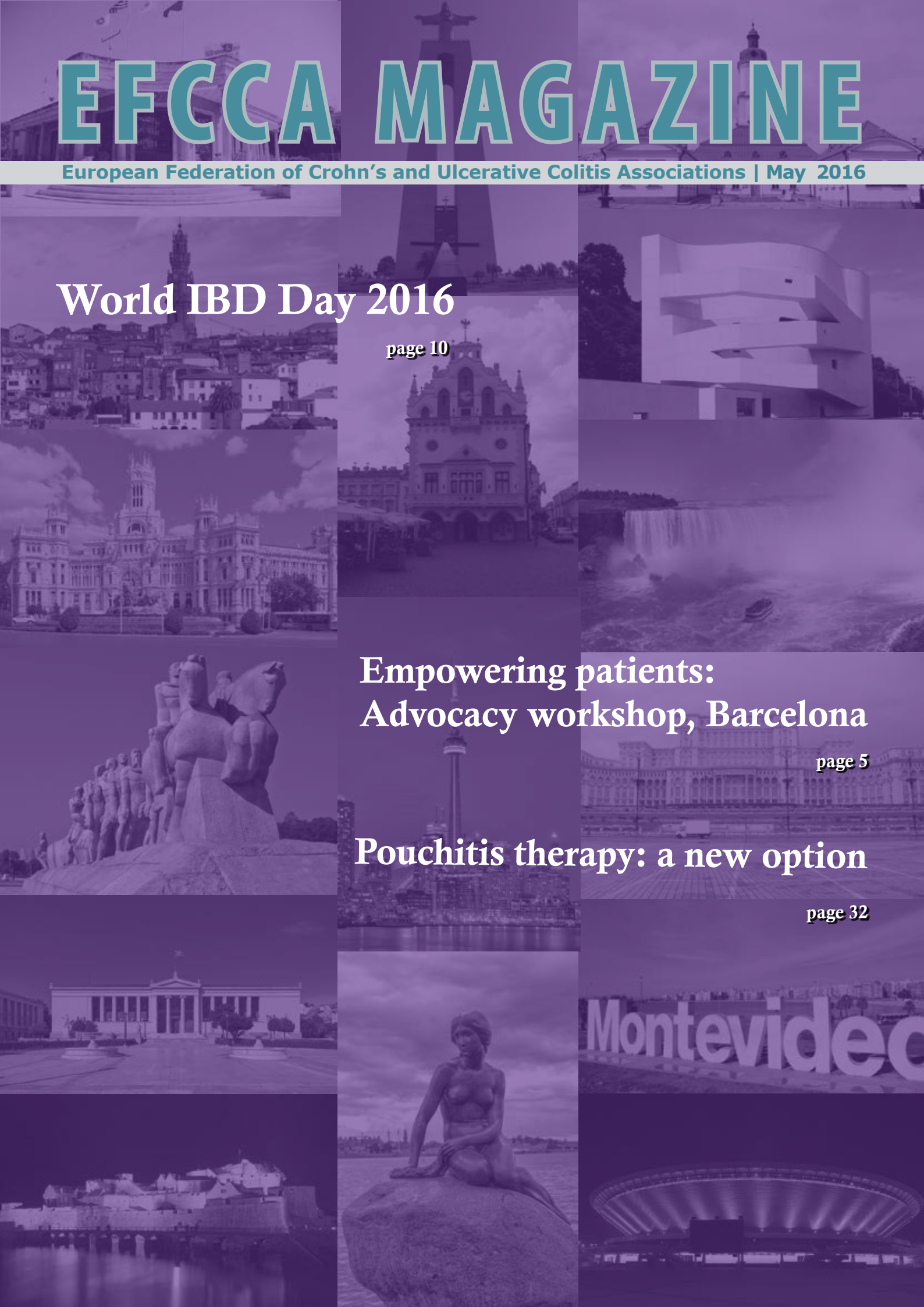
EFCCA MAGAZINE

European Federation of Crohn's and Ulcerative Colitis Associations | May 2016



World IBD Day 2016

page 10

Empowering patients: Advocacy workshop, Barcelona

page 5

Pouchitis therapy: a new option

page 32

EFCCA Members

Austria – OMCCV
www.oemccv.at

Belgium
CCV: www.ccv.be
Crohn-RCUH: www.mici.be

Bulgaria - BCUCA
www.babkuk.org

Croatia – HUCUK
www.hucuk.hr

Cyprus – CYCCA
www.cycca.org

Czech Republic – OSPs IBD
www.crohn.cz

Denmark – CCF
www.ccf.dk

Finland – CCAFIN
www.crohnjacolitis.fi

France – AFA
www.afa.asso.fr

Germany – DCCV.e.V.
www.dccv.de

Greece - HELLESCC
www.crohnhellas.gr

Hungary –MCCBE
www.mccbe.hu

Iceland – ICCA
www.ccu.is

Ireland – ISCC
www.iscc.ie

Italy – AMICI
www.amiciitalia.org

Luxembourg – ALMC
www.afa.asso.fr/luxembourg

Malta – MACC
www.macc.org.mt

Norway – LMF
www.lmfnorge.no

Poland – J-Elita
www.j-elita.org.pl/

Portugal – APDI
www.apdi.org.pt

Romania - ASPIIR
www.aspiir.ro/

Serbia – UKUKS
www.ukuks.org

Slovakia – SCC
www.crohnclub.sk

Slovenia – SAIBD
www.kvcb.si

Spain – ACCU
www.accuesp.com

Sweden – MOT
www.magotarm.se

Switzerland – SMCCV
www.smccv.ch
www.asmcc.ch

UK - Crohn's and Colitis
www.nacc.org.uk

Associate Members:

Argentina - Mas Vida
www.masvida.org.ar/

Israel - CCFI
www.ccfi.co.il/

New Zealand- Crohn's and Colitis
www. crohnsandcolitis.org.nz/

Contents

EDITOR'S EYE

United we have been standing: my "walkabout"

I joined EFCCA at the General Assembly (GA) in Vienna in 1999. Not fully aware of what I'd have found, I was appointed as the AMICI (the Italian IBD patient association) delegate in order to assist a more experienced colleague. Unfortunately this colleague stepped down a few days before the GA, and so I was alone. But since my very first minute I was not alone: I met other delegates who were there for the same reason I was.

I had some previous European experience, as a few months before I attended the Youth Meeting (at that time called "International Meeting of Young People with IBD") but still I could not have imagined which kind of journey I was embarking on.

Today, seventeen years later, I can say that this has been the experience of a life time. Not only a journey, but an adventure, a continuous challenge, and a million of different emotions.Our Australian friends have an expression for this: a walkabout. And this is what it has been for me, as at the end of it I see myself a different man. With more scars on my belly maybe, but fully aware of what a bunch of people with an ideal can realize.

Seventeen General Assemblies, hundreds of planes, thousand of people met and t learnt from. Since our GA in Dubrovnik, in 2008, I had the honour of leading this organization. It is not easy to explain what this does mean for a patient. To have the chance and the responsibility of representing other people with your very same condition is tremendous, emotional, physical and mental. But above all it is a great honour. Of which I will always be grateful.

It has not been only fun. There were moments, when it was difficult, even appeared to be impossible: but we have demonstrated that nothing is impossible when we are together, and when we work for the benefit of the people we represent. The only impossible thing is to choose one moment. Too many are now bundling in my mind. All the European Youtn Meetings, the Summer Camps, the first Congress, the first time at the European Parliament. And the people. All the delegates, all the friends and all the other people I've met visiting countries, associations and hospitals (and at an EFCCA event I even met my wife!).

My Crohn's disease has been tremendously active over the last years, but indeed I could not think of a better place where I could have spent my time than EFCCA. Through EFCCA I have realized many ideas I had (do you remember the "blueprint of a dream" ?) but essentially I have demonstrated that EFCCA could be different than in the past.

Editorial and Publication coordination:
Isabella Haaf

Graphic Design:
Isabella Haaf

EFCCA Contact details:

Rue des Chartreux 33-35
B -1000 Brussels
Belgium
Tel/Fax: + 32 2 540 8434

Chairman Marco Greco
Tel: + 39 346 800 9433
marco.greco@efcca.org

CEO Luisa Avedano
Tel: + 32 483371194
luisa.avedano@efcca.org

Secretary Ciara Drohan
ciara.drohan@efcca.org

Treasurer, Martin Kojinkov
martin.kojinkov@efcca.org

Communications
Isabella Haaf
Tel: +34 606 849 937
bella.haaf@efcca.org

Registration:
1096/97
revised 22/2/2006
No. 459814543

This would not have been possible if I were alone. I want to thank here those who believed in me: the associations that have elected me and the delegates of course, but also those few that believed in my ideas since the beginning and have spent days (and many nights and week-ends) in helping me pursuing the dream of a better, more professional and structured organization. You know who you are! Thank you.

It is evidence that I'm leaving a stronger organization, well structured and still with a great growth potential. This magazine proves it beyond any doubt.

You will read about empowerment and about one of the biggest and most important project ever realized: the ECCO-EFCCA guidelines. And what about the upcoming World IBD Day? The youth group is at its best again: the work on transition is extremely interesting and I hope it will be re-launched in all the member countries.

Our National members are doing great things: reading about them make me think about how much the life of an IBD patient has changed over the last twenty years.

It has been a tremendous journey. Some of the old friends are not here anymore (Els, Leon, Karin: I miss you so much) some other have moved to other experiences. But still, in our hearts, we are the same that met many years ago.

Some of us "are not now that strength which in old days moved earth and heaven, that which we are, we are" but still, I'm sure, as Tennyson would have said "One equal temper of heroic hearts, made weak by time and fate, but strong in will".

If I turn back I see how much I have walked. And I would make every single step again. Thank you for all this.

Only a few of you may know the origin of the EFCCA motto: "United We Stand". It was the beginning of my final speech when I was running for the first time as EFCCA Chairman. It has become the symbol, the deepest meaning of these last 8 years.

United we have been standing over these years, showing the real meaning of being a "patients' group". United we will be standing.

Marco Greco, EFCCA Chairman

Empowering patients

From 4-6 February 2016 EFCCA (the European Federation of Crohn´s and Ulcerative Colitis Associations) together with GAfPA (Global Alliance for Patient Access) organised an advocacy workshop on patient safety which took place in Barcelona and gathered over 60 patient representatives from a wide range of immune modulate disease groups.

The main objectives of the workshop were twofold: firstly, to create greater awareness amongst patient communities regarding the issues impacting access to biologic and biosimilar treatments and therefore to provide or improve basic understanding of the science and issues associated with biological medicines and biosimilars.

And secondly, to provide training on how to employ effective advocacy and communication strategies with the goal of raising awareness and understanding amongst key policy makers.

Presentations concerning the issues around biosimilars and biologics were presented by Prof Julian Panes, President-Elect of the European Crohn´s and Colitis Organisation (ECCO), University Hospital Clínic de Barcelona and Dr David Charles, MD, Global Alliance for Patient Access. Delegates were also presented with the first results of the BAB survey. The BAB survey (Biologics and Biosimilars – an open door towards a better knowledge) has been carried out by EFCCA and involved patients affected by Crohn´s Disease, Ulcerative Colitis and Rheumatoid Arthritis. The aim of the survey was to assess patients´ knowledge about biosimilars and biologics and to find out to what extent patients are aware of the issues involved around these innovative treatment options. An article about this study is currently under review for publication in the JCC (Journal of Crohn´s and Colitis).

EFCCA chairman, Marco Greco, talked about his "Role of Patient Representative" at the European Medicines Agency´s Pharmacovigilance Risk Assessment Committee and representatives from 3 patient IBD patient associations talked about the issues involving biosimilars and biologics in their own country, namely: Malgorzata Mossakowska, J-elita (Poland), Alejandro Samhan, ACCU España (Spain) and Bjorn Gulbrandsen, LMF (Norway). Suzi Makri from AGORA (the platform of organisations of people with rheumatic diseases in southern Europe) gave an overview of the above topic within the region of AGORA.

Prof. Julian Panes, ECCO President, speaking at the workshop

The second part of the programme focused more on strategies and some case studies for advocacy in particular with EU decision/policy makers. Brian Kennedy, director of GAfPa presented a toolkit on advocacy and invited participants to form into small working groups where participants were asked to ¨develop¨ a basic advocacy strategy.

We were very pleased with the level of engagement and interactions between representatives from the various disease groups. What became very evident

during the discussions and questions following the above mentioned presentations is that the subject of biosimilars and biologics is a very burning issue for all patient representatives and requires an urgent need for unbiased and accurate information. To date, patient representatives feel that there is at times contradictory information available from the scientific, regulatory and industry community as concerns this topic.

Some areas of particular concerns are the issue of switching from biologics to biosimilars, the tracing of a particular drug (ie naming the drug in order to be able to trace back in case of adverse effects), extrapolation (ie extrapolating results from clinical trials for one disease group to another disease group), increasing access to the drug (in many countries due to economic reasons patients do not have access to costly treatment options).

Participants agreed that it was important to work towards a common position of the patient community that would best protect patients´ safety. Several representatives voiced their concern that their lack of resources and often lack of time didn't allow them to successfully lobby their respective policy makers. These comments showed the importance of uniting efforts across disease groups in order to raise a critical mass and ensure that patients concerns were heard.

EFCCA would like to thank all participants for their lively contributions, interactions and for sharing their experiences. We remain committed to drive this process forward and hope to continue working with all interested stakeholders on the important issue.

An Executive Summary of the workshop has been published and is available for the EFCCA´s website. A full report will be made available in the coming weeks.

The event forms part of EFCCA´s work programme and priority issue of patient safety. The workshop has received an educational grant from AbbVie.

Delegates and speakers of the Advocacy workshop on Patient Safety, February, Barcelona 2016

Launch of the ECCO-EFCCA Guidelines

The highly anticipated ECCO-EFCCA Patient Guidelines were presented at a Press conference on March 16, 2016 in Amsterdam, preceding the 11th ECCO Congress. Panel speakers including representatives from ECCO, EFCCA and N-ECCO as well as the chairs of the two working groups on Crohn´s disease and Ulcerative Colitis.

Panel speakers at the ECCO-EFCCA Guidelines press conference, 16 March, Amsterdam

The ECCO-EFCCA Patient Guidelines are the outcome of a fruitful collaboration between EFCCA, ECCO and N-ECCO involving patients, physicians and nurses who worked together with the aim to improve the quality of life and the quality of care for people with IBD.

Following a meeting in December 2014 between ECCO, IBD Patient Association Representatives and ECCO National Representatives (both nurses and physicians), it emerged that there was an urgent need for patient guidelines. EFCCA and ECCO joined forces in order to develop these ECCO-EFCCA Patient Guidelines including topics of high relevance to patients.

In 2015, two taskforces, one focusing on Crohn's Disease and the other one on Ulcerative Colitis, were formed. Taskforces consisted of patients, physicians and nurses from different European countries. The working groups were responsible for selecting statements from the existing ECCO Clinical Guidelines which are most relevant to patients and for translating these statements into patient friendly language with the support of two medical writers from EFCCA, namely Sanna Lönnfors and Andrew McCombie (Crohn´s and Colitis New Zealand).

The ECCO-EFCCA guidelines are now being widely disseminated on the ECCO and EFCCA

Website, newsletters and other social media channels. We are also in discussion with ECCO and N- ECCO on how to proceed with the translation of these guidelines into other Community languages in order to ensure their accuracy and quality.

We are very pleased that our networking efforts with ECCO and N-ECCO have resulted in this useful tool and we look forward to continued collaboration and jointed projects. If you would like to download the guidelines please visit our website at: www.efcca.org

Photo on the left: Marco Greco, EFCCA chairman and Severine Vermeire, ECCO president, during the press conference

ECCO Congress

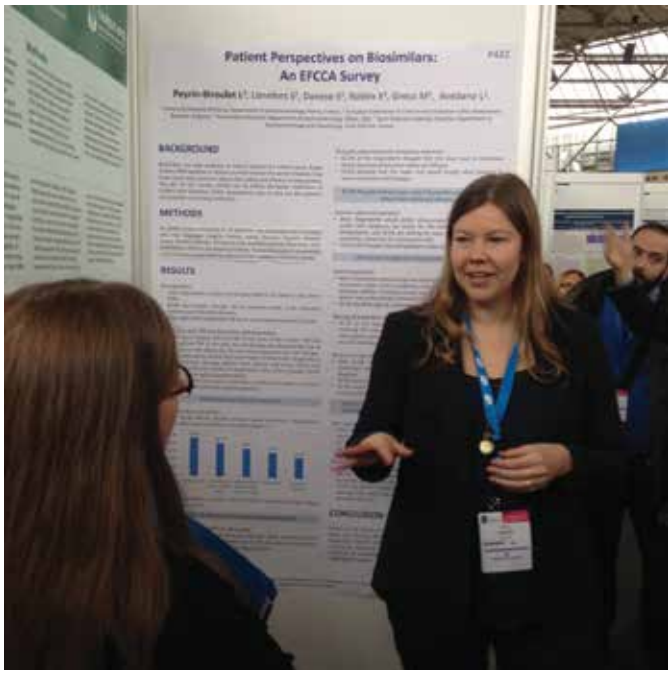
Poster presentation of the BAB Survey at the ECCO Congress receives great interest and attention from delegates.

We are pleased that our participation at the ECCO Congress this year included a poster presentation of the BAB survey (Biologics and Biosimilars – an open door towards a better knowledge) which aimed to assess patients´ knowledge about biosimilars and biologics and to find out to what extent patients are aware of the issues involved around these innovative treatment options (see also first article page 5 in this issue). The poster was presented by Sanna Lönnfors, EFCCA medical writer, who was involved in the preparation and analysis of the survey.

The 11th ECCO Congress took place in Amsterdam from 16-19 March 2016. The Congress popularity and importance has been increasing over the years and this year, in Amsterdam, over 5000 delegates met to advance the understanding of the causes of Crohn's Disease and Ulcerative Colitis, to share and discuss top-line results of therapeutic agents and algorithms, to stimulate and promote the implementation of guidelines and to ultimately further improve patient care.

The Congress also provided a good opportunity to present the work of EFCCA and to network with key stakeholders and discuss possible cooperation for 2016.

Sanna Lönnfors, EFCCA medical writer, presenting the survey



New appointments to PRAC

In March 2016, the European Commission has made new appointments for the members and alternates of the Pharmacovigilance Risk Assessment Committee (PRAC).

The Pharmacovigilance Risk Assessment Committee (PRAC) is the committee at the European Medicines Agency that is responsible for assessing and monitoring safety issues for human medicines. Members to PRAC are chosen in consultation with the Agency's Management Board on the strength of their qualifications and expertise with regard to pharmacovigilance matters and risk assessments of medicines for human use.

PRAC includes one member and one alternate to represent patients organisations and we are pleased to announce that this year EFCCA chairman, Marco Greco, has been appointed as the patient representative and Albert Van der Zeijden from the International Alliance of Patients´ Organisations (IAPO) as alternate.

Patient representatives are an integral part of PRAC and key to achieving greater inclusiveness of European drug safety systems. Their role is to ensure that patient needs as a whole are taken into account in the deliberations of the Committee. The patient representatives ensure also that communication on individual medicinal products consider specific patient requirements such as health literacy etc. Ultimately, they are bridging the gap between the statistical reality of the regulatory system and the personalised reality of clinical practice.

Digestive Health and Children

Event and exhibition on Digestive Health and Children to take place in the European Parliament on 31 May and 1 June 2016.

EFCCA together with other major organisations such as the European Crohn´s and Colitis Organisation (ECCO), the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) , the German IBD patient association DCCV, the two Belgium IBD associations (RCUH and CCV) as well as ¨inside link¨ is collaborating with the United European Gastroenterologists (UEG) in an event and exhibition on Digestive Health and Children to take place in the European Parliament on May 31 and 1 June 2016.

This event which is hosted by MEP Michèle Rivasi (Green Party) will showcase the vast amount of work undertaken by associations and experts across Europe as well as draw attention to the topic. EFCCA will be present during the event highlighting our work on IBD and in particular with view to children and young people.

World IBD Day

The month of May is a special month for the IBD community. On 19 of May, IBD patient associations and IBD ´activists´ around the world are joining efforts to raise awareness about IBD.

This year the European Federation of Crohn´s and Ulcerative Colitis Associations (EFCCA) together with it´s 31 member associations, and other IBD sister organisations from around the world are uniting their efforts around the campaign "Improving quality of life for people with IBD" in order to create greater awareness about inflammatory bowel disease and its impact on the quality of life for people with IBD.

As part of the awareness raising campaign we will be asking local, municipal and regional authorities worldwide to light up famous landmarks in purple (the colour for World IBD Day) in support of our campaign. Images of these highlighted landmarks/ buildings will be shared on international and national social media channels and many associations around the world will engage in supporting event providing detailed information about IBD and issues addressing the quality of life of people with IBD.

We are very excited to see so many countries joining this campaign and some of the landmarks that have already been confirmed by the date this issue went to press (end 27 April 2016) include the Niagara Falls in the US/Canada, the monument of Cristo Luz in Brazil, the little Mermaid in Copenhagen (Denmark), the Carter Fountain in Wellington (New Zealand), the Palacio de Cibeles in Madrid (Spain) and many other famous landmarks and/or town halls. So please check our Facebook page and the World IBD Day website if you want to keep up to date of the countries and landmarks joining us on 19 May.

At European level, EFCCA is disseminating findings of its recent study, IMPACT, which revealed the negative impact the disease has on the overall quality of life in particular as concerns education, work and private life and is lobbying with policy makers on more effective governance to ensure that social, economic and health aspects of people living with IBD are considered in all policies in order to break down barriers, prejudices and discrimination.

For further information please visit: www.worldibdday.org and www.efcca.org or write to bella.haaf@efcca.org

A world free from immune and inflammatory diseases. **That's our vision.**

At Janssen, we like to dream big. And our hope for immune and inflammatory diseases is no exception.

Through science and collaboration, we look to transform how diseases like rheumatoid arthritis, Crohn's disease, plaque psoriasis and asthma are treated today–and prevented tomorrow.

We dream of a future free of the pain and challenges for the one in 10 people worldwide living with these diseases. We are relentless in our pursuit of advancing science and delivering breakthrough medicines to make a difference in their lives.

But bringing forward new solutions isn't enough. We want to shorten the journey from diagnosis to treatment. And through our education and awareness programmes, we're here to help forge that path.

We are Janssen. We collaborate with the world for the health of everyone in it.

Learn more at www.janssen-emea.com

janssen

The image depicted contains models and is being used for illustrative purposes only.

Janssen Pharmaceutica NV

Transitions and IBD

Transition, in the context of healthcare, is the planned undertaking and making changes to children and young adults (Paediatrics) with chronic physical and medical conditions to adult based healthcare processes and systems.

by Leanne Downie, EFCCA Youth Group

During EFCCA Youth Group (EYG) meetings we discuss various topics (see previous EFCCA Magazines) and we try to "Break down taboos" which come with daily life and IBD. Any age you are diagnosed with an illness will bring its own concerns to overcome but one of the most difficult parts of growing up with IBD and being diagnosed in paediatrics is then the transition to adult care and the struggles it can bring.

Children and young adults with IBD tend to have more extensive and severe disease than adults. IBD presenting in childhood interferes with growth, education and employment as well as psychosocial development, frequently delaying adolescent developmental milestones, which can bring problems in itself.

The most important thing to remember is to make sure you share any concerns you have and ensure you keep control on your own healthcare. No one knows your condition and body like yourself so you should be the one in the driver's seat when making important decisions. There is no shame in talking openly with physicians and any other auxiliary team you have with your IBD as well as family and friends who can support the transition.

At the time when the transition tends to happen is when other important decisions are being made e.g. about your education which in itself can bring its own stresses and also bring the feeling of being overwhelmed so you need to allow for a clear mental space to ensure you are thinking clearly about your decisions.

Through sharing stories we hope to raise awareness and make people understand the difficulties and challenges we face and go through. 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 the stories we continue to share, remember them and tell them to your friends, relatives, doctors and whoever is willing to hear your story.

Moving to an adult ward

My transition to adult care was somewhat staggered as my hospital has an adolescent ward which I moved to when I was 16 years old having previously been treated at my more local hospital under guidance from Great Ormond Street Hospital.

By the time I turned 19 years old it was time to transition to the adult ward, but I was not ready. This was because after being so unwell for a prolonged period of time I'd spent a lot of time in the adolescent ward and had made friends with the long term patients there after helping each other get over our individual battles by being there for each other, we were like a little family. The facilities on the adolescent wards also helped to keep the boredom at bay with a recreation room and a TV room as well as arts and crafts and

My name is Anisah Kauser from London, England and ever since being diagnosed with Crohn's Disease at 13 years old it has been very severe which has meant I've had to adjust my way of thinking more realistically about my 'career' and 'education'. I'm 25 years old now and I've tried to hold down a job since I was 16 but I am admitted to hospital so often it became impossible to do so. When I can, I volunteer with local charities like Aik Saath (Together as One) and now Health Watch Slough who work with young people.

many activities. I was nearing the end of my hospital stay when one of the sisters on the ward wanted to move me to an adult ward but at that point I refused to move as I was soon to go home.

On my next admission I was taken to the adult ward and my fears of feeling out of place and lonely came to light. I decorated my bed space with photos of better times and went for short walks outside when I was feeling up for it to keep my independence and sanity.

I didn't feel like I was supported through my transition but if I had to do it again, I would want to pay a visit to the adult ward and have a good look at what it would be like. I also would like to meet the sisters and nurses on the ward and maybe write a bio about myself, so they have a better understanding of my personality and preferences, i.e. I hate mornings!

"I didn't feel like I was supported through my transition, if I had to do it again, I would pay a visit to the adult ward (..), meet the nurses and maybe write a bio about myself, so they have a better understanding of my personality and preferences."

For any young person going through this transition, be aware, you will need to learn how to entertain yourself in the adult ward! You also need to keep active everyday, even if it's a walk to the window to look outside, or starting to do some yoga by your bed side. Sounds impossible while you're sick but I promise you will feel much better for it.

Roundtable Discussion on Transition to Adult Care

On March 21st Thomas Hough from the EFCCA Youth Group attended a Roundtable Discussion on Transition to Adult Care in Brussels, hosted by the European Patient's Forum's (EPF) Youth Group. Here Thomas talks us through the event.

The aim of the workshop was to gather young patient organisations and relevant stakeholders to help:

- Identify both bad and good practices in national healthcare systems
- Build a thematic network of information and support for young patients
- Raise awareness of the challenges, potential pitfalls, and possible solutions related to adult care transition

Attendees at the Roundtable represented the broad range of stakeholders in the transition process such as Bart Ooijen (Permanent Representative of Netherlands to the European Union), Jamie Wilkinson representing PGEU (Pharmaceutical Group of the European Union) and Anders Olauson (Honorary President of EPF).

The event kicked off with a scene setting role play given by members of the youth group that showed some of the difficulties that have happened to them during transition. Issues touched upon were; loss of patient information, the feeling of being dropped into the alien and hostile environment of adult care, not being listened to and even talked down to from a patronising doctor due to your young age leading to a sudden change of medical treatment. All of which left the patient feeling disempowered, worried, frustrated and with an increased chance of non-adherence to treatment.

Next up and to add to the discussion were four presentations from attendees talking about either their research projects or ones they had come across. What impressed me the most about the projects was that they weren't just looking at good and bad

practices but they were also looking to develop their own tools to improve transition. For example the Milestone Project that Veronique De Roeck presented is looking into whether training mental health doctors about the needs of younger patients aids transition. The European Society for Paediatric Oncology are looking into the development of a survivor passport that could be given at the end of treatment detailing what the patient had been given but also what possible side effects they may cause in the future.

The role-play and presentations were all a set piece for the main discussion where all attendees freely spoke of their experiences, views and opinions on the current state of transition in their respective healthcare systems in Europe. Some of the young people's stories were shocking and moving at how they were left to feel belittled in their own experience of their conditions and not treated with the same care as they were in paediatric care. However it was mentioned by some that it wasn't just the patients that needed better support and care, parents also needed to be educated on the whole transition process so they can better advocate for their child in the new system or simply learn to let their child take care of their own health. Communication or lack of it between paediatric and adult care was also noted as a common problem with some suggesting that a transition co-ordinator is needed for the more complex patients or that the paediatric doctor and adult care doctor should sit in on each other meetings with the patient at least once.

Looking at more solutions to the problems peer to peer support for parents, patients and even siblings was proposed as well as a patient passport or checklist for transition. Training for adult care doctors was also suggested to make them more aware of the needs of younger patients and the paediatric system they were coming from.

Anders Olauson, made a very pertinent suggestion and request of the young people attending and that was to rebel against the current system but in a positive way and to think outside of the box when coming up with suggestions to improve the current situation as the young patients know what works best for them.

As a member of the EPF Youth Group I was really proud of what we had achieved with the roundtable by getting such a broad range of people in the same room to discuss the topic of transition and look at ways to improve it going forward. To add to the debate I also hosted a successful Twitter chat on the topic a week later using the hashtag #EPFTransition. All of which will add to the report we are creating with recommendations for all stakeholders in the transition process, and help us to take this topic forward by interacting with decision makers to improve the care for young people across Europe. Something we hope to feed into our work on transition at the EFFCA Youth Group.

UK

Innovative projects receive funds to improve lives of people with IBD

Four studies awarded charity grants totalling almost £400,000. Crohn's and Colitis UK has granted £364,724 in its Living with IBD Research Awards for 2015. Four projects will receive funding to investigate ways to improve the lives of those living with Inflammatory Bowel Disease (IBD).

For more than 30 years, Crohn's and Colitis UK has been at the forefront of groundbreaking research on Crohn's Disease and Ulcerative Colitis (UC), the two main forms of IBD. In 2015, the charity was able to grant more money to research than in previous years.

"Improving the lives of everyone affected by Crohn's and Colitis is a main focus for the charity," said Helen Terry, director of policy, research and public affairs. "We are thrilled to be investing in these projects that aim to identify useful ways of helping more people with IBD to manage their conditions. These investments are critical if we want to improve lives now and see a world in which people's lives are not limited by Crohn's and Colitis. IBD patients can be assured that the charity will continue to support high-quality research in the future in fighting the battle against IBD."

The following research projects had funding committed by Crohn's and Colitis UK in 2015:

The University of Hertfordshire will receive £115,000 for a study into the benefits and safety of high and moderate-intensity exercise training in a subset of IBD patients.

"A clearer understanding of the effects of different types of exercise training in adults with Crohn's is needed so that safe and effective programmes can be designed," said Dr Lindsay Bottoms, senior lecturer in exercise physiology.

Leeds Teaching Hospitals NHS Trust will receive £8,490 to look at how changing behaviour can affect fatigue in patients with IBD. The aim is to find ways of reducing fatigue.

"Our ultimate aim is to find a simple intervention to empower patients to deal with the difficult task of living with IBD and the fatigue this can bring," said Lisa Warren, an IBD specialist nurse at the trust.

King's College London will receive £115,000 to measure the "burden of food on quality of life in patients with IBD".

This research will look at how many people with IBD are affected by activities related to food, in order to develop tools to help them. It builds on a study – funded by Crohn's and Colitis UK – which developed a validated rating scale of the impact of food-related activities on quality of life."We do not know how many people with IBD are affected by problems with food-related quality of life, what the most common problems are, and why and when they occur," said King's dietetics specialist Professor Kevin Whelan.

Crohn's and Colitis UK presented a Health Services Award in 2015, granting £126,234 to the University of Liverpool to maximise the value of data.

"This project will develop and test new ways to capture, link and analyse information about routine IBD care," said Dr Keith Bodger, the university's senior lecturer in cellular and molecular physiology.

This article was written by Gemma Briggs from Think Publishing for the Crohn´s and Colitis UK magazine ¨Connect¨

To be as **Brave** as the patients we help

Shire's mission

Shire's purpose is to enable people with life altering conditions to lead better lives. We focus on researching, developing and marketing innovative medicines that have the potential to transform the lives of people around the world with rare and other specialized conditions.

Shire's vision is to continue to identify, develop and supply life-changing products that support physicians in transforming the lives of patients with specialist conditions. Fostering innovation and delivering value not only promises a better understanding of diseases but also provides the best hope of treating and eventually eliminating them.

History and growth

Since its foundation in 1986, Shire's endeavour to provide innovative treatments for unmet medical needs, coupled with investment in research and development, has resulted in considerable growth and diversification.

Shire's focus on improving outcomes for patients with gastrointestinal (GI) diseases

Gastrointestinal diseases affect millions of people, reducing quality of life for both patients and their families. These diseases also add to overall healthcare costs. New medicines will help reduce that burden.

- Shire understands the unmet needs of patients with GI diseases and endeavours to provide innovative treatments to the specialist physician for the benefit of the patient.
- Shire aims to be at the forefront of the development and provision of treatments for GI diseases including ulcerative colitis, chronic constipation and short bowel syndrome.
- 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.

Shire

To be as brave as the people we help.

INTSP/C-ANPROM/MEZ/16/0002 Date of preparation April 2016.

New Zealand

Camp Purple Live

It was a gray morning, but, luckily, not raining, as a bus and two vans filled with 48 children and teens arrived at the boat launch on the Waimakariri River outside Christchurch. A few minutes later the owner or Jet Thrills and Karen Clarke, an avid jet boater and nurse from Southern Endoscopy in Christchurch, were powering down the river at high speed with the children, providing a high point to the final day of Camp Purple Live.

Camp Purple Live, the CCNZ camp for children with Crohn's disease and ulcerative colitis, ran for its second year at Living Springs outside Christchurch. Forty eight children and over 25 volunteers, including four gastroenterologists and five nurses, spent five days in the sun (and a bit of rain), enjoying each other's company. Aside from the daily routine of receiving medications, occasional nighttime tube feedings, and dealing with an occasional flare of their disease, it was a normal camp experience for these kids. Activities included go carts, swimming, archery, as well as the day of jet boating. Some of the children had never been to camp before and, for many, it was the first time they were in the company of other kids with the

same diagnosis. It was an opportunity for them to test their limits. Among the volunteers were a police detective, a former All White, and a swimmer who will be trying out for the next Olympic Team, all of whom have IBD themselves. One of the physicians noted that "It was so gratifying to see how quickly the children bonded with one another", not surprising, given the tacit understanding among all the children of the challenges of living with IBD at such a young age.

The camp was funded entirely from donations and all costs to attend were covered, including airfare from all corners of New Zealand. A team of committed volunteers, almost all of whom have IBD themselves spent countless hours over several months in the planning and administration of the camp. A two day seminar for parents and caregivers was held concurrently, in which adults shared experiences and challenges of having children with the disease and were able to network with one another. One offshoot of the camp is an active Facebook page, "The IBD NZ Parent Support Group" which was created by the parents who attended. The group already has over forty members.

Next year's camp will be held in the Wellington region from13-17 January on the Kapiti Coast. The location by the ocean will provide new experiences

as well as an incredible planned excursion to the Adrenaline Forest.

This letter from the parents of one of the campers sums up what the camp was all about:

"As a family we just wanted to express our heartfelt thanks to all of you involved with the camp. To have exposure to the great doctors, nurses, volunteers and of course the organisers and families -who all have so much information to share- is immense for us, invaluable actually. We think you guys are awesome and are doing amazing things for our children-and for parents like us that is everything. Judy and I loved the opportunity to lap up the knowledge offered freely by the doctors, nurses, families and sufferers themselves. I know that our daughter will be having a great time, building lifelong friendships and coming to the realisation that there is life after her diagnosis. It is a gift to know that it will not hinder her life and most importantly that she is not alone in this predicament.

We will never be able to repay everyone involved in the camp for the amazing work done-but we are immensely grateful for all you have done for our

daughter and our family. Please pass on our thanks to the doctors, nurses, and especially the freely giving volunteers also; in the hasty departure on Monday we did not have the opportunity to thank them all.

The camp was made possible through generous donations from Janssen, Abbvie, Pharmaco, Baxter, Boston-Scientific, TG Macarthy Trust, Nikau Foundation, Pelorus Trust, EFCCA, Jetstar, and countess individual donors.

Poland

Delivering smiles

In February our support group "Brigade-J" in the town of Rzeszow celebrated its first anniversary. The group is actively working under the umbrella of the Polish Crohn's and Colitis Association "J-elita". Celebrating with non- alcoholic champagne and a special cake that had our group's logo, we presented our work over the year to an enthusiastic audience.

Our meetings have taken place once a month in one of the local biggest hospital – the Regional Clinical Hospital No. 2 . During these meeting we discussed specific health problems and/or just talked about life with the disease. Each month we had more and more people joining the support group. Usually we first talk to new attendees but we also then visit those on the gastroenterology ward that are too sick to go to the meeting. We have made new friends and our group has gotten stronger and more self confident. As volunteers we do this out of sheer pleasure of helping others.

The idea of creating such special force group

came from one of us, after having had another relapse of Crohn's disease. Most of us are already well experienced in life with IBD and our aim is to ¨infect¨ the others with optimism and cheerfulness. Our reward are the smiles on the faces of the people whom we are talking to. The meetings are very open and welcoming, we just talk and drink tea. This helps new people to open up and talk about their experiences. In our group you can also meet the hospital psychologist and have a face to face talk if needed. The meetings take place on the last Tuesdays of the month. You can show your support by liking our profile www.facebook.com/jelitapodkarpacie, this year we had over 200 likes.

Piotr Chrzanowski, Patrycja Gajewska, Konrad Kobos, J-elita, Brigade-J

France

“Ma MICI” a new pediatric tool

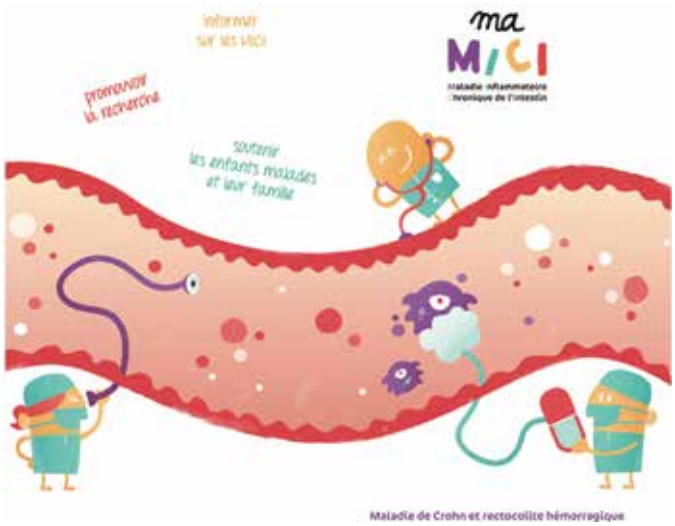
“Ma MICI” (My IBD): To give each child diagnosed with IBD the tools to cope with the disease, to better understand and manage their daily life.

IBD diagnosed sooner and sooner in children, the major pediatric units are desperately short of the right tools to help young patients.

Afa, in partnership with Gastro-pediatricians and GETAID* Pediatricians, have created a special informative program to better help children from ages 7 to 14 years old.

Who knows better than a young patient what kind of program is needed? Astrid Moriset, a young designer with Crohn’s disease since her childhood, followed by gastro-enterologists, created the tools she would have liked to have had while she was being followed at the hospital as a young child.

The « Ma MICI » Program is mainly a universe of designs in which the disease is represented in the form of a cell or an ectoplasm, sometimes glad…. sometimes sad!



But it’s also a learning tool called “livres des maux”, a play on words meaning “a book of pain or words”. The reader meets germs, viruses, lymphocytes and firemen who put out the fire of inflammation.

…And finally, it’s a daily health record which allows the child and his or her family to write down the treatments, the development of symptoms, the vaccinations, etc. A different support tool than the usual health record, it is specific to IBD and remains personal and confidential.

In a few months, a recipe book will complete the program to better manage daily nutrition through creative cooking for the whole family.

Every gastro-pediatric department should have its own program, along with therapeutic education sessions offered in more and more major units.

*GETAID (Groupe d’Étude Thérapeutique des Affections Inflammatoires du Tube Digestif) :
Inflammatory Digestive Tube Disorders Therapeutic Study Group

PEOPLE COME FIRST AT FERRING

FERRING PHARMACEUTICALS

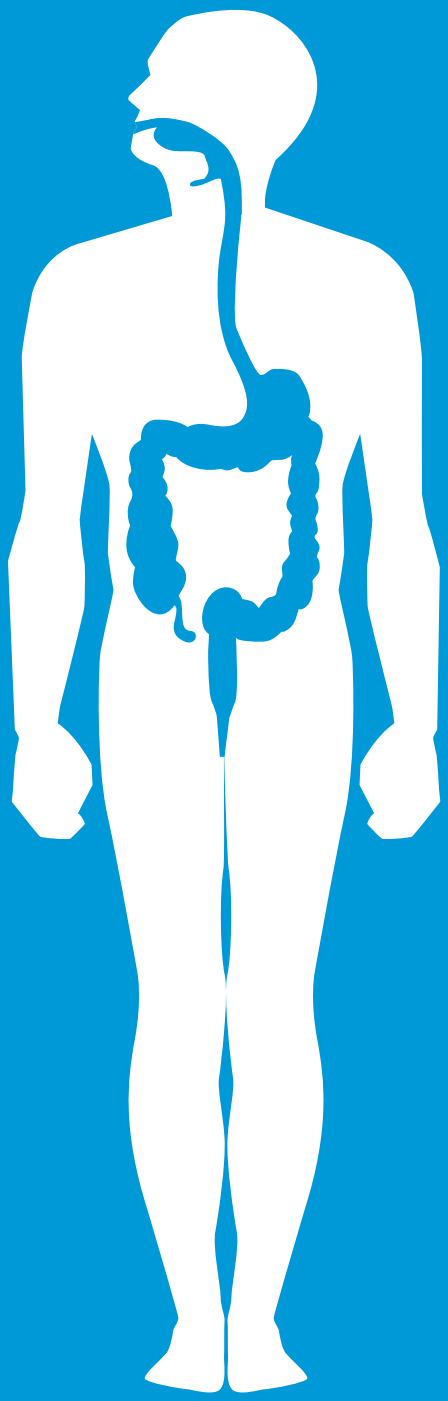
Making a difference to people's health and quality of life, today and tomorrow.

TODAY

FERRING ENJOYS A STRONG REPUTATION WITHIN THE INTERNATIONAL GASTROENTEROLOGY COMMUNITY.

Our research activities have resulted in the development of many effective products that help improve patients' lives.

FERRING BELIEVES IN THE VALUE OF SHARING KNOWLEGDE AND WORKS TOGETHER WITH PATIENTS TO RAISE THEIR VOICE.



TOMORROW

OUR COMMITMENT TO RESEARCH: LIVER DISEASE, INFLAMMATORY BOWEL DISEASE, FUNCTIONAL BOWEL DISORDER.

FERRING is a research driven company that invests heavily in its research infrastructure both in terms of people and technology.

PLEASE VISIT
WWW. FERRING.COM

PA/030/2014/CH3a

Writing to help others

Ingeborg Kuys is a Dutch author and creator of the children´s character Obbe. Her first book 'Vreemde kronkels' tells her difficult story of living with Ulcerative Colitis and led her to publish several other related books as well as children stories aimed at comforting kids that need to be hospitalised or undergo medical examinations.

I was diagnosed with Ulcerative Colitis 17 years ago. After one year of treatment the disease was easily controlled and I stayed in remission for a couple of years. However in 2002 I got sick again but this time my medication didn't work and for over 2 years I was on various different treatment, none of them worked. I struggled a lot and in the end I got so bad that I had to be hospitalized for almost 6 weeks. My doctors suggested an operation and to get a permanent stoma.

I was terrified and didn't want to do this. Because of my ill health also my four young children and my husband had suffered a lot so the last thing I wanted to do was to go through this operation and have a stoma. Somehow I was convinced that this would be the end of everything.

As I was so weak my doctors were reluctant to operate me and instead send me home to try and get a bit better before surgery. I spent 3 months at home with the help of a professional homecare as I was unable to do anything. I could hardly speak to my own children I was so weak and I slept most of the times. Miraculously I did get slightly better but before agreeing to the operation I asked for another colonoscopy and it turned out that a very small section of my intestine had improved. It turned out that the immune suppressant medicine was working after all, however very slowly and after many complications and visits to the hospital I got better again and have the disease now under control.

"Ten years ago I wrote the book I would have wanted to read as a patient myself. Now I write books for all kind of organisations in healthcare in order to help other patients getting some more information, trust and comfort about and during their diseases."

This experience had a tremendous impact on my life and I wanted to write about it and share my journey. I had found a publisher for my autobiography and my doctors from the hospital helped me to promote my book as much as they could.

The feedback was amazing. The book really resonated with people´s emotions, as it seems it was the first time that someone had actually written such an open and frank account of living through this disease.

This encouraged me to publish another book that contained a compilation of 13 stories from people with Crohn´s disease and Ulcerative Colitis including that of a famous Dutch TV presenter. She got in touch with me after having read my book. My story deeply affected her and she was inspired to share her story of living with Crohn´s disease. This book was sold within 3 weeks!

After this, there has been no stopping really. My third book was about colon cancer, which included the stories of two famous people.

I was approached several times by a pharmaceutical company about writing a children book for kids with IBD. At first I was reluctant but then I got in touch with Olga Lubbers, who was a famous illustrator and very enthusiastic about the idea. It had always been a dream of her to illustrate a children book. We created the character Obbe who talks about his bellyache and what happens at hospital giving information about medications and treatment options in a playful and easy to understand way. The idea was to make this book as comforting to children as possible through the friendly character of Obbe.

Sadly after the publication of the first book, Olga passed away suddenly and this was a very difficult moment for me. Once I recovered from the loss I decided to carry on the work with Obbe also as a tribute to her.

The following children books didn't specifically deal with IBD but were more about other diseases and general admission to hospital. The stories aimed to take away children's fear of hospital talking them through each of the hospital environment in a comforting and entertaining way.

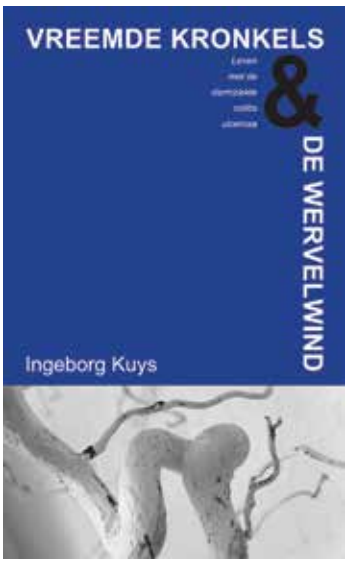
My latest work is an exciting project to translate Obbe´s stories into an animated application that kids can use when they have to be admitted to hospital. The animated digital information can be watched by children at home and allow them to learn about certain medical procedures such as for example a colonoscopy. Obbe will help them through all the relevant steps and the stories can be personalized by the hospital. The application will be piloted in 5

hospitals: 2 in Holland, 2 Belgium and 1 in Germany.

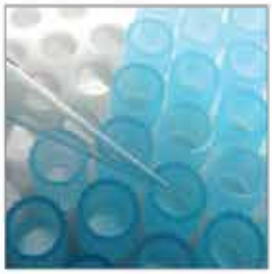
I am very proud to say that the animations will be prepared by the makers of Sponge Bob and the Simpsons.

Ten years ago I wrote the book I would have wanted to read as a patient myself. Now I write books for all kind of organisations in healthcare in order to help other patients getting some more information, trust and comfort about and during their diseases. So I can say, after all these years my disease has brought me a marvellous and thankful fulltime job with my own office at home!

www.obbe.co.nl and www.ingeborgkuys.nl (Dutch websites)



'I have to confess that I had tears in my eyes when I read the autobiography 'Vreemde kronkels'. I now have got another outlook on quality of life from people with IBD, one of the topics of my thesis then, and a subject that I was allowed to counsel to a number of students with their research on this disorder for their Phd.' Dr. Maurice Russel – Gastroenterologist (Holland)



Working to address your needs in ulcerative colitis and pouchitis

We focus on Inflammatory Bowel Disease (IBD) and the needs of smaller patient groups, which are so often overlooked.

Our lead product, alicaforsen, is currently recruiting patients to a Phase 3 clinical trial in Pouchitis – a rare indication currently without any approved treatments.

Alicaforsen is an entirely new class of drug, with the potential to offer Pouchitis and IBD patients a real alternative to existing therapies.

www.atlantichc.com

An international specialty pharma group focussed on inflammatory bowel disease

Atlantic Healthcare plc, Atlantic House, 12 Rose and Crown Walk, Saffron Walden, Essex, CB10 1HJ, UK
Office: +44 1799 513 391 **Web:** www.atlantichc.com

Atlantic Healthcare

Canada: Survey Results of the Subsequent Entry Biologics (Biosimilars)

The GASTROINTESTINAL SOCIETY represents inflammatory bowel disease (IBD) patients in Canada on a variety of health care fronts, including access to medications. During the first part of 2015, we hosted a survey on our English (www.badgut.org) & French (www.mauxdeventre.org) websites to help understand IBD patients' opinions and outlooks regarding subsequent entry biologics (SEBs) (also known as biosimilars).

To qualify, survey participants had to confirm that they were either a person with IBD or a caregiver of a person with IBD. We had 423 respondents, 317 in English; 106 in French, but not everyone answered each question, as they were not mandatory.

BACKGROUND

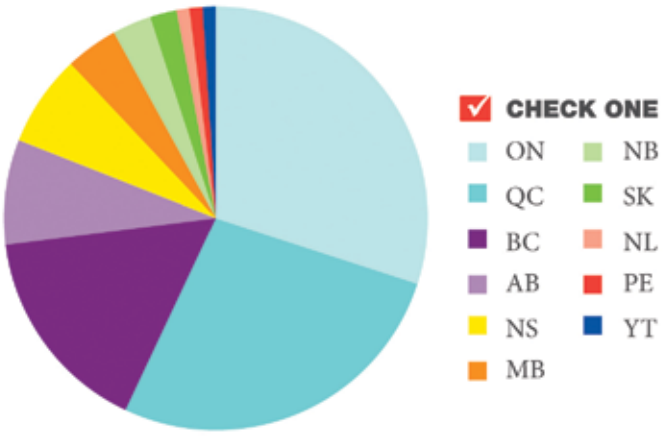
Biologics are medicines made from living cell systems, and are intended to act in certain ways in the body to correct malfunctions that might lead to disease. They can also block disease in its early stages from progressing.

Unlike most generic drugs, biosimilars/SEBs are not identical to the original biologic medicine on which they are based; they have slightly different structures, are not therapeutically equivalent, and might not be approved or tested for all the disease areas (indications) for which the reference product was approved, e.g., Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriasis.

Health Canada (the government agency responsible for drug safety) might not require a biosimilar to be tested for safety and effectiveness through clinical trials in a specific disease area before approving it for use in that disease area. (The regulations are in flux.) This is in contrast to the approval process for the original biologic, which required extensive studies in all of the disease areas for which Health Canada has approved it. The

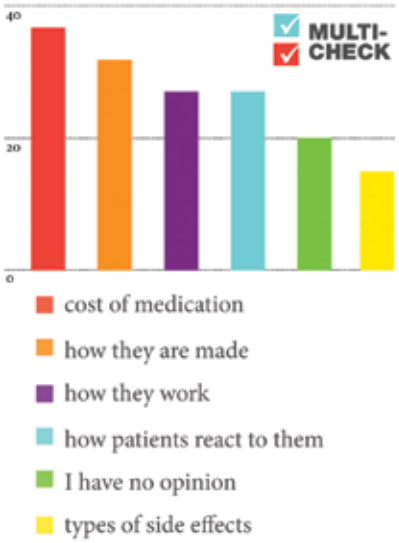
DEMOGRAPHICS

- respondents were from all ten provinces and Yukon, with close proportional representation to the corresponding populations
- the majority (66%) were female
- 91% were between 18-59 years of age, less than 1% were caregivers of children with IBD (n=5), and the remainder were older than 59
- 68% had Crohn's disease, 30% had ulcerative colitis, and 2% had indeterminate IBD



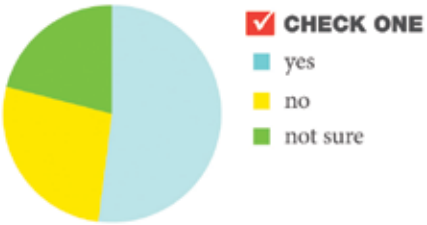
SUBSEQUENT ENTRY BIOLOGICS

HOW do you think subsequent entry biologics are different from originator biologics?



ALL medications have a brand name and an international non-proprietary (scientific) name (INN). For example, *Aspirin*® is the brand name and *acetylsalicylic acid* is the INN. If two medicines have the same INN, does this suggest to you, or imply that a patient could safely switch between the products during a course of treatment and expect the same effectiveness and safety?

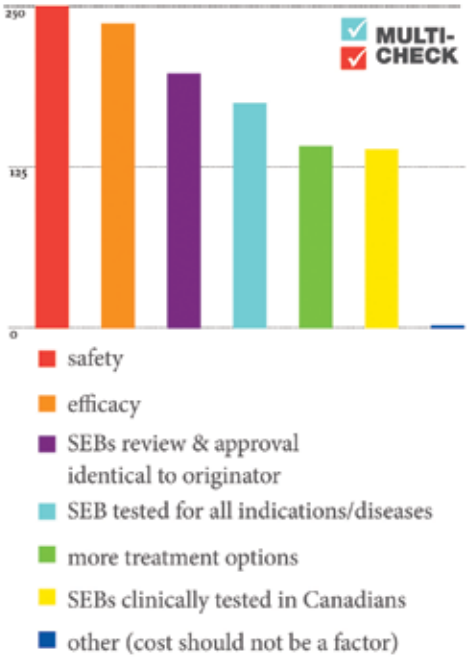
» 52% said yes, 27% said no, and 21% were not sure



HOW important is it to you for your physician to have the sole authority to decide, together with you, the most suitable biologic medicine to use to treat your disease?

» 78% said very important, 17% said somewhat important, 4% were not sure, and 1% said it was not important

WHAT factors are important to you for biosimilar/subsequent entry biologics regulation in Canada?



biosimilar agent has to demonstrate structural and quality aspects for Health Canada to denote it as similar to the original biologic and, therefore, relies on the original medicine's clinical experience, not the biosimilar's own data.

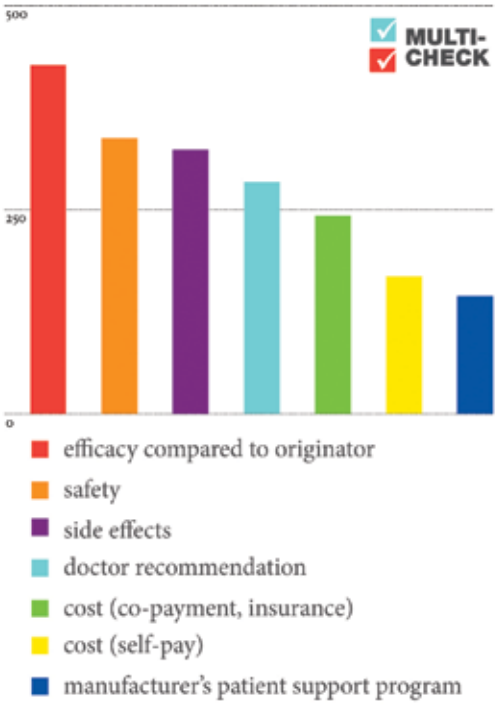
CONCLUSION

Canadians with inflammatory bowel disease who responded to our survey were quite familiar with biologics, in fact, 77% are currently taking these medications. However, while many had heard about SEBs, they expressed confusion and concern around

the use of subsequent entry biologics. In particular, they were concerned about the safety and efficacy of these products for treatment of inflammatory bowel disease, and how Health Canada will regulate them. They do not want these medications for the wrong reasons, that is, simply because they might be less expensive than the originator medications. These individuals are concerned about the possible switching of drugs between the originators and biosimilars, particularly if the government or private insurance plans switch patients to these drugs without their knowledge or consent.

Not surprisingly, 95% said that it was important for their physician to have the sole authority to decide, together with them, the most suitable biologic medicine to use to treat the disease. This patient directive is very strong.

WHAT would be the most important consideration in choosing subsequent entry biologic treatment?



HOW concerning would it be for you if the pharmacist or government/private insurance plan made the determination which biologic (innovator or biosimilar) to dispense to you on **initiation of treatment?**

» 75% said very concerning, 19% said somewhat concerning, 4% were not sure, and 2% said it was not concerning

HOW concerning would it be for you if the pharmacist or government/private insurance plan made the determination which biologic (innovator or biosimilar) to dispense to you **during your treatment**, including maintenance therapy (switch medicines without telling you)?

» 85% said very concerning, 11% said somewhat concerning, 3% were not sure, and 1% said it was not concerning

UNDERSTANDING BIOLOGIC MEDICATIONS

- 77% had at least a basic understanding of biologic medications and were currently taking an originator biologic (Remicade®, Humira®, or Simponi®)
- 76% of respondents had heard about SEBs, mostly from a physician or nurse
- 23% had heard about SEBs from the GI Society/seminar

Health Programme 2014-2020: European Commission adopts Work Programme for 2016

In the context of the EU's Health Programme 2014-2020, the Directorate General for Health and Food Safety (SANTE) has adopted on the beginning of March the Work Programme for 2016.

The funding opportunities include projects and service contracts, as well as Joint Actions planned with national authorities, in priority areas such as:

- Health of refugees and other migrants;
- Tackling antimicrobial resistance (AMR) and healthcare associated infections;
- Support to EU countries to respond quickly and efficiently to health crises (e.g. the Zika virus, pandemics…);
- Supporting the establishment of European Reference Networks, and cooperation on eHealth and Health Technology Assessment (HTA);
- Action on chronic diseases, and risk factors such as alcohol and tobacco; and
- Preventing communicable diseases such as HIV-AIDS, viral hepatitis and tuberculosis

In addition, a number of direct grants will be given, for example to the Organisation for Economic Co-operation and Development (OECD) and the European Observatory on Health Systems and Policies to promote international cooperation on country specific information on public health and health systems for the 28 EU countries. Furthermore, framework partnership agreements concluded with 14 NGOs in 2014 will be continued, and the holders invited to present their work programmes for 2017.

The overall total amount of EU funding available in 2016 covering grants and tenders is nearly €58 million. All grants for projects will be implemented through a call for proposals, organised and managed by the Consumer, Health, Agriculture and Food Executive Agency (CHAFEA) which will be launched in March 2016.

Calls for tenders for specific services described in the 2016 Work Programme will be announced on the Chafea's website.

For more information on the Health Programme, and to read the 2016 Work Programme in full, see: http://ec.europa.eu/health/programme/events/adoption_workplan_2016_en.htm

Background

With a total budget of close to € 450 million for 2014-2020, the Health Programme is the main financial instrument for policy coordination in the area of health and supports and complements Member States' efforts towards the achievement of major Commission priorities. This is done by pursuing the following four specific objectives:

Objective 1: Promote health, prevent diseases, and foster supportive environments for healthy lifestyles.

Objective 2: Protect citizens from serious cross-border health threats by identifying and developing coherent approaches and promoting their implementation for better preparedness and coordination in health emergencies.

Objective 3: Support public health capacity building and contribute to innovative, efficient and sustainable health systems.

Objective 4: Facilitate access to better and safer healthcare for EU citizens, by increasing access to medical expertise and information for specific conditions, also beyond national borders.

Pouchitis therapy: a new option

¨This article looks at a new treatment option for pouchitis that is being developed by the company Atlantic Healthcare, which is currently recruiting for clinical trials.¨

In March 2016, Atlantic Healthcare started patient recruitment into a Phase 3 trial of its novel product, alicaforsen enema, to treat pouchitis. Atlantic Healthcare is a company active in Europe, specialising in advancing treatments for small patient groups experiencing rare diseases where the treatments are often overlooked by large, international, pharmaceutical companies.

There are currently no approved drug therapies for patients experiencing pouchitis. Indeed, the only existing treatment options are those approved for Ulcerative Colitis. It is patients who fail to respond to these UC treatment regimens that require surgery to remove the diseased colon, with the remaining healthy small intestine being reconnected to the anus in the form of a pouch. As such, the use of the same therapies in pouchitis leaves a clear unmet clinical need for pouchitis patients that Atlantic, with alicaforsen, aims to address.

New Medicines for Inflammatory Bowel Disease and Pouchitis

Academics and the Pharmaceutical Industry are constantly seeking new approaches to managing Inflammatory Bowel Disease (IBD). The most common forms of IBD are Crohn's disease and Ulcerative Colitis (UC). Historically therefore, the majority of research has focussed on these two conditions.

However, this is not the end of the story. For UC in particular, surgery may be required as a last resort and it is estimated that approximately 30% of UC patients will have their colon removed (colectomy) and replaced by a surgically created internal pouch, at some point in their life. For approximately half of these patients the pouch will offer an acceptable and trouble-free outcome. However, less fortunate patients may experience Pouchitis – inflammation of their pouch – with symptoms ranging from single episodes (flares) to continuous chronic disease. In this condition patients could suffer from a range of difficult and unpleasant symptoms, similar to those experienced by UC patients (increased stool frequency, urgency to evacuate, blood in the stool, fever etc).

As there is currently no licensed product approved for the treatment of acute flares of pouchitis, the use of antibiotics has become accepted as the normal first line therapy for many patients. Unfortunately, over a period of time, the efficacy of antibiotics declines and patients may fail to respond – they become "refractory" to treatment.

Unlike IBD in general, potential new treatment options for Pouchitis are extremely limited and there are very few in development (see https://clinicaltrials.gov/ct2/results?term=pouchitis&Search=Search).

Alicaforsen is one of very few products currently in development, and the only one in Phase 3 development, the final stage of testing prior to regulatory approvals. The alicaforsen enema offers patients the potential of a safe and effective home-based treatment for acute flares. Evidence from earlier clinical trials suggests that alicaforsen provides a durable response to acute flares, lasting an average of 6 months or more following a single 6 week treatment course. For IBD in general, and Pouchitis in particular, there remain few treatment options, and as such there is a clear need for new, effective, and safe treatments.

Clinical Trials – the regulatory pathway

All new drugs have to be evaluated in clinical trials before they can be prescribed and marketed. The purpose of clinical trials is to generate data demonstrating that new drugs are both effective and

well tolerated. Safety assessments are always made to identify any side effects associated with the use of a new drug.

New drugs are studied in 3 phases of human clinical trials. The Pharma Company will work closely with the Government Regulatory Authorities to confirm that the design, conduct and reporting of these trials meets acceptable standards at all stages.

Typically Phase 1 trials will be conducted in healthy volunteers to assess safety, before moving to Phase 2 studies in patients. These "early phase" studies will provide re-assurance that there are no unexpected serious side effects and allow the trial doctors ("investigators") to map out how the drug is best administered – for example, what is the best dose and how frequently should it be given. Furthermore, these trials are able to determine measurements that best demonstrate efficacy.

Once these basic parameters are known, and assuming the drug has shown promise in early phase testing, the drug will proceed to Phase 3. Phase 3 trials are often described as "pivotal" or "confirmatory" because they provide the final evidence required for the Company to request approval for marketing, and ultimately provision to patients.

To ensure that the results of these studies are robust, a new drug will often be compared with an existing drug of known efficacy (a "comparator"), or against a "dummy" product (placebo). Testing is normally conducted under double-blind conditions, which means that neither the patient nor their Doctor, will know which treatment they are receiving before they enter the trial. The purpose of "blinding" a trial is to prevent any bias creeping into the data, for example as a result of previous favourable (or unfavourable) responses to known medications.

Conclusion

Over recent years, there has been a significant increase in the number of new drugs being tested

for IBD, including such drugs as alicaforsen, with novel mechanisms of action. Alicaforsen offers a very exciting new treatment option which has shown in clinical trials to be safe, effective, and durable even after repeat courses of treatment. This is great news for IBD patients as it will hopefully lead to a wider range of treatment options. This expanding portfolio of products provide physicians a larger and more sophisticated medicines cabinet to treat patients, who all respond differently to different therapies.

More information on IBD clinical trials can be found at ClinicalTrials.Gov (https://clinicaltrials.gov/). This is an easily searchable website that provides a listing of all current clinical trials in IBD.

About Atlantic Healthcare

Atlantic Healthcare is an international specialty pharmaceutical company focussed on diseases of the gastrointestinal tract and Inflammatory Bowel Disease (IBD). The Company's lead product is alicaforsen enema, in Phase 3 development for pouchitis, and in preparation for Phase 3 clinical development for

Ulcerative Colitis. These products are intended for patients under the management of physicians in the hospital and specialist care sector. . Atlantic also operates a Named Patient Supply (NPS) programme, enabling it to supply treatments in response to unsolicited requests from doctors and medical professionals.

NPS is facilitated by the European Named Patient Directive, which seeks to provide access to drugs that have yet to receive marketing approval.

Atlantic Healthcare's Medical advisors comprise leading specialists in Europe and North America in the field of Inflammatory Bowel Disease.

Clinical Trial of Alicaforsen enema

Alicaforsen enema is a new product being investigated for the treatment of pouchitis. A Phase 3, randomised, double-blind, placebo-controlled parallel group study is now enrolling adult patients in approximately 40 specialist hospital clinics across the US, Canada, Israel and Europe.

Alicaforsen works to reduce the levels of ICAM-1, a protein in the body which is involved in inflammation.

Patients that are experiencing an acute flare of pouchitis will be eligible for the study as long as they meet certain criteria. The key criteria are outlined in the "Quick checklist".

Each patient will receive a 6 week course of treatment, and will be followed up for a further 20 weeks. Response to treatment will be based on the patient's symptoms (collected on an electronic diary card) and endoscopy data.

Some patients will receive placebo in the trial, but this will be in addition to their standard medication. All patients, regardless of which treatment they receive in the trial, will be eligible for treatment with open-label alicaforsen post-trial, assuming they meet appropriate medical criteria.

To find out if they might be suitable candidates for the trial, patients would need to contact one of the study locations. Details of the location closest to each patient can be provided on the Atlantic Healthcare website: (http://www.atlantichc.com/patientinfo.htm)

Quick checklist ofr alicaforsen Phase 3 trial eligibility

Key Inclusion Criteria:

- Written informed consent;
- Male or female subjects, 18 years of age who have undergone an IPAA for UC
- History of pouchitis
- Must have failed one or more courses of antibiotics

Key Exclusion Criteria:

- Lack of effective contraception / Women who are pregnant or breastfeeding;
- Recent / planned changes to existing drug usage (ie subjects may be recruited to the study if they are receiving a wide range of drugs, but it is expected that their usage will not change immediately prior to or during the trial itself). Permitted drugs would include: oral 5-aminosalicylate (5 ASA), oral steroids, Immunosuppressant therapy.
- Rectal products (other than study treatment)
- Biological agents: Anti-tumour necrosis factor (anti - TNF) therapy and / or vedolizumab; are not permitted within 8 weeks of the Screening Visit.
- Infections that might cause pouchitis-like symptoms: eg cytomegalovirus or Clostridium Difficile
- Other GI conditions that might cause pouchitis-like symptoms

Ecobiotherapy:

Using microbial ecosystems for a therapeutic purpose

In a recent paper (1), researchers from Canada have coined the term 'ecobiotherapy' to refer to "the use of microbial ecosystems for a therapeutic purpose." The ecosystem need not be fully characterized; it may be an ecosystem as used in classic cases of fecal microbiota transplantation, or it may be assembled from select, isolated bacteria that are chosen for their demonstrated beneficial effects in the host.

Authors told GMFH editors, however, that this working definition may change over time and/or become more specific as this area of research evolves.

Scientists have previously observed a depletion of anti-inflammatory bacteria, particularly Firmicutes, in the intestines of patients with ulcerative colitis (UC). This study evaluated how microbial ecosystems low or enriched in Firmicutes could affect colitis susceptibility and host immune responses in mice. Researchers tested both fecal samples and synthetic mixtures of microbes.

In this study, researchers characterized the microbiota of healthy human donors and those with UC. The fecal microbiota of healthy donors was indeed enriched in Firmicutes, and the microbiota of UC donors was low in Firmicutes. Germ-free mice were colonized with either a fecal sample from these donors or a synthetic ecosystem enriched or low in Firmicutes.

Colitis was induced in the mice with dextran sodium sulfate. Mice with microbiota low in Firmicutes (as in the UC donors) showed an increased sensitivity to colitis, compared to mice colonized with ecosystems rich in Firmicutes. In the mice, low Firmicutes increased the expression of Th17-related genes and expansion of interleukin-17A-expressing CD4+ cells.

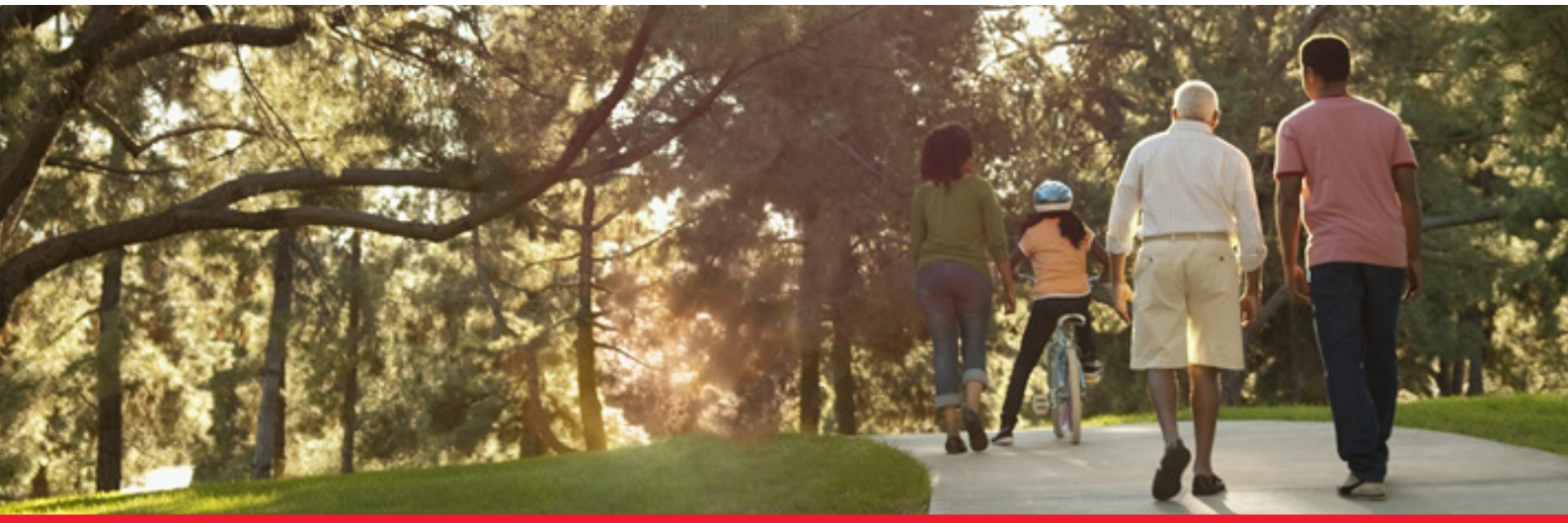
A Firmicutes-rich microbiota — whether it was taken from healthy human donors or put together synthetically — decreased colonic inflammation and downregulated Th17 pathways in mice. These experiments support the use of ecobiotherapy strategies for prevention or treatment of UC.

This artic has been reprinted courtesy from Gut Microbiota Research & Practice, author: Kristina Campbell

1 Ecobiotherapy Rich in Firmicutes Decreases Susceptibility to Colitis in a Humanized Gnotobiotic Mouse Model

Natividad, Jane M. PhD*; Pinto-Sanchez, Maria I. MD*; Galipeau, Heather J. PhD*; Jury, Jennifer MSc*; Jordana, Manel MD, PhD†; Reinisch, Walter MD*; Collins, Stephen M. MD*; Bercik, Premsyl MD*; Surette, Michael G. PhD*; Allen-Vercoe, Emma PhD‡; Verdu, Elena F. MD, PhD*

IronDeficiency.com



YOU MIGHT BE MORE THAN JUST TIRED

- Downloadable fact sheets for patients
- Fatigue survey
- Interactive symptom browser

CHRONIC HEART FAILURE

IBD

COELIAC DISEASE

CANCER

KIDNEY DISEASE

BARIATRIC SURGERY

WOMENS HEALTH

Vifor Pharma

Vifor Pharma, a company of the Galenica Group, is a world leader in the discovery, development, manufacturing and marketing of pharmaceutical products for the treatment of iron deficiency. The company also offers a diversified portfolio of prescription medicines as well as over-the-counter (OTC) products. Vifor Pharma, headquartered in Zurich, Switzerland, has an increasingly global presence and a broad network of affiliates and partners around the world. For more information about Vifor Pharma and its parent company Galenica, please visit www.viforpharma.com and www.galenica.com or contact us at communications@viforpharma.com