

EFCCA MAGAZINE



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Invisible Body Disabilities Project

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Promising results from study on complex perianal fistulas in Crohn's disease

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Invisible Body Disabilities Project

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EDITOR'S EYE

Looking ahead



It was six years ago at this same time of the year – the summer was over and autumn was just setting in – that I started experiencing the first symptoms of my disease. Symptoms I didn't know my body can experience up to this moment, symptoms I wasn't able to put into words at times, symptoms that showed me the long journey I was about to depart on – a journey that catches you by surprise and offers you the challenge of a lifetime.

It was back then - during my first time hospitalization – 26 years old and equipped with zero knowledge on who Dr. Crohn was and what the acronyms IBD or UC stand for, that I found myself sitting in the hallway of the gastroenterology department one late evening reflecting about the future and asking myself “How will the disease impact my life?”.

And it did impact on my life but in a rather unexpected way. I started reading and educating myself on the disease, learning about patients' rights, patient organizations, what their role is and how I can make a contribution to the cause. One thing led to another and in 2012 I established the IBD patient association in my home country. Soon afterwards I started meeting fellow IBD patients from other countries in events organized by EFCCA and I gradually got more and more involved in EFCCA-related projects and activities realizing how important EFCCA is for patients in and outside of Europe. I chose to embrace Crohn and started asking myself instead: “How can I impact the disease that affects our lives?”

Six years after these first IBD symptoms I was given the great honor and even greater responsibility to become the chairman of EFCCA, the association whose mission is to improve the life of people living with IBD in Europe and beyond.

So much for looking back and reflecting. It is time to roll up our sleeves and get down to work.

A lot has happened in the past few years – EFCCA has become even more professional and has currently a team of highly experienced, qualified and dedicated staff. The EFCCA family is growing each year and EFCCA has been recognized as a key stakeholder when it comes to IBD topics in Europe. Having said that, with the ever-increasing number of IBD patients along with the various debates on safety issues and new treatments, EFCCA needs to strengthen even greater its prominent role and remain at the forefront in the fight against IBD.

Below I'd like to share with you the 4 priority areas EFCCA will focus on its agenda in the upcoming period in order to successfully face the challenges of the ever-changing environment:

1. Adding value to members

The various projects and initiatives will keep on being EFCCA's core instrument in pursuit of its mission. The World IBD campaign and the EFCCA/ECCO Patient Guidelines are such two excellent examples of

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these efforts. We will strive to work on projects that are of genuine interest to our members and can make a difference.

2. Patients Safety

It is the goal that EFCCA becomes a reference point for new drugs and monitoring for any safety-related issues that may arise. For that reason, the collaborations with the EU institutions, EMA and ECCO have utmost priority. This naturally implies that EFCCA ensures the same level of transparency and profits from independent medical expertise on these topics. Therefore, an accompanying goal is the establishment of a Scientific Board within EFCCA, which is made up by IBD experts with impeccable reputation.

3. Collaboration with External Parties

We are all aware that IBD knows no borders. Thus the door of EFCCA needs to be open to other patient organizations also trying to fight these diseases. The strategic partnerships established with the physicians' organizations focused on IBD (ECCO & UEG) need to be maintained and further strengthened. EFCCA should also aim at maintaining its existing role in various EU-policy discussion forums.

4. Organizational matters

EFCCA will put even greater effort into maintaining close relationship with its member organizations. Only in collaboration with its members can EFCCA add the value and match the expectations its members have. With the ever-growing EFCCA family and the general tendency towards project-based financing, the workload has inevitably increased in the past few years. In order to be able to face this, the EFCCA staff needs to be aligned accordingly.

An overarching goal is to make sure that EFCCA remains sustainable and independent on the long run. In order to achieve this reform in the financing mechanisms and search of alternative sources of financing are required to be implemented. Fundraising campaigns, EU co-financed projects or grants are just a few of the options we have to continue exploring.

I have started this editorial with my personal story. I am sure each patient with IBD has its own. Some stories mentioned in this edition are quite positive ones! But I am also sure that many of yours or the ones of the other 5 million people living with IBD throughout the world are not so!

Let's try to bring theirs stories also to a happy end! Together! I am sure we can!

United We Stand!



Martin Kojinkov, EFCCA chairman

New EFCCA leadership

The 26th Annual General Meeting of EFCCA took place in Brussels from 27-28 May 2016. It gathered over 40 delegates for one and a half days of busy work and exchange of information and saw the election of a new EFCCA chairman.



Outgoing EFCCA chairman, Marco Greco, congratulating Martin Kojinkov as new leader of EFCCA

Martin Kojinkov from Bulgaria has become the new leader of EFCCA following an earlier announcement by former EFCCA chairman, Marco Greco, that he would no longer stand for elections due to family and work commitments. After careful consideration the EFCCA board recommended Martin Kojinkov to fill this position and EFCCA delegates voted for him unanimously during the General Meeting.

Marko Perovic from the Serbian IBD association has also been elected as a new board member and subsequently been appointed as treasurer of EFCCA. The new EFCCA Executive Board is

therefore composed of the following delegates: Natasa Theodosiou (Cyprus), Ciara Drohan (Ireland), Martin Kojinkov, EFCCA chairperson, Marko Perovic, Treasurer, Salvo Leone Vice-President, Eva Björnsdottir (Norway) and Fergal Troy, EFCCA Youth Group.

In addition to the dealing with the institutional work and activities, delegates of the GA also listened to a presentation made by Marek Lichota from **Apetitie for Life** about artificial nutrition, a subject of particular interest for people with IBD. The presentation was followed by a lively debate and exchange of ideas.

This year's General Meeting also welcomed the Turkish Association, İnflamatuvar Bağrsak Hastaları Dayanımı Yardımlasma Dernei (IBHDYD), as new EFCCA member bringing our membership to a total of 33 patient associations. We also had the pleasure to meet Janek Kapper from the Estonian IBD association who joined the meeting as observer and is applying for EFCCA membership next year. The Crohn's and Colitis Foundation of Israel (CCFI) has been elected from associate member to full member status.

The newly elected EFCCA board from left to right: Natasa Theodosiou, Ciara Drohan, Martin Kojinkov, Marco Greco (outgoing chairperson), Marko Perovic, Salvo Leone and Luisa Avedano, (EFCCA CEO). Absent: Eva Björnsdóttir, Fergal Troy.



During the gala dinner, the new chairman and EFCCA CEO, Luisa Avedano, took the opportunity to thank Marco Greco on behalf of the EFCCA board for his commitment and dedication to EFCCA and presented him with a commemorative gift for his work done. Many of the delegates stayed on after the General Meeting to support the purple EFCCA team at the Brussels 20 km race as part of our World IBD Day celebrations. See next article.

The Turkish IBD association, IBHDYD, joins EFCCA. Here with some board members. From left to right: Martin Kojinkov, Salvo Leone, Filiz Dinc, Metin Dinc, Natasa Theodosiou and Yiangos Yiangou.



EFCCA delegates during the morning session of the Annual General Meeting, Brussels, May 2016.



Against all odds

The EFCCA purple team joins 20 km Brussels race in order to raise awareness about Crohn's disease and Ulcerative Colitis.

For a third year running, EFCCA has organized a purple team made up of keen runners with IBD, IBD physicians and researchers, industry representatives as well as family members and supporters to run the 20 km Brussels race which took place on Sunday, 29 May 2016. The team of around 20 runners gathered together with supporters and EFCCA delegates at the park Cinquantaire getting ready for this challenging race across the area around the EU institutions. A grey morning got onlookers a bit worried but many of the runners were actually grateful of the mild rain that refreshed them during the race which saw a total participation of over 30 000 runners.

Of the EFCCA team the first few runners that met the supporters at the finishing line included Diogo

Barros from Portugal, a group of 3 IBD physicians from Belgium and Rudi Breitenberger from Austria. But of course we were proud of each and every one of our runners.

Some runners afterwards recounted how they were ready to throw the towel during the race but then persisted as they wanted to support our cause and show that even with a chronic disease it's possible to lead an active life. What a tremendous achievement and what a great atmosphere for all involved. Thanks to all our runners and supporters!!

This initiative forms part of EFCCA's local World IBD Day activities alongside its global campaign.



Digestive Health and Children

On May 2016 the first UEG Digestive Health Month took place, which aimed to raise awareness on digestive health conditions in Europe and to highlight the innovation on treatment and prevention of related diseases. Among the initiatives, a two-days event and exhibition “Digestive Health and Children” have been organized in the European Parliament on May 31 and June 1, 2016.

The initiatives, supported by EFCCA, ECCO, InsideLink, DCCV (German IBD Association), Crohn-RCUH (French-speaking Belgian IBD Association), CCV (Flemish-speaking Belgian IBD Association) and ESPGHAN (the European Society for Paediatric Gastroenterology, Hepatology and Nutrition), was launched with a debate hosted by Michèle Rivasi, French MEP and Vice Chair of the Greens/European Free Alliance of the European Parliament.

She moderated a policy discussion on trends in digestive health disease incidence in children, highlighting the importance of three key points to be improved: prevention, research and training of healthcare providers.

More than 30 stakeholders, including representatives from the European Parliament, the European Commission, from patient associations and healthcare professionals, took part in a debate about challenges related to Pediatric Inflammatory Bowel Disease (PIBD) treatment and care, and about the gaps in European research and legislation.

Prof. Frank Hulstaert from the Belgian Health Care Knowledge Centre, highlighted that the results from all randomized trials’ should be published and publicly available. Dr Peter Lakatos, Professor of Medicine at Semmelweis University, showcased instances of use of nutrition for therapy, as a symptomatic relief and as a method of healing bowel disorders.

Professor Séverine Vermeire, from Hospital University of Leuven, ECCO past-President, highlighted the importance of specialized Inflammatory Bowel Disease (IBD) nurses, emphasizing that they have an important role in



Luisa Avedano, EFCCA CEO, and Cornelia Sander, DCCV at the exhibition area of “Digestive Health and Children”

communicating patient’s concerns and providing personalized care.

Luisa Avedano, EFCCA CEO, made an intervention during the panel discussion stressing the need for “better transitional support into adulthood for IBD sufferers across Europe”. After the debate, MEP Michèle Rivasi and Thierry Ponchon, Chair UEG Public Affairs Committee, officially opened the exhibition “Digestive Health and Children” in the European Parliament. Patients Associations and Health Organizations were present with their information booths, displaying their materials and explaining to the audience the activities they carry on.

The presentation slides of the event and the full report “Paediatric Digestive Health Across Europe – Early Nutrition, Liver Disease and Inflammatory Bowel Disease”, which explores the opinion of a number of pediatric GI specialists, are available on the UEG website.

World IBD Day 2016

Over 120 landmarks worldwide joined our global World IBD Day on 19 May to raise awareness about Crohn's disease and Ulcerative Colitis, collectively known as IBD.

Famous landmarks from 28 countries on 5 continents were lit in purple that evening to show their support for the over 5 million people who live with Crohn's disease and ulcerative colitis.

The campaign was led by EFCCA together with its national IBD patient associations and many other IBD sister organisations and IBD activists from around the world.

"It was amazing to see so many cities and countries coming together in our efforts to raise awareness for these devastating diseases," says Martin Kojinkov, Chairperson of the European Federation of Crohn's & Ulcerative Colitis Associations (EFCCA). "On 19 May we literally turned the world purple and

highlighted the challenges with which over 5 million people are courageously coping every day."

Many of the IBD patient organisations organized information events at these famous landmarks and actively engaged with the public and media.

We would like to thank all our colleagues and friends from around the world for making this campaign such a success.

In our Members Section you will find some local events that took place, if you would like to have a full overview please visit the World IBD Day website at: www.worldibdday.org

World IBD Day 2016

#worldibdday2016
#unitedwestand2016



www.worldibdday.org

European Pain Day

EFCCA Executive Board member, Ciara Drohan, and EFCCA Communications and International Relations Manager, Isabella Haaf, participated in the European Pain Day workshop which took place on 13 September 2016 in Aachen, Germany.

The meeting brought together representatives from the patient community, the medical community and researchers from the pharmaceutical industry. Physicians and patients from various disease groups presented their scientific and personal experience as concerns pain followed by discussions aimed at defining unmet needs.

EFCCA Secretary, Ciara Drohan, talked about her own experience of chronic pain and IBD as well as presenting the work of EFCCA. Although the subject of this meeting was a very difficult one, the day was very positive as it allowed for an honest exchange of information and brought first hand experience to those that are working on research and development for pain therapies. It was also a good opportunity to make new contacts and discuss possible collaboration.



Ciara Drohan, EFCCA Secretary, at the European Pain Day

Fighting IBD

The Israeli Foundation for Crohn's Disease and Ulcerative Colitis (CCFI) organized the first high-tech conference FIGHTING IBD on 7 September 2016 in Tel Aviv, Israel. The aim of the conference was to promote the development of medical equipment, diagnostic tools, medications, and therapeutic methods directed at enhancing the well-being of IBD patients in Israel.

The conference brought together more than 120 participants and evolved around three key topics: IBD focused startups, commercially applicable IBD medical research and development, and IBD financing, thus propelling technological developments for the benefit of IBD patients.

EFCCA Treasurer, Marko Perovic, welcomed participants at the conference together with Marco Greco the Chair of the European Patients Forum. FIGHTING IBD is in itself a pioneering high-tech event, a milestone focused on IBD-related

interdisciplinary technologies, including microbiota applied projects, molecular biology developments, clinically and commercially-applicable medical and pharmaceutical research, diagnostic kits, patient-oriented cellular applications and many more. It was also a meeting point for a community of doctors, investors, patient associations and IBD-fighting innovators such as start-ups and small and medium enterprises to present a number of innovations aimed at closing the gaps in cooperation and to facilitating synergies between the interdisciplinary branches, united to fight IBD.



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Biosimilar Medicines Group Conference

The 14th Annual Biosimilar Medicines Group Conference took place in London from 28-29 April 2016. The conference is an annual gathering of the world's biosimilars experts and encourages debate amongst all stakeholders on the most relevant biosimilar topics, increases communication and interaction with international key regulators and stakeholders, the leading companies in the biosimilar medicines space and hundreds of delegates from all over the world.

Although the conference is primarily aimed at industries, there were many representatives from government agencies, regulator authorities, patient representatives as well as bank and insurance companies (as in many countries financing of such medicines is done through private insurance).

Bjørn Gulbrandsen from the Norwegian IBD patient association, LMF, attended this meeting to ensure that the patients' perspective was heard in the discussions. He participated in a panel discussion alongside Fraser Cummings, UK gastroenterologist, Klaus Martin, German representative of Polpharma Biologics, Carol Lynch, representative of Sandoz and Steinar Madsen, Medical Director of the Norwegian Medicines Agency.

Gulbrandsen emphasized the importance of information to patients from multiple source. Information from patient associations are often credible for patients and their members. He suggested that the cooperation with the patient organizations can be improved in many countries.

This particular concerns questions around switching from generic to biosimilars where information from reliable sources is essential to address patients' concerns.

Gulbrandsen talked about his experience in Norway, where the patient association has fought a battle to ensure that switching should be decided by the doctor and not at the pharmacy level and that automatic switching does not take place.

Talking about the Nor Switch study, Gulbrandsen

stressed the good practise of involving the patient association right from the start even before the study even was approved, allowing the patient association to make suggestions to the letters and information that was given to the patients.

To conclude he pointed out that there are major differences between countries in Europe with regard to how switching is implemented and how patient associations are being involved. As the patient is actually the one that has the drug injected in his/her body, it's not enough that doctors agree among themselves but also take into account the patient's opinions when considering a switch from generic to Biosimilars.

ABOUT THE BIOSIMILAR MEDICINES GROUP (formerly European Biosimilars Group - EBG)

The Biosimilar Medicines Group (formerly European Biosimilars Group - EBG), a sector group of Medicines for Europe (formerly EGA), represents the leading companies in the biosimilar medicines space. More info <http://www.egaevents.org/bios/>



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- Shire is determined to support patient advocacy groups, provide research funding and education, as well as encouraging a regulatory environment that supports innovation and value.
- Shire is committed to providing new treatment options and working in partnership with physicians that make a real difference in the lives of patients with GI diseases.



European Youth Group Meeting (EYM)

This year the EFCCA Youth Group Meeting (EYM) took place from 21st to 24th July 2016 in Ljubljana, Slovenia and was organized by the Slovenian IBD association, KVCB in collaboration with the EFCCA Youth Group (EYG) and EFCCA. It gathered 32 young people with IBD from 14 European countries and this year also representatives from the New Zealand IBD association and the Israeli Crohn's and Colitis Foundation.

The EYM takes place once a year in one of the EFCCA member countries and is educational, interactive and also fun at the same time. It is an excellent opportunity to learn about the different associations in Europe, especially the youth groups, to discuss ideas for the future and also to simply

meet old friends and make new ones. As usual, this year's EYM included some fun sporting events, a visit around town and a gala dinner.

During the meetings we discuss various topics that are relevant to youngsters with IBD and, as



seen in previous issues of the EFCCA Magazines, we try to “Break down taboos” which come with daily life and IBD.

In the following two articles we have decided to share with you the experiences of two people who attended the EYM: Bastien, a representative of the French IBD association and first time attendee and and Katleen from Belgium who has already been to three meetings.

Through these stories we hope to raise awareness and make people understand the difficulties and challenges we face and go through but also the positives the youth organisations are doing. We want to change and we want the world to find a cure. So if we can be a part of that - why stop? This is why I encourage you all to read these stories, remember them and tell them to your friends, relatives, doctors and whoever is willing to hear your story.

The bonus of having IBD

by Bastien, a first time attendee to the EYM

A bonus of IBD (Crohn’s disease or ulcerative colitis), is that you develop some good qualities. You become more open minded and supportive. You put things into perspective and learn to enjoy the small pleasures of life.

Since last September I have volunteered in the French association dealing with IBD, named AFA (François Aupetit association). I am especially active in the youth group. Within this context I had the opportunity to participate in the EFCCA Youth Meeting, which gather youth groups from European IBD associations.

It was the first time I went to this kind of meeting. To be honest, I did not know what to expect. I said to myself “just go and see what happens”. I had no idea of what the meeting would give to me and you cannot imagine my big surprise.

During these three days, I met amazing people from several countries. Everyone was friendly and enthusiastic and they immediately made me feel comfortable. It was like everyone gave energy to each other.

But what do we do at the EYM? The aim of this meeting is to give the opportunity for all the



Bastien (left) with Fergal Troy, EFCCA Youth Group leader

participants and delegates to meet one another, exchange our experiences and know-how. It is a wonderful way to share the success of activities organised by all IBD associations and come back with great ideas for the year ahead.

I will never forget this meeting and the people I met. I hope to see them again next year, to remember the great moments we share together and build new memories. I also hope to meet new people to enlarge what looks like a new family, my IBD family.

Learning from experience

by Katleen, a regular EYM attendee

My name is Katleen from Belgium. I'm 24. This was my third EYM as representative of the young patients from my country. My first experience was two years ago, in Dublin. I was asked to represent my association, which until then, didn't have a youth group.

This first meeting let me discover a lot of youth groups so I had many good ideas to create one in my country! They introduced what they had done the year before and what they would do again or not, what succeeded and what failed. I was elected a substitute this time! It made me discover more and more about the EYG and also how EFCCA in general works.

My second experience in Tampere, Finland and my third one in Ljubljana Slovenia taught me a lot too. I could this time announce that we finally built our own youth group thanks to them and present what we had done so far.

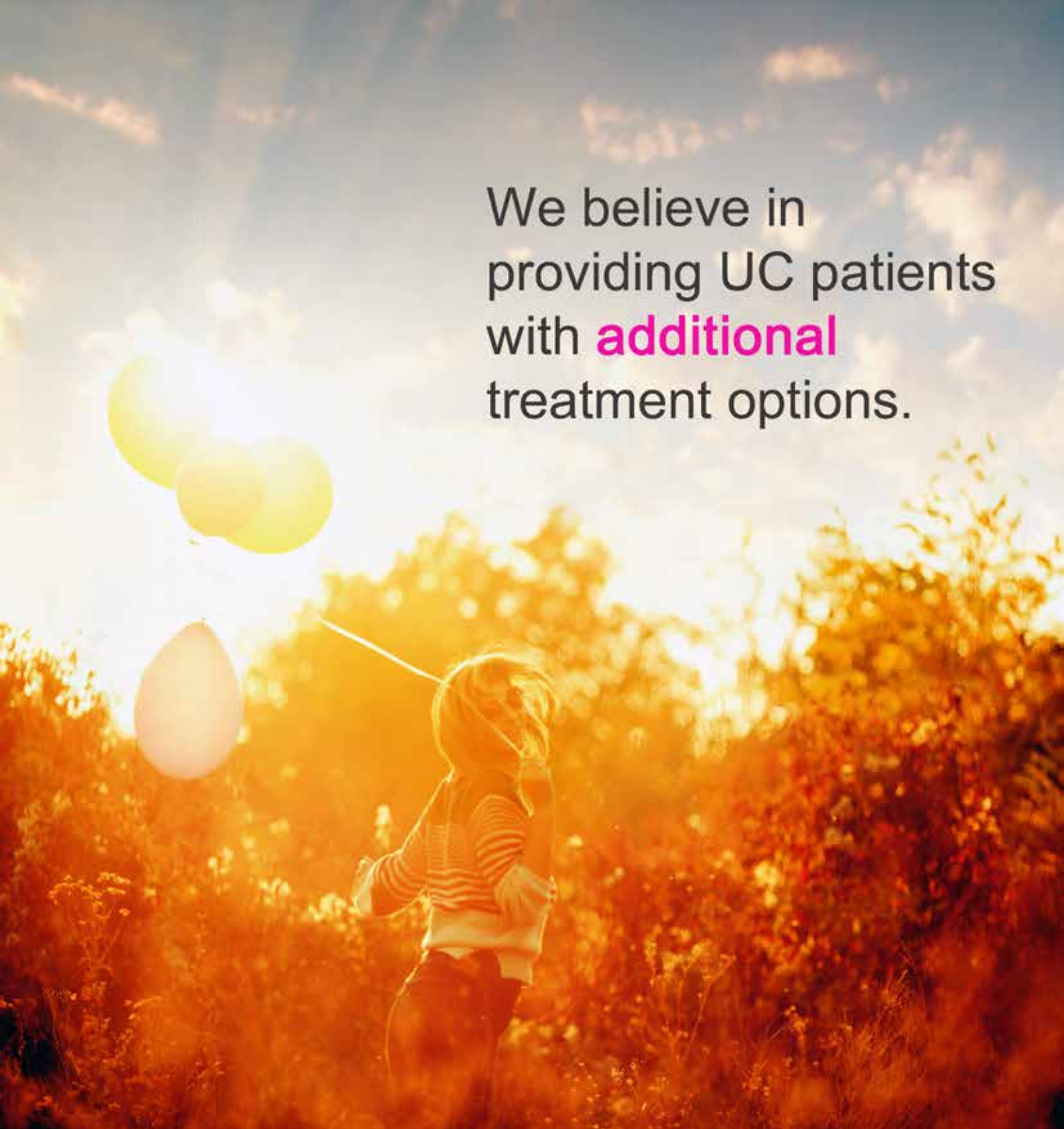
During these weekends we had workshops about interesting facts we all faced in our own countries: how to raise money, how to get young people involved in our association, how to raise awareness, how to use social media...

Each time I have learnt a lot and use this information when I go back home. And it works! When I went to the first EYM we didn't have our own youth group, now we have it and it is growing fast! But more importantly, I met a lot of people from



Katleen (left) with Fergal Troy, EFCCA Youth Group leader

foreign countries and I learnt about them and their conditions. Some of them have become very close friends I know I will have for life.

A child stands in a field of tall, golden-brown grass, holding a string attached to three balloons (two yellow, one white). The scene is bathed in the warm, golden light of a low sun, creating a soft, hazy atmosphere. The sky is a mix of blue and white clouds.

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Nordic Meeting 2016, Stockholm

Over the weekend of 11-12 June, the Nordic meeting 2016 was held in Djurgården, an island in central Stockholm. Representatives from Norway, Iceland, Finland and Sweden participated in the discussions.

Topics that were raised during the meeting included among others short updates of important events in each association, the status of biosimilars in each country, awareness raising activities on World IBD Day, advocacy work, following up on the EFCCA General Assembly 2016 as well as discussions about how to proceed with future work.

In between the meeting, the participants got to visit ABBA The Museum, an interactive exhibition about the Swedish pop group ABBA where their collected works are showcased.

All in all, a very inspiring and satisfying weekend.

Denmark

One disease rarely comes alone – Autoimmune Diseases

This year, the Danish Crohn's and Ulcerative Colitis Association (CCF) attended the People's Political Festival (aka Folkemødet) for the sixth time in a row. Folkemødet is Denmark's political festival situated on the island of Bornholm (south of Sweden). It is a meeting where everyone (the people and Media) can meet the Danish politicians and debate current political issues – or just listen.

CCF's National Chairman, Bente Buus Nielsen and our Treasurer, Inger Graversen, once again represented CCF at "Folkemødet", with our own debate in cooperation with other patient associations (IMID) under the name "De Autoimmune", and by actively participating in many of the other debates.

Our very own debate was about treatment of patients with autoimmune diseases in Denmark. The theme of our debate focused on a more holistic approach to patients with more autoimmune diseases, than just one. Many of our members (20+ percent) have more than one autoimmune disease, and quite a lot of other minor diseases caused by the prior ones. And that can cause problems, when being treated.

If you have IBD you consult one specialist (Gastro), and if you e.g. have Psoriasis you consult

another specialist (Derma). But what if you have both diseases – or more? How do the system cope with this?

Our members with more than one autoimmune disease, have to consult different specialists (one for each disease), and since they do not share clinics, the clinics can be placed all over the country. What is needed, is a more holistic approach to the diseases and their treatment.

A new, and large, patient study regarding this matter, reveals that more than half of all the participants in the study, have never been told about the risk of getting other autoimmune diseases or minor diseases related to them. And the study also shows that having more than one autoimmune disease, strongly affects the possibility of having an active life (job, sports etc.)

as well as being able to get several types of education.

The KORA-report/study was not released at the time of the “Folkemødet”, but has later been released to the media.

Other debates that CCF participated in

Patient council – 3 patients challenge politicians on health issues. Focus on equality in treatment, regardless of where you live.

Relatives – the next patients?:

Relatives sustain mayor pressure, having a family member with a chronic disease. If we are not careful and they don't receive the support they need, they will end up being sick themselves.

Health Care System of the Future – what will you prioritize?

A lively debate on what to have and not have, as a direct result of the financial pressure on the current health system.

Quality in health:

“Challenges and barriers in the Health system – the economy. We need to connect the different sectors. It would be nice to have a team (doctor/nurse) following each patient “(Ulla Astman, Chairman, Health committee Region North). “The patients are leaving the hospitals to early, and that puts pressure on the Communes” (Thomas, KL)

“The treatment procedures should be solved by the Management. The system should be for the patient, and not, as it is now, the patient connecting the system. There should be a mutual and common economy between the different sectors.” (Camilla, Chairman, Danish Patients).

“This debate started in 1983, and we are more or less at the same stage. No one in the system will take responsibility for the patient. Stop discussing it, just do it.” (Andreas, Medical association)

Flush it - find a toilet

Finally, we managed to develop our long anticipated toilet finder app (iPhone, iPad, Android). Economy was the problem, as it usually is, but with a little help from many friends... we made it.

Our wait paid off, and now it is here and the best part of the toilet finder is that we, on behalf of our members, managed to negotiate exclusive toilet-rights with the two largest supermarket chains in Denmark. We can even use the toilets, in the stores with toilets for employees only. So, from the beginning the app was loaded with toilets all over the country.

But, the app has a lot of toilets that everyone can use, and every Dane can not only use the app, but is also encouraged to put new toilets on the map, for the benefit of all users. We hope the new app will make it easier for our members to go out more, and e.g. be able to plan their shopping etc. before leaving home, knowing exactly where to find a toilet – if necessary.

To assist the app, our members also have a membership card to present in various supermarkets.

Michael Koehler, CCF Denmark

CCF membership card



Cyprus

World IBD Challenge

After the announcement of the global activity for the World IBD Day, our action team started thinking which of our buildings could be illuminated. A few rides around the cities at night, were the best way to decide which of the public buildings to choose.

Finding and fitting suitable purple filters, proved to be a real challenge but in the end we made it. The three biggest Municipalities of Cyprus gave us permission to illuminate their City Halls in purple colour. These are Limassol, Nicosia, and Strovolos (adjacent to Nicosia).

In Nicosia, we had a special activity in order to inform about the event and to make our message known through the crowd that gathered and the publicity given. First the purple lights were switched on at Strovolos City Hall and then a group of runners from the most traditional runners' club in Cyprus, started running a 5 Km distance from there to Nicosia

City Hall, holding a purple flame all the way through, thus making the invisible visible for IBD.

Upon their arrival, a short but very successful ceremony took place with speeches from the President of CYCCA, Mr Yiannos Yiangou, and the Vice Mayor of Nicosia, Mrs Eleni Loucaidou, who also switched the purple lights on at this unique old building.

Below a picture of our World IBD Day activities in Cyprus.

Yiannis Antoniadis, CYCCA

Natasa-Revekka Theodosiou, CYCCA



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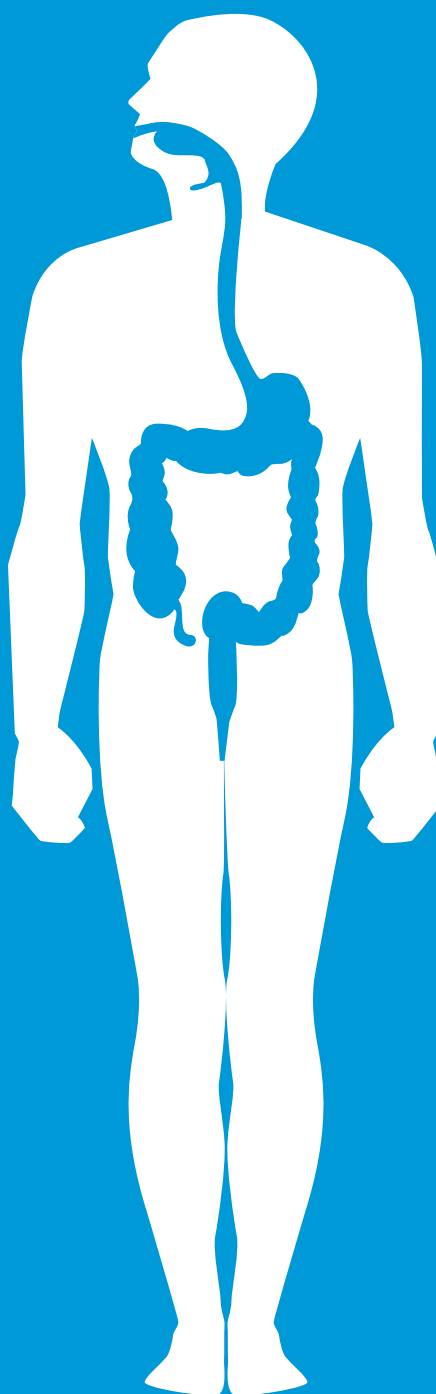
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Poland

Going purple

Warsaw's calling card as well as other monuments and landmarks in several major Polish cities lit-up in purple on May 19th in honor of World IBD Day.

Thousands of residents of Poland's major cities witnessed the largest ever happening of the EFCCA-affiliated Polish Association "J-elita", and many more were able to view the event through traditional and social media.

After dark, several places lit-up in a purple glow:

- the Palace of Culture and Science - the most distinctive building in the center of Warsaw,
- the Town Hall in Rzeszów - the capital of the Podkarpacie region in south-eastern Poland,
- the Town Hall and Branicki Palace - the capital of the Podlasie region in the north-eastern part of the country,
- the Tauron Arena sports hall, and the pedestrian and cyclist footbridge on the Vistula river in Cracow,
- the stadium in Wrocław - the capital of the Lower Silesia region in south-western Poland,
- the overpass at the Galeria Baltycka shopping center in Gdansk by the Polish seaside,
- the Radisson Blue Hotel in Szczecin - the capital of the West Pomeranian region in the north-west of Poland, near the border with Germany.

Surprised passers-by eagerly took photos with the landmarks; IBD patients proudly posed for pictures as well.

"In this symbolic way we wanted to show Poles that there are patients with IBD living among us. It is often our neighbors, or friends from school and work, but we're unaware, because they are often ashamed to talk about their illness, due to symptoms like diarrhea and abdominal pain, associated with the disease," says Agnieszka Golebiewska, president of the "J-elita" Association. "We also wanted to get the attention of decision-makers, to finally encourage them to start helping patients and facilitate their access to biological therapy."



On the eve of World IBD Day in Warsaw, a press conference was held, led by the popular Polish TV journalist Agata Mlynarska, who wrote a book about her battle with the disease. The conference was then reported by several journals, and the nationwide TV station, Polsat, showed a news coverage clip on the problems of patients.

During the meeting Malgorzata Mossakowska, the founder of "J-elita", introduced the Association, and Anita Michalik, a member of "J-elita" from Cracow, drew attention to the tragic situation of sick children in relation to the Ministry of Health limiting young

patients' access to biological therapy. The situation was also criticized by Prof Piotr Albrecht of the Medical University of Warsaw, who pointed out that when it comes to biological therapies for children, Poland lags behind several European countries, including Slovakia, Estonia and Lithuania.

The problem is serious, because, as Prof Grazyna Rydzewska, Head of the Department of Gastroenterology, which houses the country's only subdivision for patients with IBD in Warsaw, estimates in a recent report, approximately 100 thousand people in Poland struggle with IBD: 15-20 thousand suffer from Crohn's disease and 80 thousand have ulcerative colitis. Unfortunately, every fourth patient is a child.

The illumination and the conference were not the only actions "J-elita" undertook in honor of IBD Day. On May 19th the association's activists visited gastrological wards in several cities, and local branches



throughout the country organized open meetings and picnics. They also held toilet-paper battles, which have become a beloved tradition among attendees.

The purpose of these meetings is always the same: to bring a smile to the faces of patients and their relatives, and to draw attention to the problems of people suffering from IBD and their families.



UK

World IBD Day Nurse Campaign

In the UK, one in three patients with Inflammatory Bowel Disease (IBD) do not have access to a specialist nurse, but the IBD Nursing Campaign launched by Crohn's and Colitis UK on World IBD Day on 19 May is aiming to change this.

In the UK, one in three patients with Inflammatory Bowel Disease (IBD) do not have access to a specialist nurse, but the IBD Nursing Campaign launched by Crohn's and Colitis UK on World IBD Day on 19 May is aiming to change this.

IBD nurses are crucial to improving the quality of life for patients, yet six out of 10 IBD services in hospitals do not currently meet the recommended standard for the number of specialist nurses necessary to deliver the right level of service and support.

A unique email template on the Crohn's and Colitis UK website enables patients, their family and friends to email the Chief Executive of their local hospital with a personalised message and tell them how important specialist IBD nurses are.

Isobel Mason, Nurse Consultant and IBD Nursing Development Manager at Crohn's and Colitis UK, said "It seems inconceivable these roles need justifying when there is so much evidence of the contribution specialist nurses bring to patient care. More than 100,000 people are not being offered the health support they deserve or is recommended, and many more are struggling to be seen by a service that is under pressure."

The campaign will see the charity working with gastroenterologists and IBD nurses to provide new resources that can facilitate job and business planning for health service development. It is also asking hospital chiefs and IBD teams to work directly with Crohn's and Colitis UK to support the delivery of more IBD nurses locally.

To find out more www.crohnsandcolitis.org.uk/get-involved/world-ibd-day

Research

Almost half a million pounds has been awarded by Crohn's and Colitis UK to six innovative projects that will investigate possible causes of Inflammatory Bowel Disease (IBD). It is hoped that these research awards could pave the way for new treatments and ultimately a cure for Crohn's Disease and Ulcerative Colitis.

Helen Terry, Director of Policy, Research and Public Affairs, said: "We have come a long way in our understanding of IBD, but there is still so much we do not know about these unpredictable, lifelong and potentially life-threatening conditions. These investments into research are critical if we want to improve lives now and ultimately find a cure. We are delighted that we have been able to fund so many innovative projects that we hope will prove groundbreaking in learning more about possible causes and finding new treatments."

Projects set to receive funding in 2016

- King's College London will receive £88,668 to look at pain management, with the aim of developing a new intervention for IBD abdominal pain that will be compared to existing NHS pain-management programmes.

- The University of Edinburgh will receive £8,000 to investigate the role of damaged mitochondria in causing IBD.

- The University of Liverpool will receive £49,579 to develop a potential blood test for Ulcerative Colitis patients to predict how well biological drugs will work, helping clinicians make an informed choice about the best biological drug treatment.

- Leeds University will receive £116,272 to investigate bowel cancer in IBD. The study will look at the number of people with IBD who develop bowel

cancer, the people who are at most risk, and what medications may prevent it.

- The University of Edinburgh will receive £100,089 to look at the role of microRNA in IBD, thereby investigating the possibility of a new blood test to diagnose IBD early and predict how the disease

may progress.

- The University of Cambridge will receive £115,701 to research what switches genes on and off. The study will look at epigenetics in paediatric IBD.

Gemma Briggs; Crohn's and Colitis UK

Romania

World IBD Day: “ Improving quality of life for people with IBD” - Parliament Palace

On 19th of May, the Parliament Palace and several fountains in the square in front of the building have been illuminated in purple and a projection onto the façade of the Parliament showed the message “ Together against IBD - www.aspiir.ro “.

In addition, our association ASPIIR organized the event “Improving quality of life for people with IBD”, celebrating World IBD Day 2016. The event took place in partnership with the Health Commission of the Deputies Chamber of the Parliament.

It was held in the Health Commission's official room and we were joined by doctors, patients, deputies and other representatives in the relevant field such as the vice-president of the Health Commission of the Deputies Chamber- Dr. Horia Cristian; the



state councilor in the Health Department in the presidential administration- Dr.Diana Paun; the state secretary in the Health Ministry- Dr. Corina Pop; the president of the National Authority for the Healthcare Management - Dr. Vasile Cepoi; the representative of the National Society of Family Doctors- Dr. Mihaela Udrescu, Professor Liana Gheorghe, Professor Mircea Diculescu and journalists. The patients talked about the daily problems they are faced with and stressed

their need for early diagnosis and the need for better collaboration with prescribers. The discussion was also focused on the necessity of establishing centers of excellence in inflammatory bowel diseases, which could be approved next year, according to Conf. Dr. Corina Pop, Secretary of State for Health.

Isabella Grosu , president ASPIIR

Norway

Busy autumn ahead

This autumn LMF will be busy with our usual daily activities. Next weekend we are gathering all our board members, local board member teams from around the country, IBD representatives, editorial staff and the administration to our yearly “Development seminar.” The seminar will be held on the outskirts of Oslo.

This year's subject will be patient empowerment. There will be a guest speaker on the subject followed by group activities. There will also be time to socialize with some outdoor activities focusing on team building and then we will enjoy some fine dining in the evening. The weekend is always very much appreciated by our participants.

We will also be working with the Norwegian association for stoma operated – Norilco. In Norway we do not have a regular screening for colon cancer, but the authorities are working on the subject, and both organizations want to try and influence on this matter. We will also start working on a project directed at disabled toilets. Not all disabilities are visible, and we would like the signs for disabled toilets to be changed so that the sign also consists of a standing person. We have seen that the British association are working on a similar subject.

The Norwegian authorities have opened up for online ordering and home delivery of prescription

medicine. We know that our members with severe disease appreciate not having to go to the pharmacy, and being able to get their prescription medicine without leaving their home.

Arne Schatten, LMF CEO, and a gastroenterology specialist have made a new IBD information film for pharmacy employees. He has also attended the yearly IBD nurse meeting and informed on the work LMF do on a daily basis.

A couple of years ago LMF had a project called Dr Facebook where members and other people could send in questions online and get an answer from a specialist. We have now got new funding for a similar project. Four doctors will answer questions sent in by the public and give advice online via a webpage. The service will be launched in the beginning of October.

We wish you all a good and productive autumn.

Hanne Riise, LMF

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Invisible Body Project

Interview with Chiara De Marchi, founder of the Invisible Body Project

Chiara De Marchi is a photographer specialized in children and motherhood photography and her home studio is located in Selvazzano Dentro, in Northern Italy. *Sotto La Stessa Pelle* is the name of her photo exhibition representing fragments of breastfeeding daily life between mother and child, emphasizing the bond between them and trying to normalize it despite of a society always more tyrannical and judicious.



I was diagnosed with Ulcerative Colitis in 2009 and I still remember the doctor was saying: "Of all the diseases you got the most annoying, unfortunately there is still no cure and you will live with it for the rest of your life!".

That day the world fell apart and a part of me stopped living. I was sick, I hated my body with my whole being. I kept on losing weight, eating hardly anything. I looked in the mirror and I saw myself so horrible. I could not find any size of clothes that fitted well. I followed various debilitating treatments with

poor results. I felt pain in every corner of my body. I gave up even two universities and my job because I was unable to follow the lessons. I was depressed for a longtime. I became a burden and a worry for everyone. I cried everyday.

The turning point in my life came after giving birth to my firstborn son, Samuele (now 2 years old). My breastfeeding experience has been difficult. The lack of information and the discrepancy among different medical opinions about drugs, lead me first to suspend breastfeeding and then to restart it after a month.

“Seeing the traces that life leaves in people’s bodies leads to the belief that scars, visible or not, are part of your own being, of the past, of the spoils of war: the obstacles that life puts in front should never be synonymous with shame or prejudice. Education is one of the most powerful tool in the world and my primary purpose is to raise minds awareness and refine respect and understanding for all people and future generations”



Thanks to my son I was born for the second time and also my body. I learned to live with my ulcerated gut, to respect the moments of relapse, to get up stronger than before, to get better for him and for myself. He made me a stronger woman and mother and he gave me the opportunity to express myself through my work as a photographer.

I wanted to bring out my inner conflict, challenging my disease which deprived me of many dreams and that made me run into several walls and doors, to find a way to feel less alone and more strong.

Invisible Body Disabilities project is going to be a book, “Women Fighters”, of black&white photographs that accompany stories, narrations and thoughts of women suffering from inflammatory bowel diseases. A travelling photography exhibition and a multimedia platform, an art website to keep on collecting worldwide stories and powerful images of invisible fighters.

I am still taking volunteers for this first volume. I already have the publishing and distribution in place and thousands photos already taken to edit.



My intention is for this book to be successful so that I can continue on photographing and creating other 'Invisible Body Disabilities' volumes such as people facing fibrosis cystic, women dealing with cancer, endometriosis and beyond.

I have listened and read so many encouraging and amazing stories and met so many strong people facing their daily battle.

Food restrictions, misdiagnosis, blood and mucus, collateral effects due to strong meds, depression and insomnia, incomprehension, hiding because being ashamed of the disease or the ostomy, a mother that told me her daughter was excluded and mocked by some of her classmates. Isolation, so many surgeries, stress, a man that told me he suffers from anxiety and

finds difficulties to go out from home.

Doctors, hospitals, analysis. Another IBD fighter told me she lost lots of hair and she didn't accept her body losing too much weight. Fear, fever, nausea, chronic tiredness. Loneliness and tears. A woman told me she had many other complications, but invisible and people keep on saying she has nothing, all in her mind. Always looking for a toilet and try to explain the urgency. Decisions, frustration, failure. A girl told me she broke up because her partner couldn't handle the situation.

Pain all in one day. Our body records battles and collects them, it remembers raw emotions, but also positive ones, and this is where we must start, accepting ourselves, being aware, showing us unfiltered, without fear and with eyes full of hope and courage. Speaking, sharing our stories, comparing, supporting each others, precious information, new ties of friendship, even living far apart. We need to cultivate that unbreakable bond that is created by sharing, being united by the same desire to fight and rebirth, raise awareness and screaming out the pain to get out from that invisibility that surrounds us.

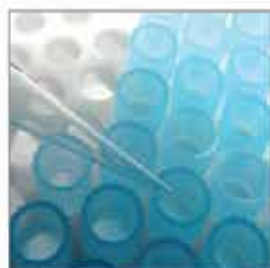
Today has happened to me, tomorrow it could happen to a beloved one, a friend, our son. Being prepared for this battle is extremely important, and so is teaching respect and education to those who know about these pathologies, but even more so to those who are not affected by these realities.

Let's raise up our voices. Together we can do a lot. Together. Thank you for the support and the special bond we are creating!

If you would like to find out more about the Invisible Body Disabilities Project please visit the following links:

www.facebook.com/invisiblebodydisabilities
www.invisiblebodydisabilities.org
www.instagram.com/invisiblebodydisabilities

E-mail: chiara@invisiblebodydisabilities.org



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EFCCA supports educational activities for IBD nurses through the N-ECCO School

The ECCO Nurses Network – N-ECCO – is now an established part of ECCO, the European Crohn's and Colitis Organisation. N-ECCO was created to provide educational opportunities for Inflammatory Bowel Disease (IBD) nurses throughout Europe and to increase networking opportunities for nurses caring for IBD patients to meet and share best practice.

N-ECCO currently counts over 300 members and we are happy about constantly increasing interest in N-ECCO and IBD nurse Membership. In 2010, the N-ECCO Committee successfully introduced a new educational activity for IBD nurses – the N-ECCO School. The N-ECCO School intends to give nurses who might still be in training and have an interest in IBD, the possibility to attend an IBD focused course. This one-day course consists of lectures and workshops and the participants are invited to join the N-ECCO Network Meeting or the N-ECCO Research Forum for their further education in the next year.

Participation at the N-ECCO School is based on nominations which are submitted by the N-ECCO National Representatives and access is only granted to ECCO IBD nurse members. Each ECCO Member Country can nominate 1 nurse for participation (36 places). After the ECCO'15 Congress, the Dietitians

Working Group of ECCO (D-ECCO) and the Nurses Committee of ECCO (N-ECCO) discussed and agreed on the importance of the involvement of dietitians in the care of IBD patients. Therefore, in 2016 the N-ECCO School was opened for dietitians interested in gaining knowledge about the basic aspects of IBD, and 20 places were thus reserved for the participation of dietitians.

The N-ECCO National Representatives are also invited to attend the N-ECCO School to support the participants from their country, with language and translations in particular as many of the nurses attending do not speak English as their first language.

Course Participants:

36 actual participants from 19 different countries (incl. 11 dietitians).

Participants of the 2016 N-ECCO School, Amsterdam. @Copyright ECCO



Course Outcome and Conclusion

With the 7th N-ECCO School, the cooperation between ECCO and EFCCA facilitated an educational programme which will improve the quality of patient care and thus benefit the welfare of patients in IBD.

The support of EFCCA allowed ECCO to offer a travel bursary to those participants who are unable to raise funding for travel and accommodation (as in some countries, industry sponsorship for nurses is prohibited). The EFCCA grant has been divided among those participants without industry sponsorship in the form of reimbursements for accommodation and travel expenses.

All course participants received a printed syllabus with the core slides, educational objectives and summary of each presentation. The nurses and dietitians who attended the school are encouraged to use this syllabus when they return to their hospital and use it as a means of informing and educating their colleagues.

Further, all presentations of the N-ECCO School (subject to speaker authorisation) have been uploaded to the e-CCO Learning platform, which is accessible for all ECCO Members.

Crohn's and Colitis Canada leads way to reduce high, chronic steroid use through PACE network

Crohn's and Colitis Canada with Inflammatory Bowel Disease (IBD) clinics at the Universities of Alberta and Calgary have embarked on a monumental project to reduce high, chronic steroid use among Canadians living with Crohn's and colitis. The project is part of a new, national Promoting Access and Care through Centres of Excellence (PACE) network.

"Three quarters of Crohn's disease and ulcerative colitis patients referred to an IBD specialist are on chronic steroid therapy," explained Dr. Richard Fedorak, University of Alberta PACE lead, gastroenterology professor and interim dean at the University of Alberta's Faculty of Medicine & Dentistry. "Simply put – this is too high. Steroids can have a variety of harmful implications and undesirable side effects on patients, including high blood pressure, increased risk of infection, mood swings and weight gain."

"In the last three years our clinic has tested three new agents, which have been approved for the treatment of IBD as alternatives to chronic steroid therapy," said Dr. Remo Panaccione, PACE lead at the University of Calgary's Cumming School of Medicine, Associate Professor in the Department of Medicine and member of the Snyder Institute for Chronic

Diseases. "It is vital we begin testing and developing new therapies that expand choices and improve the quality of life for all Canadians living with Crohn's disease and ulcerative colitis."

"Drs. Fedorak and Panaccione are PACEsetters," says Mina Mawani, President and Chief Executive Officer, Crohn's and Colitis Canada. "Their project to address chronic steroid use is of particular importance in the PACE network. We are confident their research will benefit the nearly 250,000 Canadians living with Crohn's disease and ulcerative colitis."

PACE is the largest Canadian collaboration for adults living with Crohn's disease and ulcerative colitis. It unites centres of excellence to combine areas of expertise in order to strengthen knowledge and improve patient outcomes. Crohn's and Colitis Canada is investing in five leading research centres

across the country. It is a bold step forward to close gaps in Crohn's disease and ulcerative colitis care.

The PACE model is unique for Crohn's and colitis care in Canada. PACE will facilitate a combination of independent research and collaborative learning over a four-year period. During the first year, each centre of excellence will drive its own research. The centres will then work collaboratively to develop their own competencies in all areas. For information about other PACE research at the Montreal, Hamilton and Toronto centres, visit: [PACE](#). The Universities of Calgary and Alberta IBD centres will focus on

reducing chronic steroid use for the next two years and will then begin adopting the best practices of the other centres in years three and four. The project has secured funding for the next four years, with the goal of continuing well beyond 2020.

Crohn's and Colitis Canada, along with its partners AbbVie Corporation, Janssen Inc. and Takeda Canada, are investing an initial \$2.5 million in PACE. Over time, they plan to add more centres of excellence to the network and share their findings across IBD healthcare providers to ensure learnings will benefit all Crohn's and colitis patients.

Paediatric Digestive Health Across Europe

United European Gastroenterology (UEG) is committed to raising political and public awareness of digestive health conditions, informing policy makers and encouraging research.

'Paediatric Digestive Health Across Europe', commissioned by UEG, highlights how the current health burden and economic pressure of paediatric digestive health issues have become a pandemic issue throughout the continent.

The report canvasses the opinion of a number of paediatric GI specialists, who highlight areas of digestive health that show worrying trends and require urgent attention. Three areas that receive particular focus within the review are paediatric nutrition and obesity, paediatric inflammatory bowel disease and paediatric liver disease.

"Paediatric IBD is increasing in incidence and severity and provision needs to be improved with more consistent treatment practices to improve the outlook for young people with IBD across

Europe, many of whom suffer well into adulthood." says Professor Gigi Veereman from the UEG Public Affairs Committee and Consultant in Paediatric Gastroenterology and Nutrition at the free university, Brussels.

According to the United European

Gastroenterology (UEG) survey of Digestive Health across Europe up to one in four cases of IBD are diagnosed during childhood. Childhood onset IBD accounts for 20-30% of all IBD cases and has been steadily increasing over the last few decades.

The highest reported incidence of Crohn's disease is reported in Sweden, Norway and Hungary and for ulcerative colitis in France, Finland and Hungary.

Children with IBD often present with a more severe form of the disease than adults and a more aggressive disease course which can have a devastating effect on their quality of life, as well as their education and career prospects. The onset of IBD in childhood therefore presents different challenges for the patient and the gastroenterologist with the majority being linked to the differences in diagnosing and treating IBD in children compared with adults.

To read the full report please visit the UEG website or this link.:

https://www.ueg.eu/epaper/UEG_Paediatric_Digestive_Health_Report/index.html

Estonian IBD association

Even though we are a relatively young and small association, we have had a very busy summer this year. Following the participation at the EFCCA General Assembly where I presented our IBD patient association to the delegates I went to Aarhus in Denmark to the Nordic Ostomy associations meeting in order to represent the Estonian Ostomy (I used to be an active board member of this association).

We were also contacted by the Estonian Chamber of Disabled People informing us that the Estonian Public Broadcasting was planning to make ten original series about disabled people, telling their stories and understanding how the new operational government reform will affect them in their daily life. I did not really qualify for their series but I still had the feeling that I need to write to them and tell them about me and my life – so I did.

That's how they called me in late July and told me they wanted to make a documentary about my life. My story was the first to be aired and it was huge! Everyone in Estonia could watch my story - I was so nervous and so was my wife. But in the end it was very positive and I don't regret that I participated in it. I wanted to spread the information about Estonian

Crohn and Colitis Association and this was the best chance to do it. And it worked – the following day two new people called me and came to our monthly meeting.

At the end of this month, on 26-27 September I am going to the “ERA conference 416DV81 “EU DISABILITY LAW AND THE UN CONVENTION ON THE RIGHTS OF PERSONS WITH DISABILITIES”. I hope to learn a lot from the conference and from the topic so I can later help people in Estonia ;)

Facebook: <https://www.facebook.com/ibdeesti/>
- www.ibd.ee

Janek Kapper

Janek Kapper (right) during the making of the documentary



Iron Deficiency in IBD: Survey to Reveal Patients' Perspective

New survey on the impact of iron deficiency in IBD aimed to improve quality of life of IBD patients has been successfully completed.

Survey on iron deficiency in IBD completed

Over the past few weeks, 1500 patients with Inflammatory Bowel Disease (IBD) have volunteered to answer an online questionnaire designed to investigate the impact of iron deficiency on their lives. The outcomes of the survey are expected to provide a better understanding of the burden of iron deficiency and to support efforts aimed at improving the quality of life of IBD patients. Further to this, it will provide valuable data to address gaps already detected in previous surveys, such as a general lack of awareness, late diagnosis and inappropriate treatment

of iron deficiency. The results of the survey will be communicated in the upcoming months. The survey has been developed by Vifor Pharma in consultation with EFCCA.

IBD.IronDeficiency.com

As part of its ongoing commitment to support patients with IBD, Vifor Pharma has given great attention to address the needs identified in previous patient surveys. One recurring feedback had been the need for more information on the condition. To this end, the online resource platform IBD.IronDeficiency.com helps patients recognising the symptoms of iron



“Iron deficiency affects me as a person and my way of life in a quite a big way.”

Andy, 31 years old, diagnosed with Crohn's disease when he was 16

deficiency and providing interactive features such as the symptom browser or a tool for measuring fatigue level, a crucial indicator of iron deficiency. These features can also be downloaded from the AppStore and on GooglePlay.

About iron deficiency and IBD

Iron deficiency, with or without anaemia, is a common occurrence amongst patients with IBD. Unlike other side effects, this debilitating condition is not just experienced during flare-ups, but also in

phases of remission. Iron deficiency is associated with significant loss in quality of life. Nevertheless, this debilitating condition generally receives only little consideration. An estimated 60% of all patients are still not getting appropriate treatment.¹⁻⁴

1. Evstatiev R et al Clin Gastroenterol Hepatol. 2013;11(3):269-277 2. Ott, C et al Gastroenterology research and practice 2012 . 3. Subramaniam et al Gastroenterology 148, no. 4 2015: S-456. 4. Voegtlin M et al. J Crohns Colitis. 2010;4(6):642-8.

European Medicines Agency: Better monitoring of biological medicines

The European Medicines Agency (EMA) has adopted a new chapter to its guidelines on good pharmacovigilance practices (EU-GVP), entitled “Product- or population-specific considerations II: Biological medicinal products”. Good pharmacovigilance practices are a set of measures designed to ensure the robustness of the system of safety monitoring.

The new chapter provides guidance on how to better monitor and manage the safety of biological medicines to optimise the safe and effective use of these products in Europe.

Biological medicines contain one or more active substances made by or derived from a biological source, such as blood or plasma. Some of them may be already present in the human body and examples include proteins like insulin and growth hormone. The active substances of biological medicines are larger and more complex than those of non-biological medicines.

Only living organisms are able to reproduce such complexity. Their complexity as well as the way they are produced may result in a degree of variability in molecules of the same active substance, particularly in different batches of the medicine.

Therefore the guidance seeks to support those responsible for monitoring these medicines by:

- highlighting specific issues and challenges for the pharmacovigilance of biological medicines, e.g. in relation to variability of the active substance or traceability of products;
- providing recommendations on how to address these specificities and challenges;
- outlining the roles and responsibilities of the various actors.

The GVP guidance comes into force on 16 August 2016.

The new chapter applies to biological medicines, biosimilars and medicines which contain the same or a closely related active substance but are not authorised as biosimilars. It does not apply to vaccines or advanced therapy medicinal products as separate guidance already exists for these.

More info see: <http://www.ema.europa.eu/ema/>

Promising results from a study* on complex perianal fistulas in Crohn's disease

The results of a phase 3 randomised, double-blind controlled trial aimed to assess the safety and treatment-refractory of Cx601 for the treatment of complex perianal fistulas in patients with Crohn's disease, shows encouraging results. The new therapeutic approach involves allogeneic, expanded, adipose-derived stem cells (Cx601).

Perianal fistulas are a common complication of Crohn's disease and are estimated to affect up to 28% of patients in the first two decades after diagnosis. They severely impair patients' quality of life and cause substantial morbidity. About 70–80% of perianal fistulas are complex and these are challenging to treat since they are particularly refractory to conventional medical treatment strategies (ie, antibiotics and immunomodulators) and anti-tumour necrosis factor (anti-TNF) treatments. Furthermore, 60–70% of patients relapse after stopping treatment, and only a few patients achieve long-term remission.

The study involved 49 hospitals in seven European countries and Israel for a period of 3 years. 212 patients were randomly assigned as follows: 107 receiving Cx601 treatment and 105 receiving placebo treatment.

A significantly greater proportion of patients in the Cx601 group versus the placebo group achieved the primary endpoint of combined remission (defined as clinical assessment of closure of all treated external openings draining at baseline, despite gentle finger compression, and absence of collections >2cm confirmed by MRI) at week 24 in the ITT population 53 (50%) of 107 vs 36 of 105 (34%), respectively (97.5% CI 0.2–30.3; $p=0.024$) and the ITT population 53 (51%) of 103 vs 36 (36%) of 101 (0.5–31.2; $p=0.021$).

These findings suggest that local treatment with Cx601 added on to established treatments for Crohn's disease might open new therapeutic options for refractory perianal disease. In the study, the therapeutic effect using an innovative and distinctive

primary endpoint combining both clinical assessment of fistula closure and MRI was assessed. 50% of patients treated with Cx601, compared with 34% of the placebo group, achieved combined remission 24 weeks after treatment, and the stem-cell treatment was well tolerated.

Implications of all the available evidence suggest that Cx601 might offer patients with Crohn's disease who have treatment-refractory complex perianal fistulas a novel and minimally invasive closure alternative to avoid the need for systemic immunosuppression or surgery.

Below you will find some more detailed information of the study prepared by Professor Julian Panes, Head of Gastroenterology, Hospital Clinic Barcelona and member of the study project.

1. Which is the background on this project? What were the reasons to do this research project? What prior work led up to this latest study?

Mesenchymal stem cells (MSCs) are non-hematopoietic stromal cells that exhibit multilineage differentiation capacity and the ability to mediate immunosuppressive and anti-inflammatory effects. A growing body of evidence indicates that MSCs possess immunomodulatory properties and may play specific roles as immunomodulators in the maintenance of peripheral tolerance, transplantation tolerance, autoimmunity, and fetal-maternal tolerance. Various research groups have undertaken initiatives to determine the potential for MSCs-based therapy in a

variety of immune-mediated inflammatory disorders, including acute graft-versus-host disease, diabetes, peripheral ischemia, myocardial ischemia, and immune mediated inflammatory disorders. In IBD, studies on the therapeutic benefit of MSCs has been concentrated in Crohn's disease.

Previous phase I studies using local injection of MSCs from adipose or bone marrow origin showed closure of perianal fistulas in 60 to 85% of patients with Crohn's disease, and this effect appeared long-lasting in response to either single injections or multiple injections.

2. Which was the methodology used in the trial? Why did we decide to adopt this approach?

Using autologous MSCs imposes limitations in terms of time to get a sufficient expansion of the cells, inability to get sufficient number of stem cells in some patients, and very high costs. Allogeneic MSCs were known to induce tolerance as part of their immunomodulatory effect, opening the possibility to use cells from a donor. Using allogeneic cells would allow availability of cells at any time, and considerably reduce the production costs. There was a need to test the efficacy of allogeneic adipose-derived mesenchymal stem cell therapy in an adequately powered phase III study.

3. What were the most significant findings? How do they relate to what was already known about this subject?

The patient population included in the study was in 90% of the cases refractory to the most potent therapies available for treating perianal fistulizing Crohn's disease, including immunosuppressants and anti-TNF drugs. In this refractory population injection of MSCs achieved a significantly higher rate of fistula closure, accompanied by absence of abscesses as determined by MRI. The combined clinical and radiological endpoint is considerably more stringent than the endpoint previously used in perianal fistula disease trials, which consisted only in clinical closure of the external orifice. Absence of

abscesses is relevant because persistence is associated with a much higher rate of fistula recurrence.

4. How we you plan to take this work forward? What are the implications for future research?

Several questions remain to be answered. First is how long will be the benefit of this therapy. In the Lancet publication we provide results at 24 weeks, the point at which the primary endpoint was established. A follow-up study is underway to determine durability of the benefit. Another questions is whether repeated injections, as opposed to a single injection, would be more beneficial.

The results of the study have a considerable clinical relevance. For patients that failed immunosuppressants and TNF antagonists the therapy with MSCs would be the only alternative to surgery. For patients in whom perianal Crohn's disease is the sole, or largely predominant manifestation of Crohn's disease and are not under immunosuppression, local therapy with MSC can avoid exposure to systemic immunosuppression with the associated risks.

*** Expanded allogeneic adipose-derived mesenchymal stem cells (Cx601) for complex perianal fistulas in Crohn's disease: a phase 3 randomised, double-blind controlled trial**

Julián Panés, Damián García-Olmo, Gert Van Assche, Jean Frederic Colombel, Walter Reinisch, Daniel C Baumgart, Axel Dignass, Maria Nachury, Marc Ferrante, Lili Kazemi-Shirazi, Jean C Grimaud, Fernando de la Portilla, Eran Goldin, Marie Paule Richard, Anne Leselbaum, Silvio Danese, for the ADMIRE CD Study Group Collaborators. Published online July 28 2016, The Lancet.

Inflammatory Bowel Disease patients around the world rate **low energy levels** as one of their top five concerns¹⁻³

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