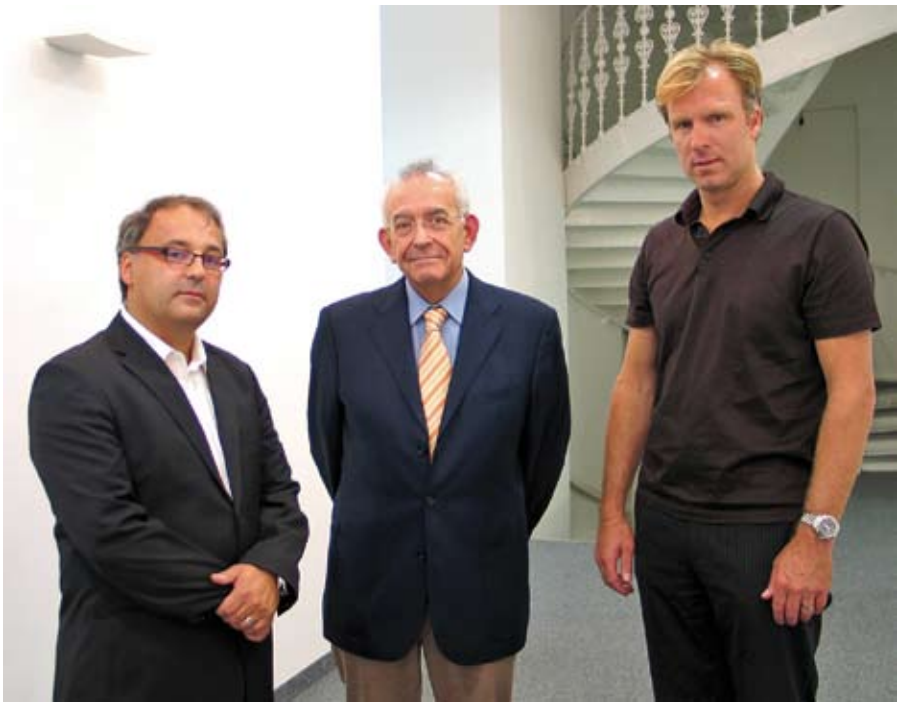
Mikael Lindholm (left) – secretary of EFCCA, Rod Mitchell (middle) – chairman of EFCCA, Nikolaus F. Pedarnig (right) – General manager of UNIDATA and co-founder of IBDIS.

IBDIS® – Standardized documentation of IBD comes true

Prof. Dr. **WALTER REINISCH**, Member of ECCO SciCom, mail: walter.reinisch@meduniwien.ac.at
NIKOLAUS F. PEDARNIG, bakk.techn, UNIDATA GEODESIGN, mail: nikolaus.pedarnig@ibdis.net

IBDIS – a tool for ECCO

By contract ECCO and UNIDATA GEODESIGN set out to stimulate the harmonization of data registration in the field of IBD by using IBDIS (Inflammatory Bowel Disease Information System) on the medical information from individual patients. As a catalogue of standardized and validated parameters related to IBD, IBDIS reconciles the challenging demands from ECCO and potential third party users, such as partners from pharmaceutical industry or regulatory authorities. Accordingly, IBDIS is available via internet and designed to support several potential applications. From a ready-to-use tool for scientific analysis to an electronic patient record **ePR** with integration into the clinical routine, or an electronic case report form **eCRF**, as applied in clinical trials, registries, biobanks or health economic studies, IBDIS poses the documentation standard which is easily to adapt to the customers' demands. For the use of IBDIS individual ECCO members or third party members may either apply for a license at ECCO or UNIDATA GEODESIGN.



Nikolaus F. Pedarnig (left) – General manager of UNIDATA and co-founder of IBDIS, Miguel Gassul – President of ECCO, Daan Hommes (right) – Chairman Scientific Committee, during a meeting of the ECCO governing board in July 2007 in Vienna.

Who can apply for an IBDIS license?

UNIDATA GEODESIGN developed three categories of online-tools to meet the needs of the IBD community:

1. IBDIS Standard Software for individual ECCO members.
2. IBDIS ePR Software for individual ECCO members.
3. IBDIS eCRF Software for the pharmaceutical industry, regulatory authorities or investigator-initiated studies of individual ECCO members.

Dependent upon the intended application and the user's specific requirements IBDIS is provided either as ready-to-use standard software or may be adapted accordingly. Figure 1 displays potential licensees, their demands for standardized patient documentation and the respective IBDIS Package which fits their needs.

Are there costs for licensees?

The IBDIS Standard Software will be free of charge for individual ECCO members. Individual ECCO membership will be applicable in 2008. However, licensees incur project fees for IBDIS ePR and IBDIS eCRF composed of a fixed start-up amount and maintenance costs. Projects using IBDIS requested by ECCO or its members shall be reviewed and approved by ECCO's scientific committee. All activities undertaken shall be in accordance with any and all applicable law and regulations, as well as general accepted international ethical standards. Figure 2 shows the relationship between the licensee, the costs and the location of data storage.

Who owns data registered by IBDIS?

An adequate confidentiality agreement between UNIDATA and the party requesting any IBDIS package shall be in place. Licensees acquire sole ownership of the captured data. Also any and all rights to inventions and discoveries that may be conceived or generated in connection with an IBDIS project shall be solely owned by the licensee.

Role of UNIDATA GEODESIGN

UNIDATA GEODESIGN acts as the owner of the IBDIS software, performing user required adaptation of the software, maintaining and supporting the proper functionality and availability of the application. In case of user requirements for adaptation of the standard software, UNIDATA GEODESIGN consults during the planning process and implements modifications.

Questions and answers

What is the difference between the IBDIS Standard Software and the IBDIS electronic Patient Record Software?
The IBDIS standard software is a free tool to build IBD-databases for individual ECCO members. Anonymous data is stored at the UNIDATA GEODESIGN facilities. The IBDIS ePR Software is adapted from the IBDIS standard software and designed to be integrated into the clinical routine setting. IBDIS ePR records personalized data stored at servers at UNIDATA Geodesign or at the clinical site.

Both licenses enable electronic data capturing about **epidemiology, location, phenotype, course of disease, complications, intestinal surgery, comorbidity and risk factors, pregnancy and therapy.**

What are the first steps to gain access and use the IBDIS Standard Software?
Access **https://documentation.ibdis.net** with your internet browser, click the "Getting Started"-button and follow the instructions on the screen.

Is there a demo-license available of the software?
UNIDATA GEODESIGN grants access to a limited demo license for all, who submit the demo License application form and the confidentiality agreement, both available at **https://documentation.ibdis.net** to UNIDATA GEODESIGN via fax.

Is the IBDIS Standard Software free for everyone?
The free use of the IBDIS Standard software tool is restricted to individual ECCO members. ECCO will grant individual membership in 2008.

Who is the owner of the data?
Every licensee has full ownership of his/her data.

Where are IBDIS-registered data stored?
The anonymous information registered by the IBDIS Standard Software is stored at the validated UNIDATA servers in Vienna, Austria. According to national or international law the database on personalized information captured by IBDIS ePR may be kept inside the respective clinical site. Data from IBDIS eCRFs are stored according to the third party member's request.

Does licensee acquire ownership of the IBDIS software?
No, the licensee acquires the right to use the software restricted by the terms of the confidentiality agreement and the software license agreement. The software itself remains property of UNIDATA GEODESIGN.

Where can I get more information about the IBDIS project and the software tools provided by UNIDATA GEODESIGN?
Please contact UNIDATA GEODESIGN or ECCO for additional information or access the corporate website: **https://documentation.ibdis.net**

Figure 1a: License for individual ECCO-members

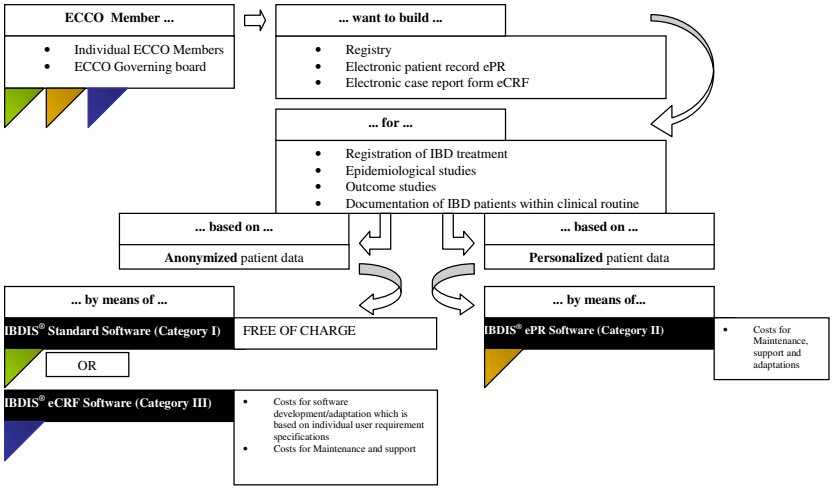


Figure 1b: License for pharmaceutical industry and regulatory authorities

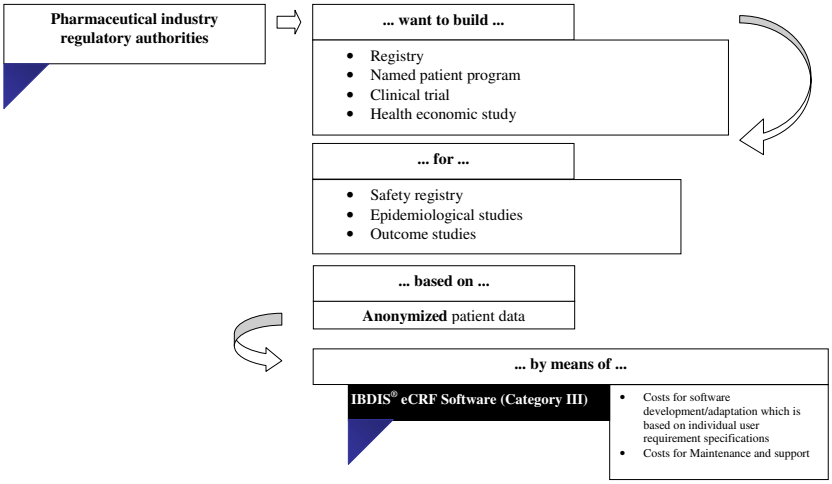
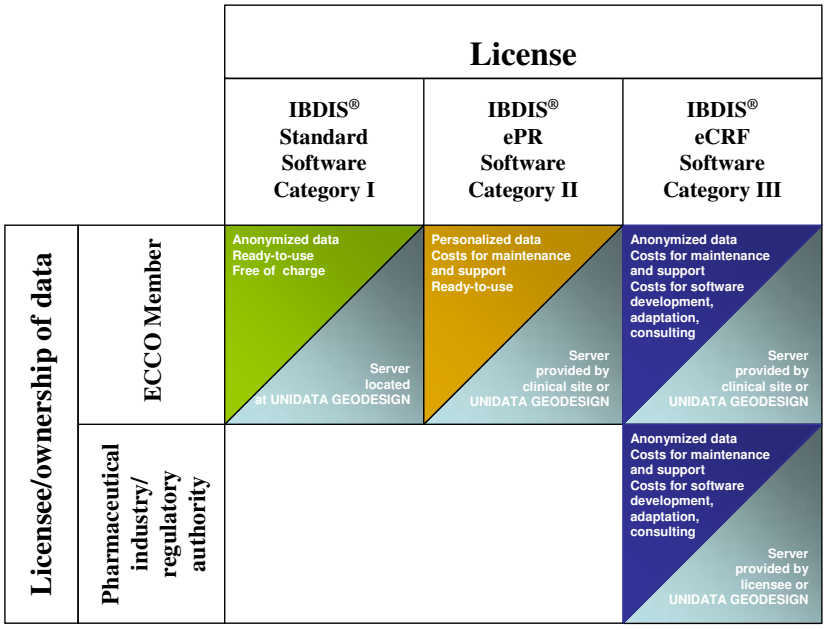


Figure 2: Licenses, costs and ownership of data



ECCO launches new official Journal

In September 2007 the first issue of Journal of Crohn's & Colitis – JCC – was released.

JCC is the official journal of the European Crohn's and Colitis Organisation (ECCO). Its aim is the dissemination of knowledge on clinical, basic science and innovative methods related to Inflammatory Bowel Diseases (IBD).

– The idea of starting a Journal came as a logical, progressive step in the development of ECCO – once the society had established its first core activities, says Dr Miquel Gassull, President of ECCO and also the Editor of JCC.

Third column

Dr Gassull refers to the meetings, seminars, consensus conferences and educational activities, like ECCO-IBD school and congresses that ECCO has organised during its first five years of existence.

– Therefore, after education and scientific activities, the third column supporting our scientific society should be a journal, he explains.

High production of new knowledge

Scientific activity in IBD is very high, both in clinical and basic sciences, which generate a great deal of new knowledge.

– Hence a high number of good scientific papers which can not always be published in general gastroenterology journals or journals devoted to genetics, immunology and other basic sciences since they have to deal also with other parts of their areas of knowledge, Dr Gassull continues.

This was also a reason taken into account by the Governing Board of ECCO for creating the new journal.

– JCC aims to gather the newest multidisciplinary, innovative and reliable information on pathogenesis, diagnosis, therapy and innovation related to IBD.

Duo of publications

Supplements to the Journal of Crohn's and Colitis are published under the title, *Journal of Crohn's and Colitis Supplements*. All subscribers to JCC will automatically also receive this publication free of charge.

At the ECCO Congress in Innsbruck earlier in 2007, the first supplement was published. It contained the abstracts from the Congress. The JCC Supplements is the perfect publication vehicle for the proceedings of a scientific symposium, commissioned thematic issues, or for disseminating a selection of invited articles.

The fist issue of JCC was published in September 2007.

In this first issue there is one review article dealing with the use of biological therapies in paediatric IBD. It also contains five original articles and one viewpoint on the use of Probiotics in Crohn's Disease.

Dr Gassull can already reveal that next issue will have two reviews – one on basic science and one with IBD-related bone disease – and of course more original articles and viewpoints.

Open for everyone

JCC is going to be published four times every year – every third month. It will publish original articles, review papers, editorials, leading articles, viewpoints, case reports, innovative methods, abstracts and letters to the editor.

Members of ECCO receive a subscription as part of their membership benefits.

– But JCC is defined as an "International Journal", Dr Gassull continues.

– It means that it is open to everyone in the world interested and working in Inflammatory Bowel Diseases. Papers from all over the world are very much welcomed.

– If someone – who is not a member of ECCO – wish to subscribe to JCC, just send a letter to the editors, or even better, get in touch with Elsevier Journals Customer Service. *(Contact details at the end of this article, editors comment).*

Peer-reviewed

All material submitted to JCC is subject to an expert peer-review process.

– The Associate Editors of JCC are Drs. Jean-Frederic Colombel (France), Yehuda Chowers (Israel), Daan Hommes (The Netherlands), Stefan Schreiber (Germany), Jack Satsangi (United Kingdom) and Severine Vermiere (Belgium). In addition, Drs. Eduard F Stange (Germany) and Simon Travis (United Kingdom) act as Special Editors for Consensus and Guidelines.

– The journal also have a wide international editorial advisory board, stressing the fact that JCC is an internationally minded journal, Dr Gassull adds.

The Journal of Crohn's and Colitis will be published by *Elsevier*.

To subscribe – or for further information about the Journal – please contact *Elsevier Journals Customer Service* at:

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PER LUNDBLAD
Senior Writer

Optimising biological therapy:
practical considerations, current practice and future prospects

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email: simon.travis@ndm.ox.ac.uk

Background:
Biological treatment of IBD is a rapidly evolving field. Published guidance (such as the ECCO Consensus on the Management of Crohn's Disease, *Gut* 2006; *54 Suppl 1:i1-58*) inevitably lags behind current practice.

Three workshops for acknowledged experts across Europe have been held to explore current thinking on starting, continuing and stopping or switching biological therapy. A fourth workshop for all National Representatives from the 25 countries of ECCO will examine access to biological therapy, from the patient perspective to local limitations on appropriate use of biotherapy. This will be held in Barcelona in January. Further series will continue, using case-based discussion of clinical dilemmas faced by all IBD specialists.

ECCO Workshops are a vehicle for addressing controversial or developing topics in the management of IBD, with a view to education and dialogue on the ECCO Guidelines at a Regional level, to improve practice on behalf of patients. They are managed by the educational committee of ECCO [**ecco@vereint.com**], with appraisal of the cited references and scientific content by SciCom.

This is a summary of the first 3 workshops.

Aims of the workshop series:
- To conduct a series of interactive meetings based on clinical cases that provide practical guidance on the biological management of IBD
- To review the evidence that supports or limits the use of biological therapy in Crohn's disease and UC
- To create a set of slides and lecture notes from each meeting that can be used as an ECCO resource

Slides and notes have been prepared as an ECCO educational resource. These will be available from October 1st. Please e-mail Sonja Rosenzweig [**ecco@vereint.com**] to register your interest. This meeting series is supported by an unrestricted educational grant from UCB SA.

Next issue of ECCO News:

Reports from:

- **Second Scientific and Annual General Meeting of European Society of Coloproctology in Malta**
- **Falk Workshop and Symposium in Dresden**
- **UEGW in Paris**

Do you want a personal subscription to ECCO NEWS?

The aim of ECCO NEWS is to reach all doctors in Europe with an interest in IBD. ECCO NEWS is an important part of the European Crohn and Colitis Organisation's ambition to create a European standard of IBD care and to promote knowledge and research in the field of IBD. The newsletter is financed through advertisements and distributed free of charge. If you are yet not on the mailing list you can have a personal paper copy sent to your postal address 4 times a year. Just send an email to **ecco@mediahuset.se** stating your postal address. The information you give will not be used for any other purpose than distributing ECCO NEWS.

TOM ÖRESLAND, Editor ECCO News

WORKSHOP 1:
Starting biological therapy
Prague, 5th & 6th December 2006

Chairs:	
Severine Vermeire, MD, PhD. Univ Hospital Gasthuisberg, Leuven, Belgium	
Milan Lukas, MD, PhD, General Faculty Hospital, Prague, Czech Republic	
Participants:	
Bjorn Moum (Norway)	**Boris Vucelic** (Croatia)
Edyta Zagorowicz (Poland)	**Fernando Magro** (Portugal)
Julian Panes (Spain)	**Milos Gregus** (Slovakia)
Pia Munkholm (Denmark)	**Sandro Ardizzone** (Italy)
Walter Reinisch (Austria)	**Willem Bemelman** (Netherlands)
Zuzana Serclova (Czech Republic)	**Daan Hommes** (Netherlands)
Jannike Van de Woude (Netherlands)	**Peter Lakatos** (Hungary)
Simon Travis (UK)	**Yehuda Chowers** (Israel)

The questions relating to starting biological therapy were facilitated through case presentations:	
Complex Crohn's Disease	**Yehuda Chowers**, Tel Hashomer, Israel
Newly Diagnosed Crohn's Disease	**Pia Munkholm**, Copenhagen, Denmark
Chronic refractory Ulcerative Colitis	**Walter Reinisch**, Vienna, Austria
Severe Ulcerative Colitis	**Julian Panes**, Barcelona, Spain

Major discussion points included observations that:

- Early treatment with biological therapy for selected patients can reasonably be expected to deliver a better outcome. Clinical information and molecular markers (eg. genetic, serologic) on which patients to select and whether early treatment alters outcomes that matter to patients (hospitalisation, surgery) are needed.

- Contraindications to biological therapy can usefully be recalled by the ***STOIC*** acronym adopted by Subrata Ghosh (**S**epsis, **T**B, **O**ptic neuritis (demyelination), **I**nfusion reaction (hypersensitivity), **C**ancer).

- Patients with a history of cancer or dysplasia in need of biological therapy should be assessed on a case by case basis.

- Response to biological therapy can be maximised by:
  - An induction regimen of two or more doses before maintenance treatment
  - Concomitant treatment with an immunomodulator for 6 months to reduce antibody formation
  - Early treatment for those with severe disease (such as Crohn's disease in multiple sites, especially in younger patients or the presence of perianal fistulae at initial diagnosis)

- Surgery should be considered alongside the use of biological therapy and not left as a last resort. Patients should be included in discussions about whether surgery or biological therapy is the most appropriate treatment choice, having had benefits and risks of each option explained. This is particularly pertinent to young women or women of child bearing potential where data indicate that pelvic surgery impairs fecundity. They require special counselling around their treatment choices.

- There are still too few data to support many clinical decisions, especially concerning newer anti-TNF biological therapies. Data from the certolizumab and adalimumab development programmes may close some of these information gaps. The challenge, then, is to address differences in access to therapy, because national guidance or reimbursement policies often lag behind clinical evidence.

- Many of the clinical questions and answers relating to starting biological therapy in Crohn's disease translate to Ulcerative Colitis although data are still limited.

- There was much discussion about whether "top down" therapy was appropriate and if so, how to identify a suitable patient. Daan Hommes remarked "only safety concerns (and cost) generally prevent people from adopting a "top down" approach to treatment. If you adopt "top down" you may be over-treating a minority of those patients you select, but if you adopt "step up" you will be under-treating the majority". Boris Vucelic reminded the panel that "top down" is not recommended in the ECCO Consensus guidelines and that we need more data to support this approach.

WORKSHOP 2:
Continuing biological therapy
Stockholm, 11th & 12th April 2007

Chairs:	
Robert Lofberg MD, PhD, IBD Unit, Sophiammet, Stockholm, Sweden	
Yehuda Chowers MD. Chaim Sheba Medical Centre, Tel Hashomer, Israel	
Participants:	
Francisco Portela (Portugal)	**Gert Van Assche** (Belgium)
Janneke Van der Woude (Netherlands)	**Joao Freitas** (Portugal)
Julian Panes (Spain)	**Limas Kupcinskas** (Lithuania)
Milan Lukas (Czech R)	**Philippe Marteau** (France)
Paolo Gionchetti (Italy)	**Simon Travis** (UK)
Subrata Ghosh (UK)	**Tom Oresland** (Sweden)
Wolfgang Kruis (Germany)	

The issues and questions relating to continuing biological therapy were facilitated through case presentations:	
Complex Crohn's Disease	**Subrata Ghosh,** Imperial College School of Medicine, London, UK
Newly Diagnosed Crohn's Disease	**Janneke van der Woude,** Molewaterplein 40, Rotterdam, Netherlands
Crohn's disease with extra-intestinal manifestations	**Philippe Marteau,** Hospital Lariboisiere, Paris, France
Chronic refractory ulcerative colitis	**Gert Van Assche,** U.Z. Gasthuisberg, Leuven, Belgium

Major discussion points included the following:

- The panel discussed the merits of scheduled vs episodic treatment with infliximab in detail. The ACCENT data shows a small but clinically significant difference in clinical response in favour of scheduled treatment vs episodic. Panel members questioned whether this was clinically relevant. Professor Ghosh confirmed that scheduled treatment was associated with greater mucosal healing and lower rates of hospitalisation and surgery and so, though the difference in response was small, felt it likely that this difference will translate to outcomes that matter to patients.
- In addition, scheduled treatment was considered to be less immunogenic and was associated with a perceived reduced need for concomitant immunomodulators. Given the safety concerns of concomitant immunomodulators with biological therapy this was considered beneficial.
- Given preliminary data that indicates that efficacy is maintained and immunity reduced after 6 months of immunosuppressive therapy, its continued use in parallel to biological therapy should be discussed and balanced with safety considerations such as the occurrence of HSTCL.
- In patients who have responded but begin to lose response to biological therapy, "recapturing" some patients can be achieved as follows:
  - infliximab – dose escalation – 10mg / kg (ACCENT1)
  - adalimumab – dose escalation – 40mg weekly (CHARM)
  - certolizumab – single additional dose – 400mg (PRECISE 4)
- There was agreement that scheduled treatment should be considered for fistulising disease.
- Direct comparison between the efficacy of the anti-TNF drugs is impossible due to the heterogeneity of the study populations and the lack of head to head comparative trials.
- Many of the clinical questions and answers relating to continuing biological therapy in Crohn's disease translate to Ulcerative Colitis although data are still limited.
- The role of the surgeon during maintenance treatment as part of a therapeutic strategy was highlighted as critical to a successful outcome. This was thought to be particularly pertinent during the complex Crohn's case where the patient presented with perianal problems. Early intervention of a surgeon (drainage and seton in this case) could have reduced the impact/extent of the fissure which was followed by the development of horseshoe extensions to the right and left with associated perianal abscess.
- Care should be taken not to confuse symptoms due to IBS with therapy failure.
- There was limited consensus about the use of biological therapy in Crohn's disease with extraintestinal manifestations. In patients with active Crohn's the dose of biological should be used appropriate to IBD (and not for example to that for rheumatoid arthritis if the EIM is arthritis).
- There are no good data relating to how long to continue biological therapy. The panel suggested that mucosal healing or perianal imaging might be used as markers in a study to define when biological therapy might be stopped, but further studies are needed.
- When biological therapy is continued, patients should be re-assessed as part of a defined treatment plan. A second opinion or further specialist advice should be sought for primary non-responders or secondary failures to biological therapy. In the case of patients primarily not responding to 5 mg/kg infliximab during induction, it was agreed that increasing the dose to 10 mg/kg was inappropriate as the ACCENT data had shown that these primary non-responders will not achieve response/remission at the higher dose.

WORKSHOP 3:
Stopping or switching biological therapy
London, 4th & 5th June 2007

Chairs:	
Professor **Subrata Ghosh**, Imperial College School of Medicine, Hammersmith Campus, London, UK	
Professor **Jean-Frederic Colombel**, Hospital Huriez, Lille, France	
Participants:	
Axel Dignass (Germany)	**Cosimo Prantera** (Italy)
Daan Hommes (Netherlands)	**Eduard Stange** (Germany)
Gerassimos Mantzariis (Greece)	**Grazyna Rydzewska** (Poland)
Herbert Tilg (Austria)	**Marc Lemann** (France)
Mike Kamm (UK)	**Pierre Michetti** (Switzerland)
Philippe Marteau (France)	**Sandro Ardizzone** (Italy)
Simon Travis (UK)	**Willem Bemelman** (Netherlands)
Yehuda Chowers (Israel)	

The issues and questions relating to continuing biological therapy were facilitated through case presentations:	
Switching biological therapy in Crohn's disease	**Pierre Michetti,** Centre Hospitalier Universitaire Vaudois, Switzerland
Stopping biological therapy in complex Crohn's disease	**Marc Lemann,** Hospital St Louis, Paris, France
Biological therapy in women with Crohn's disease planning a pregnancy?	**Philippe Marteau,** Hospital Lariboisiere, Paris, France
Stopping or switching biological therapy in chronic refractory ulcerative colitis	**Herbert Tilg,** Landeskrankenhaus Hall, Austria

Major discussion points were as follows:

Pregnancy

- ECCO guidance for managing female patients with Crohn's disease planning a pregnancy is as follows (*Gut 2006;54 Suppl 1: i1-58*):
  - The patient should be advised and supported to stop smoking
  - The patient should take folate supplements
  - The dose of 5-ASA should be reduced to ≤3g/day
  - The patient should wait for remission before becoming pregnant
- The patient should be managed to maintain remission during the pregnancy wherever possible as a flare is potentially harmful to both baby and mother. The risk of a flare following stopping medication for Crohn's disease was estimated at 70%. However, it was recognised that treatment plans should be discussed with the patient and also the obstetric/gynaecology team and an informed choice made on a case by case basis. In addition, when managing a flare the patient's previous medication history should be taken into account. For example, steroids were considered the tried and tested choice to induce remission in pregnant women, but should be avoided in patients who had previously failed to respond adequately.
- Azathioprine was considered appropriate maintenance therapy on the basis of the known safety profile of this medication.
- Emerging data from babies born to mothers taking infliximab and adalimumab during their pregnancy do not show any safety signals that differ from the normal population.
- However, it was agreed that caution should be advised when using infliximab in pregnancy due to the placental transfer of IgG1 antibodies.
- New data on the pegylated Fab fragment certolizumab pegol were presented. The substance does not cross the placenta and this may present a therapeutic advantage compared to other anti-TNF agents which do.
- Low levels of both azathioprine and infliximab are excreted in breast milk suggesting that both are probably safe during breast feeding.

Loss of response to biological therapy

- Given the lower response in patients already exposed to one anti-TNF agent, therapy with the current biological agent should first be optimised (see Stockholm meeting notes).
- Patients who lose response or develop intolerance to infliximab can be treated with other biological agents eg adalimumab or certolizumab pegol.
- Consistently lower response rates to the second biological agent do *not* support a central role for anti-infliximab antibodies as the only mechanism.
- Patients who lose response or develop intolerance to infliximab should have surgery considered and discussed before dose increment or switching therapy.

Switch due to other reasons than loss of response (eg. patient convenience, safety concerns)

- There are no data available for switching biological therapy in patients still responding to a first biological in either Crohn's disease or ulcerative colitis.
- Likewise, there are no data in IBD patients relating to switching to a third anti-TNF agent after two previous failures. Further research is needed on whether the structural difference in certolizumab pegol from adalimumab and infliximab has a benefit.

Duration of anti-TNF therapy

- The optimal duration of biological agent maintenance therapy is still unknown. Predictors of poor outcome following biological withdrawal are lacking. Discontinuation of biological therapy in patients in remission should therefore be considered on a case by case basis. Many of the panel discussed their own practice of applying an arbitrary cut off at 12 months' of remission, but data supporting this interval does not exist. ■

3rd Congress of ECCO – the European Crohn's and Colitis Organisation

ECCO

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Professor Boris Vucelic – Chairman of EduCom

The EduCom is committed to the postgraduate education in the field of IBD in Europe and to the establishment of European Consensus on diagnosis and treatment of IBD.

ECCO members (national IBD groups and individual members) come from all of the European countries.

One of the major concerns of the organisation is to realize the dream of providing equal quality of care for all IBD patients in Europe – and particularly enhancing the care in Eastern Europe.

This statement is delivered by the chairman of ECCO's Educational Committee – EduCom – Professor Boris Vucelic, in Zagreb, the capital of Croatia.

Training in USA

We meet Professor Vucelic in his office at Rebro University Hospital in Zagreb. Here he has been working as a Gastroenterologist since 1983.

His career has been remarkable. After graduating as a doctor in 1971 here (in those days Zagreb was a city in Yugoslavia) he went to USA and undertook a Residency in Internal Medicine and Fellowship in Gastroenterology in Chicago between 1973 and 1979. He received certifications as a diplomate of the American Board of Internal Medicine in Internal Medicine and Gastroenterology.

– I remained in Chicago after that and came back to Croatia in 1983. I've stayed here ever since, says Dr Vucelic.

He did his PhD in 1986, and has advanced gradually since then. He became Head of the Division of Gastroenterology and Hepatology in 1989 and Chairman of the Department of Medicine at the Clinical Hospital Centre Zagreb in 2003 – positions that he still holds today.

Clinical Hospital Centre Zagreb comprises several hospitals including Rebro Hospital, and is the clinical teaching base for the Medical School of the University of Zagreb.

So Dr Vucelic has to share his time between teaching, administrative duties and clinical work.

– I spend about 30% of my time teaching – if I include both undergraduate medical students and postgraduate courses, he estimates.

Pedagogic

There is no doubt that Dr Vucelic has all the necessary qualities that make a good tutor. He is a gentle person, highly educated but still with a gleam of curiosity that is always present in his eyes.

His explanations are constantly stringent, and he follows his thoughts to the end before he goes on to the next subject.

Besides medicine he is also very interested in history and political science, and has a vast knowledge of this field too.

He is proud to be a citizen of a newborn independent country – Croatia, or *Hrvatska* as the country is called in *Hrvatski* (Croatian) – that declared its independence as late as 1991.

Increase in incidence for IBD

Dr Vucelic was interested in Gastroenterology right from the beginning as a student of medicine.

– It's a speciality with lots of different aspects, it involves not only clinical medicine but also endoscopy, radiology, microbiology, psychiatry and much more, he explains.

His involvement in IBD began in Chicago, where he came into contact with Crohn's Disease.

– I learned a lot – these are very complex patients to handle.

But IBD was a rare disease in Croatia when he came back.

– A prospective study in Zagreb showed a very low incidence for IBD up to 1989. However, that has now changed and incidence rates in both Crohn's disease and Ulcerative Colitis are now similar to those in western Europe. Changes in incidence rates within a relatively short period of time point towards changing environmental factors as a cause since the genetic background is the same.

Several phenotypes

Genetics is a very important field in the research of IBD at present, and Dr Vucelic explains why:

– Inflammatory Bowel Diseases have many "faces" that we call phenotypes, with individual differences in the extension of disease (involvement of different parts of the gastrointestinal tract) and in the activity of the disease at a given time. It is sometimes difficult to recognize the phenotype of IBD in the early stages of disease with implications on the treatment strategy.

– The research in IBD therefore concentrates on genetic studies finding different genes for different phenotypes and on the understanding of the inflammatory process enabling us to identify targets for the new drugs.

– New expected information from this studies will enable us to make informed therapeutic decisions earlier in the course of the disease, Dr Vucelic continues.

– This is particularly important in the discussion about preferred therapeutic approach (top-down or step-up strategy).

– The top-down approach requires precise early definition of disease phenotype and severity, particularly in light of concerns about the long-term safety of biologicals. At the present time, most centres use step-up approach with ECCO consensus statement as a guidance.

Specialized surgeons important

Dr Vucelic predicts that in the future we will have the genetic markers of different IBD phenotypes and validated clinical parameters of severity, enabling physicians

to make informed therapeutic decisions with better control of the disease and less complications.

– We will also have new drugs, particularly biologicals. The experience from Rheumatology clearly shows that we need alternative solutions when drugs we use don't work or loose its efficiency.

Dr Vucelic also emphasizes the key role played by the surgeons in the treatment of IBD patients.

– All IBD patients should be treated by a team with the experienced IBD surgeon as a member of the team.

To illustrate the need of specialized surgeons, Dr Vucelic points out that the short bowel as a result of surgical resection is more commonly the consequence of multiple sequential surgeries done to deal with complications of initial surgery than as a result of repeated elective surgeries.

He also emphasizes that IBD is not a Bowel disease only!

– It is a systemic disease with a lot of extraintestinal manifestations of the disease, complicating an already complex disease with frequent local complications such as fistulas, abscesses, stenosis and cancer of the bowel.

Dr Marko Brinar, a young colleague to Dr Vucelic, is going to Leuven University Hospital in Belgium for a year as a part of the young physicians network programme.

EduCom

This takes us into the importance of EduCom.

– Our goals with EduCom are as follows: First, we want to equalize the quality of IBD care throughout Europe that requires not only more funds and better equipment but more importantly better educated medical professionals.

– The second goal is to create a network of young physicians interested in IBD who will cooperate in the future. These young people are the "seed" for the new IBD centres throughout Europe.

–The third goal is to create the European IBD Nurses network with emphasis on their education.

ECCO IBD School

First, there is the annual ECCO IBD School for Junior Gastroenterologists. These courses have been highly successful and take place immediately before the ECCO Congress every year.

– What we do is that we select two or three people from each country to come for a day and a half. It's very interactive teaching – we cut down traditional lectures and concentrate on more case-based teaching instead.

Different teachers – same material

The ECCO Workshops are the next thing on EduCom's agenda.

– It's a new idea. We've made an effort to establish the consensus on treatment of Ulcerative Colitis and Crohn's Disease and now we want to help in the implementation of the Consensus.

– Therefore we are going to run four or five ECCO workshops per year in different countries in Europe. Some of them are going to be regional and some local. We selected important statements from the consensus and created cases around them. The library of slides was created consisting of many consensus statements with clinical cases and relevant literature information. For each workshop, six to seven sets are chosen from this library to be presented by ECCO and local teachers.

– The main point is that the workshops will use the same teaching material with the same message, given by different speakers. We plan to involve between 70 and 100 people per workshop.

Dr Vucelic continues by telling us that the first two workshops will be held in Zagreb (November 2007) as a regional workshop and in Vienna (December 2007) as a local workshop.

Nurses

The third programme that EduCom is in Charge of was presented for the first time earlier in 2007, at the ECCO Congress in Innsbruck. It was the first ECCO Nurses Meeting.

The purpose of the meeting was to create a platform for the development of an IBD nurses network in Europe, to analyse the current working practices and to develop continuous nurses education.

– We feel that the nurses are a very important part of the IBD team. Today there is a gap between the need for highly qualified nurses and the real situation. Very few countries can afford specialized nursing teams, the nurses have to perform other tasks as well.

– But the increased frequency of IBD patients requires the development of more centres. Therefore EduCom is trying to create a network for IBD nurses in Europe. One of the ways of achieving this is to create an educational program for IBD nurses.

Will stay in the family

At the next ECCO Congress in Lyon, Dr Vucelic is going to step down from the position as Chairman of EduCom. But he will remain as a member of the EduCom.

– When ECCO was founded five years ago, we were lucky to have a group of enthusiastic people whose agendas weren't personal. There were no conflicts, everybody was just concerned with developing the organization, he recalls.

–That's the reason why ECCO has been so successful. He stressed that he feels privileged indeed that he have been a part of ECCO in its early developing years.

PER LUNDBLAD
Senior Writer

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Report from DDW 2007 in Washington

By Dr **GERASSIMOS J. MANTZARIS**

Introduction

This year 'the fellowship of the four American Gastroenterological Societies', the Gastroenterological Association, the Association for the Study of Liver Diseases, the Society for Gastrointestinal Endoscopy, and the Society of Surgeons for the Alimentary Tract, held their annual meeting, known as Digestive Diseases Week, in the capital city of the USA, Washington DC. Over the years, the DDW has been recognized as the most successful and well attended annual meeting in Gastroenterology. The 'beauty' of DDW lies mainly on a balanced scientific program that merges ideally basic and clinical science, or, as has been sent before, 'one plus one equals one'. As a result, the DDW has become a forum that attracts thousands of physicians and researchers, academics, clinicians, basic scientists, medical students, etc from all over the world because it offers everyone solid ground to satisfy his/her interests and keep him updated on the most recent scientific information.

The universal interest for Inflammatory Bowel Diseases is reflected by the progressively increased number of the AGA 'Immunology, Microbiology and IBD club' members and the continuous growth in the volume of the IBD abstracts submitted to the DDW. Because the construction of the annual scientific program of the DDW is a sensitive dynamic process that takes seriously into account the trends in the specialty, in the last 20 years we have witnessed a steady rise in the volume of the sessions allocated to the AGA's IBD club: oral and poster presentations, lectures, combined symposia, etc, are an integral part of the 4-day core meeting. This year's DDW was not an exception since pioneer scientific work from many countries around the world was presented. Topics covered nearly all aspects of IBD from epidemiology and genetics to intestinal immunopathology, mechanisms of disease, diagnosis and differential diagnosis, laboratory markers of inflammation, disease activity indices, imaging and endoscopy, new aspects of the medical therapy (including critical evaluation of the efficacy and safety of the biologicals), evaluation of surgical techniques in IBD, and cancer surveillance.

Genetic studies have mainly focused to IL12 and IL23 genes: it was suggested that interaction between IL23R and IL17A and between IL23R and IL17RA haplotypes as well as variants of the IL12B (and therefore, IL12 and/or IL23) are probably involved in the overall susceptibility to CD. Furthermore, an uncommon coding variant, Arg381Gln, in the IL23R gene was suggested to confer protection against IBD. In familial CD, persistent susceptibility to the colonization by *Candida* albicans, a commensal yeast of the human intestinal tract that has been identified as an immunogen for ASCA, and/or a lack of modulation of ASCA response towards this indigenous microbial agent was found. The HLA-G 14bp Ins-Del polymorphism influences potentially the response to methotraxate in Inflammatory Bowel Disease.

Apart from genetic factors, chemokines were viewed as additional major players in the pathogenesis of Crohn's disease. For instance, expression of chemokine CXCL16 is enhanced in intestinal inflammation and polymorphisms of the CXCL16 p.Ala181Val were thought to be associated with early onset and ileal involvement in Crohn's disease. Chemokines were also tested with promising results as potential targets for therapeutic intervention in IBD.

Colorectal cancer, a feared complication of longstanding colonic IBD, was one of the main topics, as highlighted by the increasing number of scientific work presented at the DDW. The appropriate timing of surveillance colonoscopy in IBD, the potential advantage of using dyes (chromoendoscopy) versus traditional random-biopsy surveillance colonoscopy to enhance identification of flat or subtle dysplasia or early colorectal cancer, the natural history of polypoid dysplasia, the outcome of sporadic adenomas and adenoma-like DALMs in ulcerative colitis patients, and risk factors for small bowel cancer in patients with Crohn's disease, were some of the most important topics that were extensively discussed during DDW.

In the report that follows we have selected a potpourri of abstracts for more extensive and, if possible, critical presentation. This should by no means be considered as selection of the best abstracts. This is impossible for a short report of what was presented during a 4-day meeting and it is certainly an insult to the excellent work that was presented orally or as posters.

One final comment: as usual, clinical and basic research from European IBD centers contributed significantly to the stimulating and fruitful discussions and accounted considerably for the success of the IBD sessions at this year's DDW. Indeed, nearly all European and neighboring countries represented in ECCO submitted abstracts that were presented orally or as posters. In addition, IBD experts from Europe participated actively in abstract selection committees, served as invited speakers, and/or chairs in IBD sessions. ECCO should actually learn from the AGA's experience. We should strengthen our efforts to motivate European researchers to submit their work to the ECCO meetings but also to the UEGW meetings as they do it for the DDW. Furthermore, we should attract more IBD experts from USA and other countries to become members of our society. We need to 'activate' these people in the process of constructing the scientific program for the ECCO meetings, abstract selecting committees, award committees, etc.

Conventional and Novel therapies for Inflammatory Bowel Disease

Genetic tests to determine the response to methotrexate?

Baburajan and his colleagues (Gastroenterology 2007;132:Abstract 189) studied 171 IBD patients treated with methotrexate (MTX) and another 94 patients treated with azathioprine (AZA) for more than 3 months. They evaluated the presence of polymorphisms in the HLA-G gene in relation to response to treatment with MTX or AZA. HLA-G antigens are inducible MHC class Ib molecules. In rheumatoid arthritis patients treated with MTX polymorphisms have been identified both in the membrane-bound and in soluble HLA-G gene and have been shown to increase the production of interleukin-10. IL-10 is a cytokine that plays an important role in the down-regulation of inflammation in various chronic inflammatory disorders, including Crohn's disease. The investigators showed that HLA-G gene polymorphisms were associated with response to treatment with MTX but not AZA (RR 1.7, p<0.01 vs 0.8, p<0.53). They speculated that MTX upregulates IL-10 production and this in turn acts as an anti-inflammatory cytokine mediating the immunosuppressing effect of MTX. This does not seem to be the case for AZA.

Developing strategies to reduce the post-operative recurrence of Crohn's disease.

Surgically-induced remission of ileo-colic CD achieves a long-lasting remission but the majority of patients will inevitably show signs of endoscopic and/or clinical relapse by the end of the first post-operative year. Faecal diversion, elemental diets, metronidazole (at a dose of 0.5g tid for 3 months) and ornidazole have all been shown to reduce the incidence of post-operative relapse but all these treatments are either unacceptable in the long-term or associated with severe toxicity, including potentially irreversible peripheral neuropathy. In control clinical trials aminosalicylates and azathioprine have been shown to reduce severity of post-operative

Photo: Lagniappe Studio

relapse but in real life success rates have been disappointing, especially for aminosalicylates. In a recent GETAID publication it was documented that despite increased use of azathioprine in recent years the rate of surgery for CD has not declined. However, this may be due to late administration of azathioprine, i.e. long after irreversible structural damage has occurred in the gut. In this year's DDW several groups of investigators presented work on the prevention of post operative relapse of CD. One of these was presented by S. Vermeire on behalf of Geert D'Haens and co-workers (Gastroenterology 2007;132:Abstract 288). They studied a cohort of 81 CD patients (54% male) who had undergone a recent ileo-caecal resection and had more than one risk factors for early severe post operative recurrence according to GETAID (that is, age <40 years, perforating disease, need for steroids at surgery, and at least one previous ileo-colic resection). Patients received immediately after surgery a combination of open label metronidazole (250 mg tid, i.e. half the dose in the previous study of Rutgeerts and colleagues from the same center) for 3 months and either azathioprine (100-150 mg/day depending on body weight) or placebo. Patients were followed for one year post-operatively for signs of clinical and endoscopic recurrence, the latter being assessed by ileocolonoscopy at 3 and 12 months. The primary end-point was severe endoscopic recurrence (as indicated by a Rutgeert's i-score of at least 2, which means more that 5 aphthae in the neo-terminal ileum). Of 81 patients, 73 and 61 were re-evaluated at 3 and 12 months post operatively, respectively. Recurrence rates are shown in figure 1. Very severe post operative relapse (Rutgeerts scores i3 and i4)

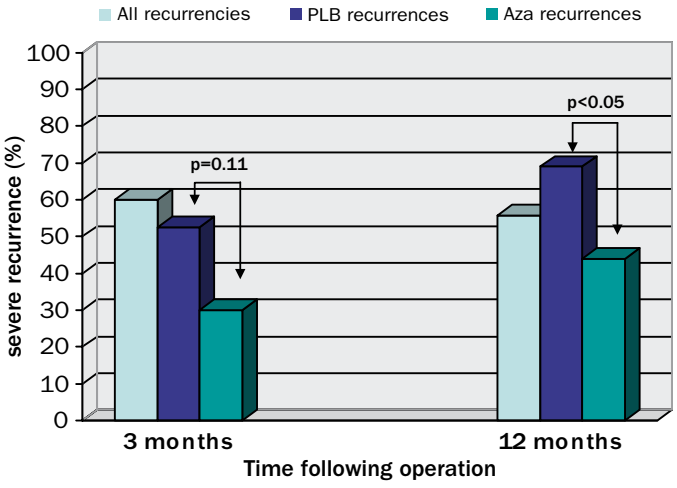

Figure 1: Severe (Rutgeerts i2) post-operative endoscopic recurrence of CD patients treated with metronidazole 0.25 g tid for 3 months and azathioprine (100-150 mg/day) or placebo for one year.

Digestive Disease Week is considered the largest and most prestigious meeting in the world for the GI professional. Close to 17,000 gathered in Washington, D.C. for DDW 2007, making the meeting the best attended DDW to date. (Photo: Lagniappe Studio)

was very rare [3/ 73 patients (4%) at month 3 and 12/61 (22%) patients at month 12]. However, significantly more patients had severe endoscopic relapse on placebo than azathioprine at 12 months post operatively (figure 1). In addition, absence of lesions was more commonly seen in azathioprine- than in placebo-treated patients (7/32 vs 1/29, p=0.04). Between months 3 and 12, 12 patients discontinued the trial for adverse events related to treatment or flares of CD, but numbers were evenly distributed between the azathioprine- and placebo-treated groups; however, liver toxicity was more common in azathioprine treated patients. Thus, this study showed that a combination of metronidazole and azathoprine in the immediate post-operative period reduces significantly the annual severe post-operative endoscopic recurrence of CD in patients at high risk for severe recurrence. Metronidazole probably reduces the risk of early recurrence (<3 months) until azathioprine has been fully active to protect patients from late recurrences.

On behalf of his colleagues at the University Hospital in Vienna, Dr Pavol Papay presented another abstract focused on the ability of azathioprine to prevent re-operation after a 1st operation for Crohn's disease (Gastroenterology 2007;132:Abstract 289). They reviewed retrospectively the charts of 333 CD patients who had received azathioprine post operatively for less than 2 months or at al, for 3-11 months, 12-36 months, or for >36 months. Overall, 132 patients underwent a second operation for CD but significantly more of these patients had either not received azathioprine at all or had been treated for less than 2 months (49% vs 24%, p<0.001). The protective effect of azathioprine was parallel to the duration of treatment irrespective of the indication for the 1st operation (fibrostenotic or internal fistulizing disease). Due to the retrospective analysis of data detailed information regarding other potential risk factors for post-operative recurrence, type of intestinal anastomosis, etc could not be provided but of parameters available for multivariate regression analysis the duration of azathioprine treatment was shown to be the sole factor associated with a 2nd operation.

Long term treatment with azathioprine: Can Nodular Regenerative Hyperplasia (NRH) develop?

Cases of NRH have been reported in patients treated long-term with azathioprine (AZA). Jack Cosnes presented data on behalf of GETAID (Gastroenterology 2007;132:Abstratc 290) on the prevalence of NRH in azathioprine-treated CD patients. They identified a cohort of 2269 patients treated with azathioprine between 1974 and 2006 but they excluded 273 patients because they stopped treatment for azathioprine intolerance, 83 for surgery, 130 patients because they were treated for less than 2 years, and 29 patients because they developed unexplained liver biological abnormalities. NRH was sought in 1730 patients who were treated with azathioprine (target dose 2.5 mg/kg/day) for a median period of 30 months and were followed up for a median period of 50 months after starting treatment. Diagnostic criteria were acquired thrombocytopenia and portal hypertension, but the diagnosis was confirmed by liver biopsy. Finally, 13 patients were diagnosed with NRH after a median period of 44 months (14-214) with a cumulative risk of 0.7±0.2% and 1.3±0.5% after 5 and 10 years, respectively. In univariate analysis, male gender, small bowel involvement, prior small bowel resection >50cm, bowel perforation, colonic sparing, and disease duration were all related to development of NRH (p<0.05). In a Cox model hazard ratios were 8.3 and 3.3 respectively for male gender and small bowel resection of >50cm. Therefore, although the risk for developing NRH at five years in azathioprine users was small (0.7%) this figure mirrors only the classical clinical cases; the number of undetected, subclinical cases is probably much higher. The message is, therefore, that physicians should be alert to diagnose NRH in patients treated long-term with azathioprine and especially in males who have undergone extensive small bowel resection when then number of platelets is unexpectedly reduced and signs of portal hypertension develop.

Immunosuppressives and male infertility

Some years ago work from Korelitz and colleagues had suggested that male patients with IBD should probably not be exposed to azathioprine at least 3 months before conception. Uma Mahadevan and her colleagues (Gastroenterology 2007;132: Abstract 287) presented fertility data on IBD patients exposed and unexposed to azathioprine or 6-MP. They examined semen samples using flow cytometry to define abnormal chromatin structure as an increased susceptibility of sperm DNA to acid-induced denaturation. This prospective study included 20 men with IBD (12 on azathioprine /6-MP) who were in remission and were not allowed to take sulphasalazine, corticosteroids, biologicals, or other immunosuppressives. Men on azathioprine /6-MP were more likely to have numerically but not statistically (because of small sample tested) exces-

sive DNA fragmentation and high DNA stainability than those not receiving immunosuppressives. This abnormal sperm DNA integrity may be associated with male infertility and/or foetal developmental abnormalities but since the number of patients is small this hypothesis needs to be further tested in a larger number of patients.

Are vaccination programs undermined by concomitant immunosuppressive therapy?

A potential mechanism of action of azathioprine /6-MP is exerted via down-regulation of the lymphocyte function. This may have profound effects on vaccination programs. Dotan et al (Gastroenterology 2007;132:Abstract 286) have evaluated the *in vivo* and *in vitro* effects of azathioprine /6-MP on cellular and humoral immune responses in IBD patients. This was a prospective study in patients referred for treatment with azathioprine for flares of IBD, prevention of post-operative recurrence, or initiation of infliximab therapy. The *in vitro* effect of azathioprine /6-MP was tested on peripheral blood lymphocytes (counts, phenotype, and response to various mitogens and antigens) as well as total and subclass immunoglobulins at baseline and at weeks 12 and 24 of treatment. The *in vivo* effect was assessed by the response to various vaccines [Pneumovax, tetanus, influenza, and *Haemophilus influenzae* type B (HIB)]. 36 IBD patients were included in the study and only 6 were in corticosteroids; 49 healthy controls were also studied. They showed that leukocyte and lymphocyte counts were diminished in patients on azathioprine /6-MP, the responses of lymphocytes to mitogens (ConA, PHA) as well as the response to vaccinations were comparable in IBD patients and controls. These results offer reassurance that at least at doses used in routine clinical practice for the treatment of IBD neither azathioprine nor 6-MP are so immunosuppressive agents as to undermine vaccination programs.

Lack of early clinical response and/or endoscopic healing after the 1st course of steroids may help selecting UC patients for early immunosuppressive therapy

Although corticosteroids remain the mainstay for the treatment of UC few studies have evaluated the short term (1 year) outcome and fewer the rate of endoscopic healing after treatment with corticosteroids. In this respect, Ardizone and colleagues from Italy (Gastroenterology 2007;132:Abstract 78) followed prospectively a cohort of 108 patients (70 males), with active, moderate-to-severe disease who needed their first course of systemic steroids within the first year of the diagnosis. Patients were followed clinically and endoscopically at 3 and 6 months post-treatment and then every 6 months for 5 years using the Powel-Tuck (P-T) and Baron indices, respectively. Three groups were identified on the basis of their early clinical remission (P-T score 0) and endoscopic healing (Baron score 0) at month 3, group A (complete response, P-T 0 and B 0), partial response (group B, P-T score 0, B score 1-3), and no response (group C, persistence of clinical and endoscopic activity). The long-term outcome was evaluated on the basis of this early response. Thus, at 3 months, 46.6% of patients had completely responded to corticosteroids, 25.2% had partially responded, and 28.2% had not responded at all. The 5-year colectomy rate was pretty similar in the 3 groups (overall 14.5%). However, in groups of partially or not responded patients immunosuppressive use as steroid-sparing agents was more common (p=0.029), hospitalizations were more frequent (p=0.006), and time to next flare was much shorter (p=0.001) compared with group A. During the 5-year follow-up, 55% of patients were in complete remission at each study point but 73% relapsed during the 1st year after treatment with systemic steroids. The interesting point of this study was that patients in group B, i.e. patients achieving clinical but not endoscopic remission at 3 months after treatment with corticosteroids, are endangered by more frequent relapses, hospitalizations, and finally immunosuppressive use. These patients should be considered as candidates for early treatment with immunosuppressants as is the case in non responders to the first corticosteroid course (group C of this study).

Some news on 5-aminosalicylates

New formulations of aminosalicylates have been recently in the market and various dose regimens have been tested. In this year's DDW Michael kamm and colleagues (Gastroenterology 2007;132: Abstract T1296) presented the results of a multicenter, randomized trial with MMX mesalazine, a novel high-strength formulation of mesalazine in UC. 362 patients with mild-to-moderate UC who had been induced in clinical and endoscopic remission on oral MMX mesalazine were randomized to 1.2 g bid or 2.4 g once daily of this formulation of mesalazine for one year. The study end-points were clinical and endoscopic remission at month 12. At the end of the trial period 92.5% of twice daily treated versus 88.7% of once daily treated patients with MMX mesalazine were maintained in full remission. In an analysis of patients treated with 2.4 g/day of MMX mesalazine, Lichtenstein and colleagues (Gastroenterology 2007;132: Abstract T1284) found that clinical and endoscopic remission (complete mucosal healing) was achieved in 68.6%, 68.1% and 43.3% of patients with mild (n=70), moderate (n=351), and severe (n=30) mucosal inflammation at baseline, respectively. In an intestinal disease that affects only the mucosal layer, like UC, these results emphasize the importance of an objective end-point of disease remission for RCTs, mucosal healing.

Kruis and colleagues (Gastroenterology 2007;132:Abstract 898) confirmed that in addition to MMX mesalazine classical mesalazine may also be dosed once daily without affecting the outcome of treatment. In a multicenter, randomized European trial in 381 patients with mild-to-moderate UC, investigators found that Salofalk®, a Eudragit-L coated mesalazine, given as a single 3 g dose once daily was equally effective to the classical 1g tid regimen in achieving clinical and endoscopic remission of disease after 8 weeks of treatment (remission rates 79.1% vs 75.7%, respectively).

Novel and investigational therapies in IBD

Extracorporeal leukapheresis was first used for the treatment of IBD in Japan and trials are ongoing in the rest of the world to evaluate the efficacy of this method. In the very last IBD session of this year's DDW, Maria Abreu presented data on behalf of an international group of collaborators (Gastroenterology 2007;132: Abstract 1033) on a novel, investigational therapy, extracorporeal photoimmune therapy (ECP). In this technique, peripheral blood leukocytes of IBD patients are

collected and treated *ex vivo* with 8-methoxypsoralen and ultraviolet light. This induces apoptosis of the autologus leukocytes which are subsequently re-infused and are probably distributed in various organs and tissues where they exert immunomodulatory effects. This method has been used experimentally in the treatment of various autoimmune and idiosyncratic diseases. In the present study, 28 patients with active (CRP >10 mg/L), moderate-to-severe (CDAI 220-450) Crohn's disease refractory treatment with all known therapies, including immunosuppressants and biologicals, were offered ECP initially in twice-weekly sessions for 4 weeks followed by twice-weekly sessions every other week for another 8 weeks in the context of an open-label, uncontrolled trial. The primary efficacy end-point was clinical response (reduction of CDAI by ≥100 points) or remission (CDAI<150 points) at the end of the sessions (week 12). Six patients discontinued treatment because of worsening (1) or persistently active disease (5). 50% of patients (14/28) achieved a clinical response, which was rapid as 13/14 patients responded by week 6. 25% of patients (7/28) were able to achieve clinical remission with a reduction of CDAI by >200 points. Amongst responders there were 7/14 patients who had either not responded or were intolerant of biologicals. Response to treatment was also evidenced by an increase in the median IBD quality of life questionnaire score (from 120 to 150) and a slight decrease in the median CRP levels (from 12.1 mg/L to 9.7 mg/L). One patient developed anaemia apparently as a result of the frequent blood sampling. Therefore, this trial raises hopes for the non responding patients even to anti-TNFα therapy that needs to be confirmed by a proper RCT.

In the same session, Satish Keshav and colleagues from London and Oxford presented data (Gastroenterology 2007;132: Abstract 1031) on an orally administered, highly specific antagonist (CCX282-B) of the chemokine receptor CCR9, which is expressed by mucosa-homing intestinal leukocytes. Because CCR9 and its ligand CCL25 are implicated in the pathogenesis of Crohn's disease, inhibition of CCR9 may be a specific and promising therapeutic approach to the treatment of CD. Investigators enrolled 71 patients with moderate-to-severe CD in a phase II-RCT. Patients received at a 2:1 ratio 250 mg CCX282-B tablets once daily or placebo for 4 weeks. The study focused on 39 patients most likely having definite active disease as indicated by a CDAI score ≥330 and a CRP ≥7.5 mg/L. Across the entire cohort, 49% of patients had a 70-point reduction in the baseline CDAI score *versus* 45% of placebo. However, in the cohort of the 39 patients with more active disease, the response rates were 58% for actively treated *versus* 31% for placebo-treated patients (p=0.006). The drug was well tolerated. This is the first study based on a chemokine specific inhibition of leukocyte trafficking into sites of intestinal inflammation. The excellent tolerability and safety profile of CCX282-B offers encouraging evidence for clinical benefit in Crohn's disease.

Severine Vermiere (second from the left), Belgium, member of ECCO:s Scientific Committee, were one of the members of the team that presented "The Best of UEGW 2006" at DDW. Each member had scanned the programme in Berlin for "hot topics" to be presented in this American Gastroenterological Association Institute – UEGF joint session in Washington. (Photo: Lagniappe Studio)

The rosiglitazone story: Anti-diabetic drug for active ulcerative colitis?

Aminosalicylates are first-line treatment for mild-to-moderate ulcerative colitis (UC). However, some patients may not respond to or are intolerant to aminosalicylates. In a late breaking abstract Lewis and collaborators presented work that has suggested that rosiglitazone (Avandia), an anti-diabetic drug, may be an effective second-line therapy for UC Gastroenterology 2007;132: (Late-breaking abstract 639a). Rosiglitazone belongs to a new class of drugs, thiazolidinedione ligands, that are peroxisome proliferator-activated receptor-gamma subtype ligands (PPAR-gamma). It has been used for the treatment of diabetes mellitus and recently controversy has been arisen regarding its potential association to risk for myocardial infarction. In the Lewis et al multicenter study 105 UC patients with mild-to-moderate UC were randomized in a double-blind fashion to oral rosiglitazone (4 mg bid) or placebo for 12 weeks. The primary endpoint of the study was at least a two-point reduction on the Disease Activity Index (DAI). Secondary endpoints were a) decrease in DAI score ≥3; b) clinical remission, defined as a DAI ≤2 at the end of the study), and c) endoscopic remission defined as a DAI ≤2 and a normal mucosa at the end of the study. At the end of the treatment, nearly half of rosiglitazone-treated patients (44%) compared to approximately one-fourth of placebo-treated patients (23%) achieved clinical remission (p<0.03). Furthermore, 37% of rosiglitazone-treated compared with 13% of placebo-treated patients had a decrease in DAI score of ≤3 (p<0.01). Finally, clinical remission was achieved in 17% of rosiglitazone-treated patients but only in 2% of placebo-treated patients (p<0.001). The response to treatment was rather rapid and evident from week 4 of the trial and was accompanied by a statistically improved quality of life of actively treated patients. The safety profile was acceptable and no myocardial infarctions or any other significant cardiovascular complications were noted. Some patients developed peripheral oedema, which is expected with this class of medicines. Therefore, rosiglitazone may be an effective second-line therapy for patients with active UC and especially those who are intolerant of of refractory to treatment with oral aminosalicylates.

GERASSIMOS J. MANTZARIS

Report from Young ECCO (YECCO)

On March 1st 2007, during the ECCO Congress, YECCO met for their second plenary meeting. About sixty young clinicians and investigators joined the assembly.

Furthermore, Prof Gassull (President of ECCO), Prof Vucelic (Chairman of EduCom), Prof Hommes (Chairman of SciCom), Prof Travis and Reinisch (members of ECCO SciCom) joined the meeting too. We had the great opportunity to present our proposals and our ideas to the main ECCO representatives. During the debate, it was clear that a dialogue between YECCO and ECCO was necessary to officially include our group into the ECCO statutes.

> “Some days later, Prof. Gassull wrote a letter to our group announcing that YECCO has been officially included in the ECCO statutes

Meeting in Amsterdam

With this aim, a further meeting between Prof Hommes, Prof Vermeire, Marc Ferrante and me took place in Amsterdam, on April 3rd. We discussed about membership and structure of the group, the possibility for one YECCO representative to join an ECCO Committee, how to propose and manage YECCO activities (in particular exchange programs, scientific projects and workshops). The discussion was very positive and I was invited to present all the proposals during the SciCom meeting in Vienna.

YECCO proposals

On July 4, I had the honour to present our proposals to the ECCO Scientific Committee. The following topics were discussed:

- All YECCO members should become ECCO member with a reduction of the membership fee (25%);
- Possibility for one YECCO member to become ECCO SciCom member;
- Possibility to apply for ECCO fellowship, ECCO grants and Travel Grants
- Possibility to organize activities especially addressed and driven by YECCO members (scientific projects, YECCO workshops);
- Possibility to co-chair scientific sessions during the ECCO Congress;
- Possibility to participate in the organization of the ECCO IBD Course every year;
- Official acknowledgment of YECCO representatives (Chairman and Deputy Chair);
- Possibility to meet twice a year in a plenary meeting;
- Proposals for travel grants, YECCO driven scientific projects and YECCO workshops.

All these topics were discussed with the members of SciCom in order to find an agreement. The discussion was very positive and the kind support and suggestions by Prof Travis, Prof Vermeire and the other SciCom members, helped me to amend our proposals.

Official inclusion

On July 5, the Governing Board dedicated a large part of their meeting to YECCO. Some days later, Prof. Gassull wrote a letter to our group announcing that YECCO **has been officially included in the ECCO statutes**, in the following way:

- Young ECCO should incorporate all ECCO members under 35 years of age, with a reduced membership fee.
- Young ECCO group will have a “Chair” and a “Deputy Chair”, both elected by all ECCO members under 35, that will transmit all inputs generated to the Governing Board.
- The Young ECCO group will have one member in the Scientific Committee and one in the Educational Committee, elected under the same conditions as the other members. All ECCO members under 35 can apply to these positions.
- Young ECCO members will be active during the ECCO IBD Course and in ECCO Congress.
- The YECCO members can apply for fellowship, grants and travel grants (you can find detailed information at **www.ecco-ibd.org**)
- YECCO members can propose scientific projects following the standard procedures decided by the SciCom.

YECCO representation

According with this new status, Silvio Danese has been elected as member of SciCom and he will be the YECCO representative in this committee. There will be a call for a EduCom representative in the near future. ECCO also approved our proposals for travel grants and, at the moment, we are working with ECCO to start YECCO workshops.

For more information concerning YECCO, please send an email to **youngecco@yahoo.com**

GIONATA FIORINO, MD
Chair of Young ECCO

Inflammatory Bowel Diseases 2008

Thursday, February 28, 2008

11:45 –12:45		**Satellite Symposium**
13:00 – 13:10		**Welcome by Miquel Gassull and Jean-Frédéric Colombel**
13:10 –17:00		**Pathogenesis of IBD: What's New and What's the Relevance to Clinical Practice?**
13:10 – 13:55	*Tandem Talk*	New Discoveries in IBD Genetics and insights into Therapeutic Development
13:55 –14:40	*Tandem Talk*	Of Mice and Men: Relevance of Animal Studies to Human Research
14:40 – 14:55	*Oral presentation*	Best Abstract 1
14:55 – 15:10	*Oral presentation*	Best Abstract 2
15:10 –15:30	*Lecture*	Defensins: What's their Role in Crohn's Disease?
15:30 –16:00		Coffee break
16:00 –16:30		**Pathogenesis of IBD: What's New and What's the Relevance to Clinical Practice?**
16:00 –16:30	*Lecture*	T-Cell Co-stimulation and Therapeutic Implications
16:30 –16:45	*Oral presentation*	Best Abstract 3
16:45 –17:00	*Oral presentation*	Best Abstract 4
17:05 –18:05		Satellite Symposium
20:30		**Welcome Reception**

Friday, February 29, 2008

07:15 –08:15		**Satellite Symposium**
08:30 –12:00		**Live Endoscopy: management of IBD**
10:00 –10:30		Coffee break
12:00 –12:30	*Lecture*	**IBD-related Cancer**
12:30 –14:00		Lunch and poster viewing
14:00 –17:00		Pathology, Radiology and Surgery in Adult and Paediatric IBD: What the Gastroenterologist Needs to Know
14:00 –17:00	*Panel discussion*	
14:00 –14:30	*Case presentation*	Longstanding UC with Dysplasia
14:30 –15:00	*Case presentation*	Refractory Pouchitis
15:00 –15:30	*Case presentation*	Extensive Small Bowel in Crohn's
15:30 –16:00		Coffee break
		ECCO Fellowships & Grants
16:00 – 16:15	*Oral presentation*	Report from 2007 ECCO Fellowship
16:15 –16:35	*Oral presentation*	Announcement of the 2008 ECCO Fellowships & Grants
16:35 –16:55	*Lecture*	The History of Severe Colitis
17:00 –18:00	*Satellite Symposium*	
		ECCO IBD-Party in Exhibition Hall

Saturday, March 1, 2008

07:25 –08:25		**Satellite Symposium**
08:30 –10:30		**Risks Associated with IBD**
08:30 –09:00	*Lecture*	Malignancy and Lymphoma in IBD
09:00 –09:15	*Oral presentation*	Best Abstract 5
09:15 –09:30	*Oral presentation*	Best Abstract 6
09:30 –10:00	*Lecture*	Opportunistic Infections in IBD, Diagnosis and Prevention
10:00 – 10:15	*Oral presentation*	Best Abstract 7
10:15 –10:30	*Oral presentation*	Best Abstract 8
10:30 –11:00		Coffee break
11:00 –13:00		**Management of IBD**
11:00 – 11:10	*Case presentation*	Complex Fistulizing Crohn's Disease
11:10 – 11:30	*Lecture*	The Evaluation of Fistulizing Perianal Crohn's Disease
11:30 – 11:50	*Lecture*	The Combined Management of Fistulizing Perianal Crohn's Disease
11:50 –12:05	*Oral presentation*	Best Abstract 9
12:05 –12:20	*Oral presentation*	Best Abstract 10
12:20 –12:50	*ECCO Lecture*	Flexible Therapy in IBD: Is It Possible?
12:50 –13:00		Concluding remarks

IBD CONGRESSES 2007/2008

Congress	Date	Venue	Further information
International			
European Society of Coloproctology (ESCP) Second Scientific and Annual General Meeting	26–29th September 2007	Malta	www.escp.eu.com/malta/index.php
Internal Medicine: Focus on Gastroenterology	17–24th of October, 2007	Fort Lauderdale, FL, United States	sandra@continuingeducation.net
Case Based Approach to the Management of Inflammatory Bowel Disease	3–4th of November, 2007	San Francisco, CA, United States	info@ocme.ucsf.edu
Update on Digestive Diseases for Physicians and Surgeons 2007	9th November, 2007	Toronto, Canada	ce.med@utoronto.ca
Inflammatory Bowel Disease: State of the Art for the Practicing Clinician	16th of November, 2007	Boston, United States	hms-cme@hms.harvard.edu
New Zealand Society of Gastroenterology Annual Scientific Meeting	21st–23rd of November, 2007	Christchurch, New Zealand	steven.ding@cdhb.govt.nz
Frontiers in Intestinal and Colorectal Disease Fifth Annual Congress A Multidisciplinary Approach	28–30th of November 2007	London, UK	www.stmarkshospital.org.uk/Files/St%20Mark's%20Flyer.pdf
2007 CCFA National Research and Clinical Conference – 6th Annual Advances in the Inflammatory Bowel Diseases	7–9th of December, 2007	Miami, Florida, United States	www.advancesinibd.com
4th Annual Winter Course on IBD, Intestinal Failure and Nutrition	6th–9th of March, 2008	Sundance Resort, Utah, United States	www.northwesternevents.com/profile/form/index.cfm?PKformID=0x742613e
Updates in Medicine: Gastroenterology	26th of March– 9th of April, 2008	Osaka/Kyoto, Japan	www.continuingeducation.net
New Advances in Inflammatory Bowel Disease	13th of September, 2008	San Diego, California, United States	
2008 Gastrointestinal Oncology Conference	25th–27th of September	Arlington, United States	email@isgio.org
ACG 2008: American College of Gastroenterology Annual Scienitfic Meeting and Postgraduate Course	3–6th of October, 2008	Orlando, FL, United States	www.docguide.com/crc.nsf/congresses/
Falk Workshop: Digestive Diseases: State of the Art and Daily Practice	12th of November, 2008	Santiago de Chile, Chile	symposia@falkfoundation.de
Czech Republic & Slovakia			
6th Postgraduate Intensive IBD Course	4–5th of December, 2007	Prague	jelena.vavrova@vfn.cz
France			
15th UEGW	27–31st of October, 2007	Paris, France	www.uegw.org
Inflammatory Bowel Diseases 2008 3rd ECCO Congress	28th of February– 1st March 2008	Lyon, France	www.ecco.ibd.eu
Germany			
Falk 160-162 Gastro-Congress	10–14th of October, 2007	Dresden	www.falkfoundation.com
Hungary			
Falk Symposium 164: Intestinal Disorders	2nd–3rd of May, 2008	Budapest	symposia@falkfoundation.de
Italy			
IBD Congress and Course	14–15th of December, 2007	Milan	maurizio.vecchi@unimi.it
Latvia			
III Latvian Gastroenterology Congress	10th of November, 2007	Riga	http://www.kongresu-nams.lv
The Netherlands			
First ICC (Initiative on Crohns and Colitis) symposium	26th of September, 2007	Amersfoort	r.vd.hoeven@tramedico.nl
Autumn National Congress for Gastroenterology	4–5th of October, 2007	Veldhoven	secretariaat@nvge.nl
Norway			
Ahus symposium 2007 "Colorectal disease, inflammation and cancer"	11–12th of October 2007	Oslo	e.e.westgaard@medisin.uio.no
United Kingdom			
Recent Advances in Inflammatory Bowel Disease	15th–16th of October 2007	London, United Kingdom	www.mahealthcareevents.co.uk/cgi-bin/go.pl/conferences/detail.html?conference_uid=23

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