EFCCA MAGAZINE

European Federation of Crohn's and Ulcerative Colitis Associations | May 2015

19 May
World IBD Day

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

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

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

Getting our voice heard

Looking back over the past months I am once again amazed by the commitment and dedication shown by the IBD community – EFCCA Member Associations in 30 countries, a Youth Group more and more solid and ready to deliver leaders of tomorrow and … thousands of volunteers - to tackle the many challenges posed by IBD.

The challenges remain immense and the IBD epidemic is showing no signs of relenting, as evidenced by the increasing number of contacts and requests to share information and actions we are receiving from many countries and groups of people of IBD. The prevalence and impact of the disease will continue to grow and we need to keep on working together and amplify our voices.

In this issue we will mainly focus on some of the top priorities of our work plan: patient safety, World IBD Day, our next General Assembly (GA) and our 25th Anniversary. I would also like to pinpoint to an interesting scientific article "Mongersen, an Oral SMAD7 Antisense Oligonucleotide, and Crohn's Disease¨. It concerns a new drug which is showing promising results in the two trials carried out so far. Of course more trials are foreseen but this new drug has become the talk not only of the medical community but the wider Crohn´s community. We will keep you posted on this. I would also like to highlight an interesting series of article exploring alternatives to pregnancy which have been prepared by the EFCCA Youth Group.

I am proud to say that people with IBD are at the centre of our activities and projects and this has resulted in an increasing interest from other organisations and patient support groups to join us. This year, during our 25th General Assembly, we will be welcoming two new members from Greece and Romania to our Federation.

EFCCA is reinforcing advocacy around the importance of fighting against IBD on different levels: the Symposium on Patient Safety on the second day of our GA, on 30 May, is a very important sign of our stronger position in the healthcare community and among the European institutions. We are proud to announce that internationally renowned experts have already confirmed their attendance and we are confident that the proposed debate will offer an excellent opportunity to learn more about biologics and biosimilars and give an opportunity to all our delegates to express their view points, concerns and questions.

Our forthcoming General Assembly will be an important moment for us to strengthen our common work and it will provide us with new opportunities for collaboration as we want to see IBD firmly implanted on political agendas in Europe and beyond.

Editorial and Publication coordination:
Isabella Haaf

Graphic Design:
Isabella Haaf

Contributions:
Áslaug Eva Björnsdóttir, CCFA, EFCCA members, Giovanni Monteleone, Marianne, N-ECCO, Daniel Sundstein, Tine, Victoria Marie

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

May is a very important month for the IBD community. On 19 May World IBD Day is officially celebrated and many of our members are planning exciting activities to raise awareness of Crohn´s disease and Ulcerative Colitis not only on that day but throughout the whole month of May.

Here, in Brussels, we are organising a big team of runners from over 15 different countries to run at the annual Brussels 20km marathon in order to raise awareness. Most of the runners are people with IBD but we are pleased to say that this year they are also joined by gastroenterologists, family members and friends facing the challenging run of 20 km together with them. In the words of our treasurer Martin Kojinkov, who run the marathon last year "we want to show the world that having a chronic disease does not mean you cannot participate in an active and fulfilling life".

Other members have come up with great ideas such as asking public institutions to light up their buildings in purple colours on the 19 of May (in the UK and Ireland). Many of these events will feed into the global World IBD Day campaign that is being organised by EFCCA together with its sister organsiations such as Crohn´s and Colitis of America, Crohn´s and Colitis Australia and many more. We have launched a video campaign giving space for people from all over the word to be heard on 19 of May under the headline #UnitedWeStand2015. You will find out more in this issue.

It's wonderful to see so many countries coming together in our joint effort to raise awareness for these devastating diseases and I am sure we will succeed in our endeavour. I look forward to working alongside you all and to celebrating our 25th anniversary in the hope that our efforts and dreams will lead us to a stronger and more and more effective IBD community.

United we stand!!

Marco Greco, EFCCA Chairman

EFCCA at the 20 km Brussels marathon to raise awareness about IBD

On 31 May 2015, a team of over 45 runners from 15 European countries will participate in the annual Brussels 20km marathon in order to raise awareness about Crohn´s Disease and Ulcerative Colitis, collectively known as inflammatory bowel disease (IBD) and which affect over 3 million people in Europe alone.

The team is being organized by EFCCA and the event will feed into the overall global awareness raising campaign for World IBD Day, officially marked on 19 May, a few days before the Brussels race.

Most of the runners are people with IBD. They are joined by gastroenterologists, family members and friends facing the challenging run of 20 km together with them. "*We want to show the world that having a chronic disease does not mean you cannot participate in an active and fulfilling life*" said last year´s runner Martin Kojinkov, from Bulgaria and member of the EFCCA Executive Board.

"*It's wonderful to see so many countries coming together in an effort to raise awareness for these devastating diseases,*" says European Federation of Crohn's & Ulcerative Colitis Associations (EFCCA) Chairperson Marco Greco.

"We wish our runners good luck on the day and urge everyone to support our cause and make people with IBD more visible".

For more information please contact Isabella Haaf, Communication Manager at bella.haaf@efcca.org or tel: +34 606849937.

Some of the participants after last year´s 20 km Brussels race

Global World IBD Day campaign

This year a record number of countries will join in World IBD Day awareness efforts to highlight the global impact of Inflammatory Bowel Diseases (IBD).

More than 40 countries across the globe are joining together this year in a unified effort to raise awareness about Crohn's disease and ulcerative colitis to mark World IBD Day, held every year on May 19. This year's efforts center around a global video campaign encouraging anyone impacted by IBD to share their story in a short video with the unifying theme of "United We Stand." Worldwide, five million people live with Crohn's disease and ulcerative colitis.

"We are excited to be part of this campaign. The internet and universal appeal of videos, makes this an easy way for everyone to connect and get involved no matter where they are located." says the European Federation of Crohn's & Ulcerative Colitis Associations (EFCCA) Chairperson Marco Greco.

How to get involved!

The campaign calls for anyone affected by Crohn's disease and ulcerative colitis patients, caregivers, gastroenterologists, nurses, family and friends to submit a YouTube video sharing their story. Videos should not be longer than 20 seconds. It should include your name, your city and country, two sentences about how IBD has impacted your life and end with the message "United We Stand in the Fight Against IBD".

For social media, use #UnitedWeStand2015. Videos will be made public on 19 May 2015 and can be viewed on the World IBD Day website (www.worldibdday.org).

"Cases of inflammatory bowel diseases are growing at an alarming rate worldwide, including in some of the most impoverished countries in the world," says Dr. Raymond Cross, Co-Chair of the Crohn's & Colitis Foundation of America's Patient Education Committee. "World IBD Day gives the IBD medical and patient community an opportunity to join forces in the fight to raise awareness and help find cures."

More information: www.worldibdday.org

Videos will be made public on the World IBD Day YouTube channel and the World IBD Day website (www.worldibdday.org) on 19 May, if you would like to submit a video please visit the website for more information.

About World IBD Day

World IBD Day is led by patient organizations on four continents and is officially celebrated on May 19. Patient groups from Argentina, Australia, Brazil, Canada, 28 European nations, Israel, Japan, New Zealand and the United States are working together to raise awareness of IBD.

IBD, which stands for inflammatory bowel disease, is comprised of Crohn's disease and ulcerative colitis — two serious, chronic digestive diseases that affect five million people worldwide. Crohn's disease and ulcerative colitis directly affect the digestive system and cause intestinal tissue to become inflamed, form sores and bleed easily. The disease has a tremendous impact on the physical and emotional well-being.

There is no cure, no known cause, and little public understanding of the pain and chronic suffering with which IBD patients courageously cope every day of their lives.

World IBD Day is coordinated by EFCCA.

Policy roundtable

EFCCA will be involved in the lunch policy roundtable "Managing IBD: the impact of public policies on ensuring patient access to treatments and sustainable management chronic diseases in a more competitive healthcare environment" that will take place on 19 May in the Renaissance Hotel in Brussels.

In line with its mission to raise awareness about IBD and as part of the numerous initiatives organised worldwide for World IBD Day, EFCCA will participate in the debate to give voice to the needs and priorities of people with IBD. This event is supported by an educational grant from Hospira.

EFCCA Annual General Meeting

Brussels, 29-30 May 2015

This month we are going to celebrate our 25th anniversary since the foundation of the European Association of Crohn´s and Ulcerative Colitis Associations. During the last few weeks we have been very busy organising the AGM such as preparing the necessary AGM documentations and organising logistical matters.

We are pleased that out of our 30 members 28 members will be able to join us at this important event where we will present our yearly activities, budget and plans for the future. Elections to several positions in the EFCCA Board will take place and several representatives of the EFCCA Youth Group will present their work and proposals. On the second day of the AGM we are organising a Symposium on Patient Safety, which will also be open to the public and which is generating great interest from our stakeholders (See below).

We are excited to welcome two new members to the EFCCA family, namely the Romania IBD association ASPIIR and the Greek IBD association, HELLESC bringing our total membership up to 32 members including 29 IBD associations in Europe and 3 associate members beyond Europe.

We are going to have an intense but hopefully successful meeting ahead and we look forward to seeing all our colleagues again.

Symposium on Patient Safety, 30 May 2015

Patient safety is a very important subject for EFCCA. It is also a serious concern for many EU Member States and patient safety has becomes a key priority on the European health agenda, both at EU level and in individual Member States.

Within this framework last year we launched a survey entitled BAB – Biologics and Biosimilars to assess patients knowledge about biosimilars and to find out to what extent patients are aware of the issues involved around biosimilar medicines. The scientific coordinator of the BAB survey is Professor Laurent Peyrin- Biroulet - from the Department of Hepato-Gastroenterology CHU in Nancy, France.

During the Symposium on Patient Safety, which will take place on the second day of the EFCCA Annual General Meeting in Brussels, the 30 May, we will provide an interim report of the BAB survey sharing some of the preliminary findings.

We have also invited two physicians to present the issues around Biosimilars and Biologics. Professor Maurizio Vecchi, Associate Professor of Gastroenterology, University of Milan, and Director of Gastroenterology and Gastrointestinal Endoscopy Unit at IRCCS Policlinico San Donato Milan, will present the state of the art as concerns biosmilar medicines and Professor Matthieu Allez, Head of Service, Department of Gastroenterology, Saint-Louis Hospital, APHP Université Denis Diderot Paris, will give his viewpoint on biological medicines.

Professor Julian Panes, the ECCO Elected President, will be the moderator of the panel discussion. Other participants will include Ms Hilda Juhasz from the European Commission, DG Enterprise, who has been involved in the publication "What you Need to Know about Biosimilar Medicinal Products".

This publication was prepared in order to provide the different target groups with adequate information on biosimilar medicinal products. Under its Platform "Access to Medicines in Europe", Member States, EEA countries and relevant stakeholders were invited to a project group on biosimilar medicinal products in order to take stock of the availability of biosimilar medicinal products in European national markets, and to define the necessary conditions for an informed uptake and adequate patient access to these products. This project group, in close co-operation with the Commission services, decided to prepare this information paper including a specific Question & Answer part targeting patients, physicians and payers. The European Medicines Agency contributed to the paper within their responsibilities and competence. The paper is a consensus document agreed by the project group Market Access and Uptake of Biosimilars and adopted by the Steering Group of the Process for Corporate Responsibility in the field of Pharmaceuticals.

We have also invited representatives from the World Health Organisation and the European Medicine Agency and we are waiting for confirmation.

The objective of this symposium is to have an open discussion on the two different positions for using biosimilars or biologics medicines whilst receiving first hand and accurate information.

We think this is a very important opportunity for our members to learn more about the topic and to actively contribute in the discussions on these very important issues and to share them with the wider IBD community.

The Symposium is the first public moment this year of a wider work programme and EFCCA is planning further events and targeted training sessions addressed to its members in order to enhance knowledge and skills for people with IBD.

For more info contact the EFCCA office.

Launch of the Patients' Informal Communication Network

EFCCA joined the Patients´ Informal Communication Network that has been launched by the European Patient Forum early March this year. The network is made up by people in charge of communications of their respective patient support groups within the EPF membership.

The objective of this Patients' Communication Network is to have a place where those responsible for communication can share all their news and activities and to be more successful in communication activities by receiving a boost from their peers. The idea is to exchange information that can benefit the entire patients' community and not to put own interests ahead of the others' interests.

It is very difficult for patients' organisations to stand out from the crowd given the huge number of existing interests groups in Brussels and limited resources of patient support groups. Having a network of communication people will help to disseminate information more rapidly and easily to make our voice heard in the mass and reach the grassroots community.

The network will take shape through physical and virtual meetings of the communication people. It will not be mandatory to attend all meetings and it will be possible to join the group for those who are not Brussels-based for free via teleconference.

The first meeting took place on 2 April and gathered representatives from 9 different disease groups. Participants identified the following challenges in terms of communication:

- Limited space at European level to disseminate patients' & health activities
- A lot of information – how to stand out from the crowd and communicate scientific information effectively to our target audiences?
- Members diversity – difficult to engage our members as different resources and needs

Participants were in agreement that the informal network could be beneficial to all, allowing membes to learn about initiatives and activities that others are doing at the moment. It would also allow for an exchange of information on advocacy practice and ideas on new and successful ways to share communication activities. It was agreed to meet on a regular basis once a month.

13th EGA-European Biosimilars Group Conference

Marco Greco, EFCCA Chairman, participated in the EBG Conference on 23-24 April, in London, as panel discussant. This international conference, organised by the European Biosimilars Group aimed to offer in-depth overview of biosimilars, to present the current key topics, and update on the latest regulatory and market developments.

Marco Greco together with representatives from the European Patients Forum and the International Alliance of Patients' Organisations represented the patients' perspective in the panel discussion "Multi-stakeholders' approach: how to work together around the introduction of biosimilars"

For EFCCA this represents a further opportunity to give voice to people of IBD about these topical issues.

Life with IBD: Exploring alternatives to pregnancy

During an EFCCA Youth Group (EYG) meeting about one and a half years ago we decided on a series of topics to be included in the EFCCA Magazine. The overall topic we decided on was "Breaking down taboos" since we all have experienced difficulties regarding taboos around IBD and living with this chronic disease.

You may already have seen or maybe also read the previous articles from the EYG regarding pregnancy, being a parent with IBD and being a parent to an IBD-patient. These have all been topics facing some of the obvious taboos in an IBD life. Many people with IBD not only face issues such as having to deal with medication side effects and surgery. When it comes to intimacy with another person we also face many difficulties considering that our disease involves faeces and visible scars that only come forward when taking off one´s clothes.

People with IBD have a higher risk of being childless because of all the above mentioned factors. Luckily, the higher risk is minimal but men and women with IBD still exist and we want their voices to be heard aloud and taboo-free. I hope you enjoy as much as I did reading the two brave interviews below. They are excellent and unique and they allow you to better understand the struggles, frustrations, tears, disappointments and happy moments these women went through, but also how they used their experience with IBD in the best possible way.

We in the EFCCA Youth Group are all young people. We haven't yet adapted to these diseases or this life situation, neither to Crohn's Disease nor to ulcerative colitis. Through these 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 these stories, remember them and tell them to your friends, relatives, doctors and whoever is willing to hear your story.

My IBD made me stronger

Interview with Tine

Tine, from Norway, is 42 years old and has no children of her own. She has been seeking for adoption for 10 years. She was diagnosed with Crohn´s disease in the beginning of the 80s. She previously worked as a pre-school teacher, but now is unable to work because of her disease.

How has Crohn´s disease affected you?

Since my childhood I had very aggressive symptoms of Crohn's disease and because of that I had many surgeries which left me with about 1 m of small intestine. I've had also some of the large intestine removed. One of the surgeries led to serious complications, which have affected me very much but it has led me to be who I am today. I have a great and big network of friends with IBD, they are all very important to me and make it easier living with a chronic disease.

What made you consider adoption?

There has always been something wrong with my health as long as I can remember, so I didn´t think that getting pregnant would be easy. Indeed, it was

difficult and after trying for couple of years to get pregnant we realized that it probably wouldn't work the natural way.

We talked to several doctors and my previous surgeons told us that it was unlikely that I got pregnant the natural way because of all the complications I had, especially after one particular surgery. The doctor decided to apply for assisted insemination (IVF). We were very hopeful in the beginning but this treatment proved to be very exhausting. It was a huge stress on my body, but luckily during this period my Crohn´s disease was in remission.

Tine, 42 years, decided to go for adoption after several IVF treatments failed

After seven tries with IVF and no positive result we decided to end the treatment. It was a relief when it was over although it wasn't a "positive" result. It had been a big psychological burden and I felt low a lot of the time. My body was tired afterwards because of the hormonal treatment.

It was also very difficult because at my age it seemed that "everybody" was getting pregnant and not only once but several times. It draws on you when you have to hide your own sorrow of the situation in front of others who just want to share the "good" news about their own pregnancy. We decided early on to go for adoption if the IVF treatment didn't succeed. When we finally got in contact with the adoption agency in 2005 we got our hopes about being parents renewed.

Has your chronic disease affected the application process?

When you decide to adopt you must receive a report from the Children and Family Department of your municipality. This report also recommends whether you are fit for adoption or not. It needs to then be approved by the Children and Family Department at national level before you can apply for adoption in a foreign country. Each country has different requirements for the applicants. We chose to apply for adoption in China.

The excitement was big when we had to start the process in our own municipality where we had a lot of interviews in order to be approved. The donor country has its own specific demands and Norway has its own specific demands.

When you are chronically ill and disabled, as I am, you don't feel that you have the best cards in your hand. And your state of health is one of the examination points in the application process. The officials from the municipality talked a lot to us about my health situation. They came to visit at our home and we went for interviews to their offices. They had interviews with us together as well as separately in two rooms where we couldn't communicate with each other. This particular interview gave me a feeling of being under suspicion for not speaking the truth. We were a bit scared that they wouldn't recommend us because of my history of health. You never know, right?

When you are chronically ill and can't have a child of your own, then you have an invaluable experience both about yourself but also as a couple. The childlessness was not our first adversity in life. In many ways being chronically ill makes you stronger: you must plan every day, there are constant changes you must adapt to, you must deal with the health system and public institutions, you meet many

disappointments and you realize that sometimes you can't control your own life. One learns to live in good as well as in bad times.

The fact of showing strength while being chronically ill, was what we wanted those officials to write down in their report, but I got a little insecure about their view of a "chronically ill human being" and what their thoughts were about living with this chronic disease. Chronically sick persons have a unique experience which many other people don't have and this ability can be used in other situations. We finally got our recommendation from the municipality. They wrote in the report that the experience we had because of the health problems would support us in our role as parents. We also got approved by the State.

How much of an emphasis is put on health in the application process for an adoption agency?

Health is an important issue when applying for adoption. The Norwegian adoptions rules demand health certificates, which is a standard procedure for all applicants. It is your General Practitioner who fills out the certificate and he/she must inform about any serious physical or psychological diseases and include some words about your health history. A prognosis for the next 20 years must also be included. A full examination with blood pressure, hearing and sight must be done. If you have any chronic diseases or reduced ability to work a report must state whether you are fit to handle everyday life and your ability to take care of a child, both in the short term and long term. You must also fill out a health scheme, self-answering a lot of questions about your health.

My IBD specialist has also given me a health declaration as a supplement to the medical declaration for the Children and Family Department which was put in the application. I had also given the authorities permission to receive information from both my doctors and from the labour authorities.

Does the Norwegian adoption agency have their own rules about chronic illness or is it the adoption countries?

Norway has its own adoption law and all Norwegian adoption agencies must follow these laws when working with adoption procedures. It is the social authorities who will approve an applicant.

Do you know if there are adoption countries that allow people with a chronic disease such as IBD to adopt?

I don't know if there are any rules or laws that says that an IBD-patient cannot adopt. I think it is more an individual evaluation of the health situation based on a case to case evaluation.

How long did your process take?

We started the process with our municipality in 2005. Unfortunately they misfiled our case, so it took much longer than usual and we only got our approval from China in the winter of 2007.

We have been in the process for adoption for 10 years now. This is due to a very long waiting list in China where they have almost stopped with foreign adoption. It is a very slow process and we don't know if we get to adopt at all. What we know is that the earliest possible time is in 2016.

There is no doubt that this is a very exhausting process to go through. It is an extra stress factor to worry about your health being an issue also. This will also have an effect on your partner's destiny if you are not getting approved or you can't get or have a child.

We have learned to live childless unwillingly and it goes much better now than before. Life is meaningful without a child. If we should stay childless we will be happy just the two of us and we have a lot to look forward to together. In a way as a couple we have become very connected because of the childlessness and health problems.

If there are no other options...

Marianne from Norway is 36 years old, married and has two young girls. She has managed to have these girls with the help of a surrogate mother. She´s been diagnosed with Crohn's disease since 1996.

How has Crohn´s disease affected your life?

I have a very aggressive form of Crohn's disease and I have had 11 surgeries. For about 8 months I had an ostomy but I got Pyoderma Gangeosum around the ostomy and luckily it was possible to reverse the ostomy. It was really painful and the bag didnt sit on the skin properly not even one day. When this happened I stopped eating and drinking because the pain was unbearable. The skin was operated many times and I was in and out of hospital countless times during that phase.

I always had problems and my doctors struggle to find medication to keep me healthy. I have tried almost everything and now I have an "okay" life with Humira. I always have to be close to the toilet because I only have 2,5 meter of intestines left and I am also having problems with fistulas for which I have been operated between 50 and 60 times. I am now in a new program in Tromso Hospital in Norway where a plastic surgeon and gastroenterologist work together to get the fistulas to heal. So far nearly 50% of my fistulas have healed. I hope the rest will also heal when I return to hospital. It will be my 4th round of treatment.

What made you consider alternatives to pregnancy?

I was advised to get pregnant and advised against it. We tried IVF without luck several times. I think it´s my body that decides if I am healthy enough to get pregnant or not. My body was not ready for pregnancy and the quality of my eggs was also bad. Every time the IVF didn't work I was very disappointed. Also the idea of giving birth scared me because of the risk of rupture knowing that I don't heal in that area. Having a C-section in my stomach also didn't seem very attractive consideration the amount of times I have been operated on. My belly is already full of scar tissues!

We looked into the possibility of adoption but we found out that even if we got approved in Norway it was not certain to get approved in the adoption country. It could also mean years of waiting and eventually getting rejected. We felt my age had to be taking into consideration and that's why we started our research into having a surrogate mother for the child.

How much of an emphasis is put on health in the application process of a surrogate agency?

I had to inform the agency about my health condition and they received several reports from our doctors. We also had to give blood samples and I had to go through gynaecological examinations that had to be sent to the doctors in India where we were looking for a surrogate mother. We also had to fill out a lot of information about ourselves.

Does having a chronic disease affect the application process?

No, it did not affect our process but I believe this could be the case when you are looking to adopt. That´s why we decided to choose a surrogate mother.

How long did your process take?

We spent about a year in researching and figuring out which country and which clinic we wanted to use. For us it was important that the surrogate mother was really taken care of well, that we had contact with her and that she would have a good pregnancy. My eggs were used for this process and we finally got pregnant after one unsuccessful attempt, so our daughter was born within 2 years of starting this process. She was born in 2010, after one year our surrogate mother wanted to help us again and our second daughter was born in 2012.

How did you feel throughout the process?

Well, it´s a tough process. Not being able to be there where your child is was hard. It was not possible for us to be there throughout the whole pregnancy because of Indian visa rules. We were there just before the first pregnancy. We had our ups and downs but it was mainly a good experience and what a fantastic day when we finally got our first daughter in our arms.

Would you recommend going through this process for others with IBD ?

If there are no other options, it's good to know that you have an alternative. This is not for everyone and you have to remember that it's not us, the people who want the child that are the ones to be considered most. It's the surrogate mother who´s the most important player in this. You have to trust each other and believe that they make the right decisions if anything happens.

"My body was not ready for pregnancy. Every time the IVF didn't work I was very disappointed. We looked into the possibility of adoption but we found out that even if we got approved in Norway it was not certain to get approved in the adoption country (...) that´s why we started our research into having a surrogate mother for the child."

Did you get any support in this process?

We had skype meetings with our surrogate mother and our doctor throughout the whole pregnancy. We also got weekly updates on mail. Sometimes we even talked on the phone with the doctors.

Any other comments or something you would like people to know that are in the same position you have been in?

Never give up, there is always hope! It might just take a little longer then you hoped for, but it is totally worth the extra wait.

EFCCA Youth Group Meeting

Our annual EFCCA Youth Meeting (EYM) will take place from 16-19 July 2015 in Tampere, Finland. Below you have the first announcement with more details and we look forward to seeing you there.

During this meeting we are planning to have the following two workshops:

"Transition from IBD-child to IBD-youngster"

We want to engage youth delegates in a bigger discussion on the transition phase from being a patient and child to being a patient and an young adult in the different European countries. How is the system working in matters of changing department in hospitals, changes in the life situation in terms of changing school, moving away from home and maybe also changing from a paediatrician to a gastroenterologist? After the discussion we will try together with the delegates to create a list of what we as a youth group propose being the best solution/ advice for young people in such a transition phase.

"What should a national association do to attract young members?"

This subject will also be presented briefly at the EFCCA General Assembly. We aim to present to national representatives what we think is important to do when engaging young members in the national boards and work in a voluntary patient organization. During the EYM 2015 we will have a bigger discussion with the delegates about what they think the national associations should do, what they should offer to attract young people to work in the organizations and what they expect of the national committee on how to maintain them in this work. After this we will make a list on best practises.

The first announcement to the
18th International Meeting for Young People with IBD

EYM 2015 - Finland

Tampere, Finland, 16 – 19 July 2015

http://www.efcca.org
contact: daniel@sundstein.dk

Welcome to Finland!

The CCAFIN, in collaboration with the EFCCA Youth Group (EYG), and EFCCA are pleased to announce that the annual meeting for young people with ulcerative colitis or Crohn's disease in Europe will take place in Tampere, Finland from **16 to 19 July 2015**!

Programme

As always, the meeting is designed to be educational, interactive and also fun. You can expect:

- Interactive workshops
- Learning sessions about the different associations in Europe
- A sporting event!
- A gala dinner, on our last night
- Visits to the local area, after the meetings of the day
- News about EYG projects, and ideas of how you can contribute
- We aim to have fun whilst learning, working together and sharing ideas as a friendly and understanding community.

The official language for the event will be English.

What to do now...

- Contact your national association and inform them about the next EFCCA Youth Meeting.
- Check with your national association to decide who will be your associations 2 delegates this year.
- After the deadline on June 10 you will receive the official paper including an additional registration form, fill this in together with your national association.

Serbia

UKUKS – Serbian Association for IBD

It has been a busy couple of months in Serbia. We had a lot of activities, most important of them being our education project for doctors. It has been conducted in 8 cities so far, with 3 more cities to follow.

Our accredited education program has been presented to around 300 gastroenterologists, general practitioners and other interested doctors. The team of our associate gastroenterologists is doing presentations that contain general information about IBD, its symptoms and recommendations for treatment and a part is devoted to IBD in pregnancy.

UKUKS also conducted a pharmaco - economical study, which is built around the costs of IBD treatment in Serbia. It was done with a questionnaire that our association distributed to our members. Professor Slobodan Jankovic has processed the statistical data received. The results of this study will be presented on World IBD Day.

Most of our work is being followed up by the media under the catchphrase "so that life doesn't stop" (almost literal translation), which has found good acceptance with patients but also the public and the professional sector.

UKUKS has become a member of the commission for approving biological treatment in IBD. We follow and contribute to its work with our observations. UKUKS has been one of the associations to attend the meeting with the Director of the National Fund for Health Insurance, and has been invited to a "one on one" meeting in the near future. The purpose of the meeting will be to consider more treatment options for IBD patients in Serbia.

From left to right: Dino Tarabar, gastroenterologist, Jelena Tomic, UKUKS member, Zeljko Gardlo, HUCUK chairman (Croatia) speaking during last year´s World IBD Day conference.

UKUKS has an associate psychologist, Dr Lela Trikos, who provides psychological counselling with our members. She has prepared some work on how to behave and adapt to problems that IBD patients meet in every day life, such as school, at work, emotional problems etc.

We have so far published several brochures including publications on how to live with Crohn‘s, how to live with ulcerative colitis and a dietary brochure. We are currently preparing a brochure for parents who have children with IBD.

Visit our redesigned website – www.ukuks.org. It now pulls a Facebook stream from our page so it always has some fresh data and information.

Stefan Djakovic UKUKS

Iceland

A different tummy-ache

In autumn of 2014, the Icelandic Crohn´s and Colitis Association (CCU samtokin) published a booklet about Crohn´s disease and Ulcerative Colitis aimed at young children. This booklet is based on a children´s book that the Finnish association, Crohn ja Colitis ry, published in 2012.

We had seen this Finnish book during one of our Nordic meetings and it was really nice and cheerful. We thought that such educational material for young children would also be very useful in Iceland and we got permission from Finland to publish the book. The illustrator of the Finnish book is Eeva-Kaisa Suhhonen, but by sheer coincidence, she is married to an Icelandic man and they live in Iceland. In cooperation with her, we decided to change the story a little, both shorten it and add new pages and adapt it to Icelandic circumstances. The outcome was this booklet about Anna and Elias. The name of the book translates as „ A different tummy-ache“.

The association decided to send the booklet for free to all its members, because we felt it was well suited both for sick children and/or sick parents with young children, to help explain how mom or dad felt. It was also sent to all elementary schools and kindergartens in Iceland and was formally delivered to the Children´s Hospital on January 5th 2015.The booklet has been very well received and we have gotten a lot of positive feedback. Much so that we have already established a connection with Medikidz to publish a further book about Crohn´s and Colitis in Iceland.

CCU Iceland.

Romania

Happy Day for You

From 15th-25th January 2015 the Romanian IBD association ASPIIR organised in partnership with Duha Tangram from Prague the project "Happy Day for You". The project has been funded by the EU under the Erasmus+ programme 2014-2020.

Teenagers suffering from inflammatory bowel disease (IBD) tend to become prisoners of their home, as they have to manage flare ups, which heavily impact on their personal and social life. This might result in loosing self-confidence and self-respect leading to self-isolation. The Romanian IBD association ASPIIR initiated this project to address this issue and to focus on social inclusion, on encouraging communication, on confidence building and on overcoming the boundaries generated by a chronic disease or by a disability.

The "Happy Day for You" project included 10 teenagers from Romania, Spain and the Czech Republic. Some of these teenagers had chronic diseases, some had other disabilities and some were healthy teenagers. They all participated in a ten day circus workshops, where they learned to help each other, to respect each other, to be freehearted and to talk about the health problems they were dealing with. Through playing and specific circus techniques under the guidance of specialized trainers, we strengthened the team spirit and had a great time together. We laughed a lot and thus created an environment where people lost their inhibitions caused by diverse diseases. We also had the chance to discover and enjoy Prague's delightful and historical places.

Queuing up for the circus practise

Our mission is to help patients live a better life

Shire's mission

Shire is one of the world's leading specialty biopharmaceutical companies - but, more importantly, we make a difference to people with life-altering conditions, enabling them to lead better lives.

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 (R&D), has resulted in considerable growth and diversification.

Shire's focus on improving outcomes for patients with 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 and chronic constipation.
- Shire is determined to build and maintain relationships with patient advocacy groups, both through providing 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/IN/MEZ/14/0035 Date Of Preparation: April 2014

Awareness raising campaign

ASPIIR is carrying out a campaign to increase awareness about inflammatory bowel disease and its risks and implications, which will run throughout 2015.

It´s planned in various towns of Romania and in March we organized such an event in Calarasi, a town in the South-Eastern part of Romania, where we also showed our art exhibition "Perspectives: Art, Inflammation and me" (as previously reported in the EFCCA Magazine). The exhibition was held in the the Calarasi Municipal Museum and people could see it from 19th March to 5th April 2015.

Isabella Grosu, president of ASPIIR, speaking during the opening event of "Perspectives: Art, Inflammation and me" exhibition in Calarasi

During the opening event on 19 March 2015, we invited several representatives from the local authorities such as the chairwoman of the Calarasi Physicians College, from the health authorities but also the culture department as well as artists, teachers and people in general who we thought could contribute to the better understanding of the implications related to a chronic disease, such as IBD, and to understanding the role of art as a form of expression, of awareness, the role of art in transposing dramatic experiences into artworks with moving messages.

Moreover, some young students from the "Trepte" theatre supported us in increasing awareness through some artistic performances.

Isabella Grosu - president ASPIIR

Slovakia

Patient – doctor seminar, Košická Belá

Last year, on the occasion of World IBD Day, the Slovak Crohn´s Club organized a three day workshop in Košice in Eastern Slovakia which took place from 8-11 May 2014.

The workshop was open to IBD patients and their families and looked at different treatment options and latest therapeutic developments in IBD. Presentations were made by gastroenterologists from Košice and Prešov and chaired by Dr M. Zákuciová, first Vice-president of a gastroenterologist company in that region.

The workshop was filled with interesting lectures and gave plenty of opportunities for patients to ask doctors more detailed information and to discuss common concerns and worries. The workshop was followed by a sightseeing tour of Slovakia´s second biggest town and we also climbed up Folkmar rock with a breathtaking 360-degree view over valleys, hills and the Ruzin dam.

Slovak Cohn´s club

France

Keep moving!!!

Chantal Dufresne, President of AFA, opened the 2015 AFA General Assembly with the words, « KEEP MOVING! », as she enthusiastically listed all of the 2014 achievements and announced the numerous projects to take place in 2015.

The highlight of the 2015 GA was, as usual, the presentation of the 13 research grants for a total of € 240 000. All the recipients were present and the members of the AFA Board of administrators had the pleasure of handing the grants to each one. The most unusual one this year was the study which Professor Bruno Bonaz will carry out on relieving intestinal pain through hypnosis and his work on stimulating the vagus nerve: "When the intestine is connected to the brain".

He gave a talk on his work to explain the processes and the way he undertakes this study. The other project worth mentioning is the work on the influence of physical activity on reducing fatigue from IBD. Professor Guillaume Savoye in Rouen is heading this study.

We were fortunate to learn that many new research projects are getting underway with members of the AFA Scientific Committee at the head of each one. Prof. Laurent Beaugerie introduced the project with GETAID on the benefits/risks in biotherapy including 800 gastroenterologists from 17 countries. Prof. Laurent Peyrin-Biroulet presented the first results of BIRD on the study of the impact on daily life with IBD. He was also elected new president of the AFA Scientific Committee. AFA is very proud of its team and looks forward to a very busy, intense and stimulating year ahead in France!

New AFA Scientific Committee with AFA President, Chantal Dufresne (right) during the General Assembly 2015

Afa launches new info campaign: “Who is the champion?”

Around the date of the World IBD Day next 19 May, a large information campaign will be launched by AFA and its partner, ABBVIE.

The objective is to raise awareness in supporting patients suffering from IBD and to salute and acknowledge their courage and determination faced with the consequences of their disease, handicapping them as much as thrusting them into the unknown. A radio campaign with soundbites of TV and radio celebrities whose well known voices will emphasis the message, in the press, on bill boards and on the AFA website. The campaign is entitled « They deserve first place! » documenting real life patient accounts of their lives with IBD.

The aim of the campaign is to value and not stigmatize the patients who fight daily to live a better life…to value their «small and big success stories», their enormous efforts, which no one seems to notice. It’s a campaign to illustrate the daily challenges that face people with Crohn’s disease and ulcerative colitis, whether at work, at school, in social life... These IBD patients deserve to be in first place!

An example of one of the three settings: The scene of a children’s race.

Who is the champion?

In the foreground: the winner reaches the finish line.

In the center: the second child hasn’t yet reached the finish line and finishes his race.

We would normally think the champion is the one who gets there first, but in fact, this morning, Nicolas is the real champion!

Chantal Dufresne, President – AFA France

Poster translation

«Who is the champion?”

«Nicolas, 9 years old with Crohn’s disease, deserves first place»

«Despite the abdominal pain he suffered from the day before the race, he managed to finish the race.»

Crohn’s disease along with ulcerative colitis are intestinal bowel diseases affecting 200 000 people in France, of which 20 000 are children.

AFA, France

NICOLAS, 9 ANS, ATTEINT D'UNE **MALADIE DE CROHN*** MÉRITE D'ÊTRE AU PREMIER PLAN.

Malgré les douleurs abdominales qui le tiraillaient la veille de sa course, il a franchi la ligne d'arrivée.

*La maladie de Crohn, comme la rectocolite hémorragique, fait partie des maladies inflammatoires chroniques de l'intestin qui touchent près de 200 000[1] personnes en France, dont près de 20 000[1] enfants.

POUR EN SAVOIR PLUS
RENDEZ-VOUS SUR
www.cestquilechampion.fr

afa Vaincre la maladie de Crohn et la rectocolite hémorragique | abbvie

[1]Maladies inflammatoires chroniques de l'intestin : l'ère des biothérapies, traiter les MICI au-delà des symptômes - Laurent Peyrin Biroulet - Monographie - La revue du praticien - Novembre 2014.

Cyprus

“What do you know about Crohn´s Disease and ulcerative colitis?”

In recent years we have observed a growing interest in Crohn’s and Colitis diseases from our members in Paphos, so we decided to organize an information conference and also an introductory meeting in Paphos.

This conference was held with great success on March 21, 2015, under the title “What do you know about CROHN’S disease and ULCERATIVE COLITIS?”. Special thanks are given to Aliathon Holiday Village hotel management who hosted our conference, offering great assistance and support to our association.

In his opening speech, the Mayor of Paphos, Mr Phaedon Phaedonos raised interesting issues such as the importance of cleanliness in public toilets and the need to increase the number of public toilets in the municipalities. He also referred to the case of an employee of Paphos Municipality who is an IBD patient and the positive treatment that he had from the municipality. Finally, he expressed his support to the Association for its efforts to ensure a better quality of life for patients.

The Association always attempts to urge patients to speak freely about their problem without fear of stigmatization and to share their experiences with

Board members with the Mayor of Paphos (in the middle) and the gastroenterologist Dr Theodora Demetriou (first on the left).

others. So this year in Paphos, one member of our Board, Ms. Elena Stylianou, shared her own interesting experience with Ulcerative Colitis from which she suffers for a number of years.

The second part of the conference included a presentation by Dr. Theodora Demetriou, Gastroenterologist of Paphos General Hospital. Through her presentation, among other very interesting topics, she gave detailed information on latest medication, specialized drugs and guidelines followed by ECCO for women during pregnancy.

Natasa-Revekka Theodosiou, CYCCA

New Zealand

Our first summer camp

On January 25th 2015, 45 children (aged 9-19 years) from throughout New Zealand gathered in a small conference room on the mezzanine level of Auckland airport. It marked the beginning of a week long camp, the first in New Zealand for kids with Crohn's disease and Ulcerative Colitis.

It was an uncomfortable beginning. The majority of the kids arrived on their own and did not know anyone else in the room. For most of the children, it was the first time that they had been in the company of someone their own age who shared the same condition.

By the end of the week the change was dramatic. Being with other kids on the same medications, with the same symptoms, and the same challenges, allowed the children to relax, develop strong friendships, and a sense of belonging that is difficult to convey in words. Activities were challenging and included laser tag, rock wall climbing, rope courses archery, and a confidence course.

The camp was conceived and run by Crohn's and Colitis NZ (CCNZ) and represented over a year of hard work by a small committee. The cost of the camp, including airfares, as well as a two day networking and educational seminar attended by twenty parents, was entirely underwritten by CCNZ.

There were several challenges, especially for an organisation which was established only five years ago. Money needed to be raised, policy and procedure

medical manuals written, campers and volunteers recruited, and medical personnel approached to staff the camp. The list of things to do seemed endless. Planning a full week of activities, arranging transportation for campers and volunteers from all over the country, deciding how to administer medications, and obtaining and reviewing the medical histories of each child.

But committed volunteers often do what others might consider impossible.

The feedback from the campers was overwhelming and we truly believe we made a difference to the lives of many of these kids. In a post-camp questionnaire 100% of the children responded that they would recommend the camp to other kids with IBD. Every volunteer has volunteered again for next year!

One child captured what the camp was all about:

"I enjoyed talking to other kids going through the same conditions as me because I didn't know a lot of people with Crohn's, because I am the only person in my family with Crohn's disease. It's not that I want more people with Crohn's, but I loved knowing that I wasn't alone. I loved all the activity's not only because they were fun but because it made everyone trust one another more."

You are invited to watch a video that appeared in the NZ Herald:

http://www.nzherald.co.nz/life-style/news/video.cfm?c_id=1503081&gal_cid=1503081&gallery_id=147807

A heartfelt thanks to all our volunteers and medical team for their hard work and commitment in making Camp Purple Live such a success. The warmth, caring and leadership demonstrated cannot be overstated.

Special thanks to our principal sponsors Jetstar, Auckland Round-The-Bays Run, Janssen, AbbVie, and Pharmaco and to the NW Chapter of the CCFA for their help. Your support and generosity helped make our dream become a reality. Now we are looking at Camp Purple Live 2016!

Crohn´s and Colitis New Zealand


abbvie
OUR NAME HAS CHANGED.
OUR COMMITMENT TO GASTROENTEROLOGY ENDURES.
The partner you once called Abbott is now AbbVie. Our name has changed but our commitment to join you in improving patient care does not. We stand by our promise to develop and deliver innovative medicines and work with you to elevate the standard of care in the treatment of inflammatory bowel diseases.
abbvie.com
©2013 AbbVie.

Take a walk in my shoes...

by Victoria Marie, a blogger, fundraiser and campaigner who over the past few years has been on a whirlwind of a journey. Colitis and ME is her chance to talk openly and honestly about her illness and the turbulent journey she faces in coming to terms with a life long incurable illness.

When you're young you don't think about being sick, you think it only happens in later life. You go day to day working too hard, partying a bit much and shopping until you drop. I was enjoying a hectic life running from one job to the next, one party to the after party, one sleep over with the girls to the next. I was 21, beginning to travel to different places and starting to figure out who I was as a person... finding my feet. I was beginning to feel comfortable within my own skin, just setting out in life. Then all of a sudden all I had ever known came to a stop and everything I had ever known came crashing down around my ears. Something happened that meant never again would I be the person I was only just starting to get to know.

Almost six years ago now I was diagnosed with Ulcerative Colitis and it changed my entire world. All that you thought you knew about life – forget it. All of those plans you have in your calendar – clear them. All that you thought you had planned out on the table – forget it all. Life is about to change forever, and no you don't get a say in it at all!

You may have heard about Crohn's Disease or Ulcerative Colitis (both forms of Inflammatory Bowel Disease) in the news recently so here is a little more about them and firsthand experience of my journey with Ulcerative Colitis.

The cause of Ulcerative Colitis and Crohn's Disease are still very much unknown as each case is unique to the individual but are thought to be down to an imbalance of bacteria in our guts/colons. In the average person there is 'good bacteria' fighting off the 'bad bacteria'. When it comes to those with the illness its thought our good bacteria is working overtime and trying to fight off an infection (the bad bacteria) which does not even exist. So instead of attacking the bad bacteria it attacks the wall of our intestines instead, this leads to inflammation, ulcers, cramps and pain.

The main symptoms just to get you up to speed are fatigue, more trips to the loo, loss of appetite, weight-loss, swollen joints and many more. Not to mention all of the secondary symptoms from medications and problems caused by taking them long term. Alongside these there are things such as anaemia, anxiety, depression etc, the list is endless! This results in extensive trial and error to find a medication to soothe the symptoms but as of yet there is NO CURE. Some unfortunate souls end up having to have serious invasive surgery to avoid blockages, ruptures and all sorts of complications. Removing someone's colon is a drastic treatment option, not a cure; there are far too many now living without parts of their colons/intestines.

"Creating my blog opened up a whole new world that I never knew existed and has provided me with so many wonderful opportunities to advocate on behalf of the 5 million people tackling IBD every single day."

I started nipping back and forth from the bathroom, I didn't think anything more of it; I assumed I had an upset stomach. I was too afraid and highly embarrassed to talk about it so I simply stuck my head in the sand and did nothing about it. BIG MISTAKE! I left it – I just ran back and forth to the bathroom all day and night long. I threw up continuously, suffered numerous fevers and had no appetite though I was starving inside. I shoved my head under the duvet, where I spent every day too weak to move thinking I was dying. In the end I was 6 stone thin and bones when I EVENTUALLY checked myself into the hospital. By then sleeping on pillows with one wedged between my knees became the norm just to try and find comfort.

I was passed the point of dehydration and exhaustion when I rolled myself into A&E, I jammed my body between the chairs in the waiting room because my head felt like a boulder. I can't imagine how terrified my family must have been to watch me deteriorate in such a horrible way and to this day that is one of my biggest regrets. To have put them through so much torture as they watched day by day pleading with me to get checked out. I waited a whole year – what an idiot!! A whole year because I couldn't muster the courage to discuss my symptoms.

Life has never been the same since back then in 2009, my illness has taken away everything I once knew; I have been through the ringer and I'm not yet sure I have come out the other side. My illness is invisible to the unsuspecting public which is where a lot of frustration and the lack of understanding comes from. Inflammatory Bowel Disease (IBD) is commonly confused with (Irritable bowel syndrome) IBS which is an entirely different illness. Just because a person does not appear to be sick, please do not assume that all is well. "But you don't look sick" is often the sentence that gets banded around which is totally unhelpful when many spend so much time struggling to get healthcare professionals to listen.

I used to be care free; I came and went as I chose. Now my days are filled with anxiety and worry as my illness is so unpredictable. I can't make plans with family or friends for the want of not letting them down. Due my illness being so unpredictable I often have to cancel or alter plans at the last minute which causes much friction and frustration understandably so. I can spend weeks looking forward to an event/outing only for my tummy to play up the night before and ruin all of my plans.

Not only has my diagnosis of Inflammatory Bowel Disease turned my world on its head, the whole family also feels its effects. Gone is the care free spirit who could pack her case and head in any direction she so chose. All of the simple pleasures I once enjoyed now

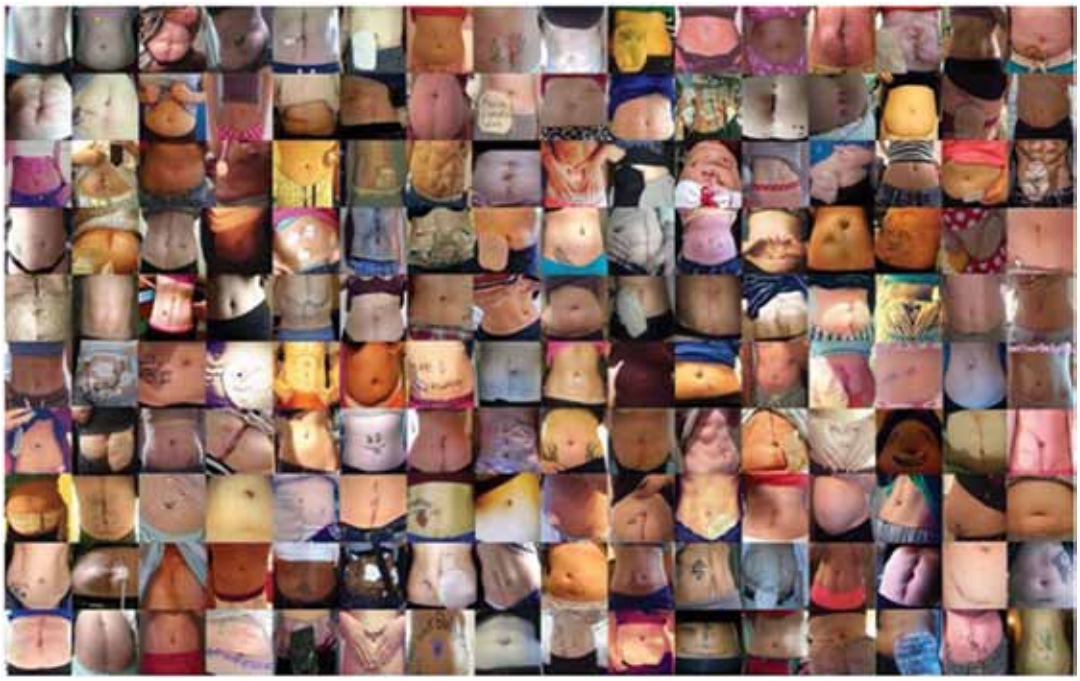
seem so far out of reach. I struggle to hold down a job as employers are oblivious to the seriousness of these illnesses; where once was the hard working dependable staff member now is a person who feels a burden and out of place. Gone is the work-a-holic and in its place is the chronic fatigue character who I sometimes fail to recognize.

What do I wish people knew about my Ulcerative Colitis? Though I may laugh and smile I am dealing with more than any young person should have to deal with. Imagine your intestines being covered in ulcers and having food pass by them each day of your life, painful right? Simply because you see me out in public does not mean I am feeling great, IBD fighters tend to put on a brave performance and will rarely let you in on the true extent of how we are really feeling. Despite the hand I've been dealt, I am doing my utmost; I have an illness that will forever be at my side. Unlike the flu it is an illness which is with us every second of every day and is involved in every choice we make. It's safe to say that Ulcerative Colitis has now become my shadow try as I might to ignore it.

Some people react to their diagnosis with the attitude 'This illness will not beat me' they find some super human strength to scale mountains and achieve their every goal but it's important to remember that for some, simply fighting such a life altering illness can be hard enough without pushing themselves to the brink. Aside from those marathon runners and rising stars there are those who are confined to the house too worried, afraid and exhausted to do much more than get dressed in the mornings. Both Crohn's Disease and Ulcerative Colitis are unique to each individual person, there is no one size fits all nor is there a manual on how to cope with IBD.

Despite all of this, underneath I am still the same emerging soul that I once was only now I am stronger in every way imaginable. I went for many years without talking to a single person who has Ulcerative Colitis or Crohn's Disease therefore back in December of 2013 I started a blog and 'Colitis and ME' was born. I have never made a better decision in my life! Creating my blog opened up a whole new world that I never knew existed and has provided me with so many wonderful opportunities to advocate on behalf of the 5 million people tackling IBD every single day.

I began by talking about my journey with my illness and in flooded messages from people who are facing the exact same troubles as I am. I can't begin to explain the amount of comfort and support that comes from talking to another individual who is in your shoes. Since then I have been inspired to co-found the #GetYourBellyOut awareness campaign along with Gem Willingham,



Victoria Marie through her work has been inspired to co-found the #GetYourBellyOut awareness campaign along with Gem Willingham, Lorna Haymes and Sahara Fleetwood-Beresford encouraging many around the globe to be proud of sharing their IBD stories with the world.

Lorna Haymes and Sahara Fleetwood-Beresford encouraging many around the globe to be proud of sharing their IBD stories with the world.

There is a whole team working behind the scenes to try and gain more awareness of these torturous illnesses. There are advocates running marathons, rowing the Atlantic, organizing charity balls and so forth all in a bid to raise the much needed funds to put towards research. There is so much hope that one day we will all receive the cure we all so desperately deserve, to prevent young children having to suffer and to give others a break from the relentlessness of Ulcerative Colitis and Crohn's Disease.

Many don't like to talk about Inflammatory Bowel Disease and I can whole heatedly understand why. To discuss running back and forth to the bathroom all day is not something people want to talk about. Those who tackle Ulcerative Colitis and Crohn's Disease develop a super human strength, they battle on and take every knock after knock. These illnesses are very challenging and it is time they were taken seriously. What I would like more than anything is for people to be educated about both Ulcerative Colitis and Crohn's Disease, so that we can live in a world which has a little more kindness and understanding to those already struggling a great deal at the hands of our illness without having to deal with the burden of judgement.

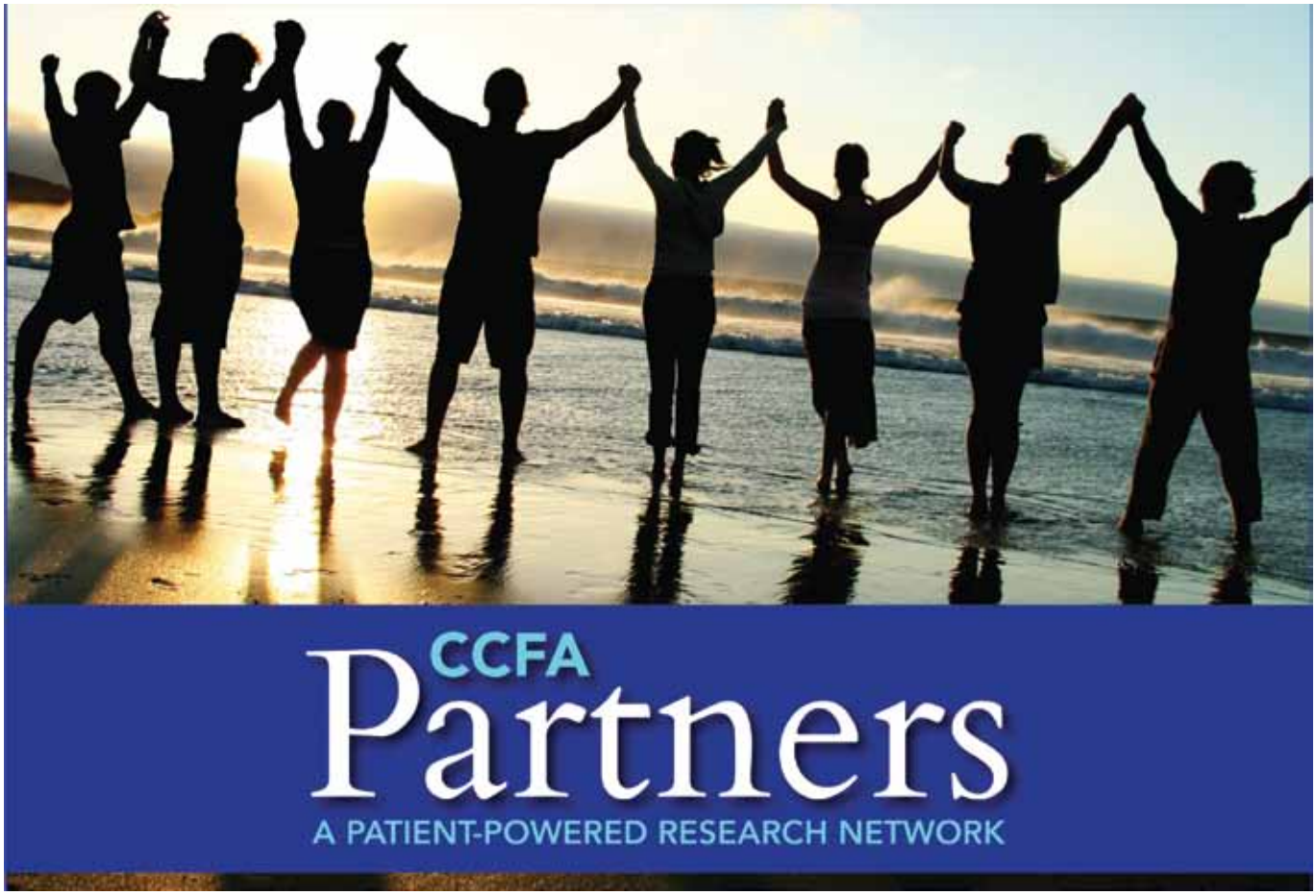
Take a walk in my shoes... I guarantee it will change you in every way imaginable.

With love, Victoria Marie of 'Colitis and ME'

To hear more please join me over on my blog www.colitisandme.blogspot.co.uk where you can contact me from there. I look forward to hearing from you all.

Introducing the new CCFA Partners!

CCFA Partners is an ambitious program from the Crohn's & Colitis Foundation of America (CCFA) designed to improve the quality of life for patients living with inflammatory bowel disease (IBD) through research and education.



This revolutionary research network for individuals with Crohn's disease or ulcerative colitis is easy to join—create an account and complete a short online survey to get started! In return, you'll have access to these great features:

- Tools to better understand your health and what treatments and lifestyle choices work best for you.
- Participate in ground-breaking research.
- Influence IBD research by proposing, discussing, and voting on research questions.

Get started now! After you join, we'll ask you to complete an online survey every six months. We look forward to partnering with patients like you.

Patients and researchers can join now at www.ccfapartners.org.

CROHN'S & COLITIS FOUNDATION OF AMERICA

Workshop on communicating clinical trial results to meet public needs

The European Forum for Good Clinical Practice (EFGCP) is organising a "multi-stakeholder workshop on communicating clinical trial results to meet public needs" to take place on 29 May 2015 in Brussels Belgium.

Why returning results of clinical trials to participants?

Returning results of clinical trials to participants allows for investigators and sponsors to honor the essential contributions and voluntarism of study participants, while improving the transparency of those trials. There are two distinct options for making clinical trial results available in lay language: on an individual participant level through the study investigator or with a more general public approach by posting aggregate results onto a webpage. Both options provide opportunities and may also pose some practical challenges.

The new EU Clinical Trials Regulation: making results available to the wider public

The second option for returning results is the actual focus of the new EU Clinical Trials Regulation adopted by European legislation makers in 2014. This revised framework will bring significant advances regarding available public information about clinical research and its results compared to today's situation. It will for the first time ensure that layperson summaries of all clinical trials will be published on an EU database, enabling trial participants to better understand the value of their contribution and increasing transparency for the general public.

We are now at a critical stage in the process where new rules have to be developed to implement legal requirements into daily practice. Pragmatic guidance needs to balance increased public information needs with seamless integration of new steps into global clinical research operations, while safeguarding the privacy of patients, preserving the scientific rigor and trust in the regulatory systems, and maintaining the incentives for investments into European biomedical research.

Objectives of the workshop

This workshop aims to facilitate a dialogue among stakeholders to understand the wishes and expectations of patients and share experience and best practices of sponsors. A common understanding of the opportunities and challenges of various options is essential to achieving a successful implementation of the new rules in a globalised research environment.

More concretely, basic principles and specific tools that are consistent with health literacy principles will be discussed to ensure the content of lay summaries is practical, relevant to patients, and understandable. In addition, the workshop will investigate how such summaries could best be communicated to ensure that they are reaching their intended audience to maximise their usefulness.

In summary, the discussion aims to help develop a vision and framework that addresses stakeholder needs while increasing transparency and value for public health. Representatives from a patient organisation can benefit from a waiver or one of the 10 grants available to fund participation to the workshop.

For more information please contact: conferences@efgcp.eu

About EFGCP

The European Forum for Good Clinical Practice (EFGCP) is a non-profit organisation established by and for individuals with a professional involvement in the conduct of biomedical research. Its purpose is to promote good clinical practice and encourage the practice of common, high-quality standards in all stages of biomedical research throughout Europe. http://www.efgcp.eu/

NECCO School, Barcelona, Spain, February 18, 2015

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 2013 the first N-ECCO Consensus statements have been published in JCC, aiming at providing practical value at a local and national level to develop nurses' roles in caring for patients with IBD

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 (33 places).

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:
37 participants from 16 countries

Evaluation:
The evaluation forms completed by the nurses afterwards provided us with valuable feedback on this year's performance as well as improvements for the future. Participants were highly satisfied with the selection of the speakers, who all presented topics relevant to the nurses' clinical practice. It was

a pleasure to see that the satisfaction with this year's N-ECCO School has slightly increased compared to the previous year.

Course Outcome and Conclusion:

With the 6th 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 funds for travel and accommodation (as in some countries, industry sponsorship for nurses is prohibited). The EFCCA grant will be 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 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 nursing colleagues.

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

A short report on the N-ECCO School in Barcelona will be printed in the 1st issue of the ECCO News 2015.

N-ECCO School Programme:

The programme of the 6th N-ECCO School featured a full overview of IBD history in order to give nurses a basic introduction to the specialty by expert speakers. Our aim was to teach basic knowledge in a clear way for nurses, with the objective of improving nurse education throughout Europe.

European Patients' Rights Days, What has been done

In 2002, Active Citizenship Network (ACN) together with a group of European citizens organizations established a European Charter of Patients' Rights, which includes 14 basic rights.

All these rights, based on the Charter of Fundamental Rights of the European Union, are crucial in matter of European citizens and healthcare services. The majority of these rights are also embodied within the Council conclusions on Common values and principles in EU Health Systems adopted in June 2006.

The reinforcement of these rights will become effective only with the cooperation and commitment of all healthcare stakeholders in every EU country. It is thus essential to increase awareness regarding the importance of patients' rights and everyone's responsibilities in guaranteeing their respect. We believe that celebrating a European Patients' Rights Day every year in all the EU Member States would greatly contribute to this goal. It is a common occasion to inform, discuss and take commitments to improve patients' rights in Europe and in each member state.

For this reason ACN, together with citizens' and patients' organizations throughout Europe, have taken the initiative to organize for the last six consecutive years the European Patients' Rights Day.

The 1st European Patients' Rights Day was celebrated on 29 March 2007 in Brussels at the European Parliament, with over 180 delegates from 25 countries representing the interests of patients, public administration, policymakers, healthcare providers, legislators and industry stakeholders. The event concluded with the commitment from ACN and participating organizations to push forward for the institutionalization of the European Day, the adoption of the Charter, and campaign for its implementation in all countries along with the celebration of the2nd European Patients' Rights Day in all EU countries.

Mongersen, an Oral SMAD7 Antisense Oligonucleotide, and Crohn's Disease

Giovanni Monteleone, M.D., Ph.D., Markus F. Neurath, M.D., Ph.D., Sandro Ardizzone, M.D., Antonio Di Sabatino, M.D., Massimo C. Fantini, M.D., Ph.D., Fabiana Castiglione, M.D., Maria L. Scribano, M.D., Alessandro Armuzzi, M.D., Ph.D., Flavio Caprioli, M.D., Ph.D., Giacomo C. Sturniolo, M.D., Francesca Rogai, M.D., Ph.D., Maurizio Vecchi, M.D., Raja Atreya, M.D., Ph.D., Fabrizio Bossa, M.D., Sara Onali, M.D., Ph.D., Maria Fichera, M.D., Gino R. Corazza, M.D., Livia Biancone, M.D., Ph.D., Vincenzo Savarino, M.D., Roberta Pica, M.D., Ambrogio Orlando, M.D., and Francesco Pallone, M.D.

Crohn's disease is a chronic inflammatory illness that primarily affects the terminal ileum and right colon. Crohn's disease–related inflammation is segmental and transmural, leading to various degrees of tissue damage. At disease onset, most patients have inflammatory lesions, which become predominantly strictures or penetrating lesions over time. Mucosal healing can be promoted with the use of immunosuppressive drugs and anti–tumor necrosis factor a (TNF-a) antibodies; however, more than one third of patients do not have a response to these therapies. The efficacy of these drugs may also diminish over time, and they can increase a patient's risk of opportunistic infections and cancer. Therefore, there is a need for novel drugs that target the major inflammatory pathways in Crohn's disease.

The gut inflammation associated with Crohn's disease is characterized by abnormal decreases in the activity of the immunosuppressive cytokine transforming growth factor (TGF)–ß1. This is caused by increased levels of SMAD7, an intracellular protein that binds TGF-ß receptor and prevents TGF-ß1–associated and SMAD-associated signalling. Consequently, SMAD7 is a potential target for suppression of Crohn's disease–associated inflammation.

Mongersen (formerly GED0301) is a formulation containing a 21-base single-strand phosphorothioate oligonucleotide that hybridizes to the human SMAD7 messenger RNA (mRNA) and facilitates RNase H–mediated RNA degradation through a classic antisense mechanism. Mongersen was developed in a proprietary modified release tablet designed to deliver the active substance primarily into the lumen of the terminal ileum and right colon. This is achieved through the pH-dependent coating of the tablet, which consists of methacrylic acid–ethyl acrylate copolymers.

Mongersen has previously been shown to down-regulate Smad7 and prevent and alleviate Crohn's disease–like colitis in mice. Studies conducted with mucosal cells from humans with Crohn's disease showed that inhibition of SMAD7 production by mongersen restored TGF-ß1 signaling, thereby suppressing inflammatory cytokine production. In a phase 1 study involving 15 patients with active Crohn's disease, we observed a clinical response (defined as a decrease of >70 points in the Crohn's Disease Activity Index [CDAI] score) in all participants 8 days after the first dose of mongersen; there was also evidence of a durable effect of the drug. Pharmacokinetic analysis of plasma before and after treatment suggested that mongersen was not systemically available; it was detectable in the plasma of one participant at a level only marginally above the lower limit of quantification. Therefore, we sought to better define the efficacy and safety of mongersen for treating adults with active Crohn's disease.

Methodology

Patients

We enrolled patients (18 to 75 years of age) who had moderate-to-severe Crohn's disease (CDAI score of 220 to 400; scores can range from 0 to 600, with higher

scores indicating greater disease activity) 1 week or more before enrolment, with inflammatory lesions in the terminal ileum, right colon, or both, as documented with the use of ileocolonoscopy and contrast ultrasonography of the small intestine, magnetic resonance enterography, or computed tomographic enterography within 1 year before enrolment, and had steroid-dependent or glucocorticoid-resistant disease, as defined by guidelines of the European Crohn's and Colitis Organization.

Because the active compound of mongersen is released in the terminal ileum and right (proximal) colon, we excluded patients with known lesions in the stomach, proximal small intestine, transverse colon, or left colon. Patients were also excluded if they had strictures, fistulae, perianal disease, extraintestinal symptoms, active or recent infections, or a history of cancer.

Patients could continue to receive stable doses of oral prednisolone (≤40 mg per day), budesonide (≤9 mg per day), or mesalamine during the 2-week treatment period; they could also receive a stable dose of immunomodulators (e.g., azathioprine, mercaptopurine, or methotrexate) if therapy had been initiated 6 or more months before initiation of the study treatment. Antibiotic agents, glucocorticoids, immunosuppressive drugs, and biologics could not be initiated before study entry or during the 2-week treatment period.

Patients received no treatment with anti–TNF-a antibodies or other biologic agents within 90 days or antibiotics within 3 weeks before the date of their enrollment in the trial. Female participants used two forms of contraception throughout the study. We excluded women who were pregnant or breast-feeding, as well as persons with previous proctocolectomy or intestinal resection resulting in the short-bowel syndrome and persons with a clinically significant abnormality on electrocardiography or laboratory testing. Patients who had worsening of disease (increase of ≥70 points in the CDAI score) could receive rescue therapy with biologic agents, immunosuppressive drugs, or both after the 2-week treatment period, and for those who were in clinical remission after the 2-week treatment period (CDAI score <150 at both day 15 and day 28), glucocorticoids could be tapered.

The study protocol was approved by the institutional review board or ethics committee at each of the 17 study centers in Italy and Germany.Written informed consent was obtained from patients before they underwent screening for eligibility. Eligible patients underwent randomization between September 2011 and June 2013

Mongersen

Mongersen is a 21-base oligonucleotide with the sequence 5-GTC GCC CCT TCT CCC CGC AGC-3. The phosphorothioate chemistry consists of replacement of a nonbonding oxygen with a sulfur atom in each of the internucleotide linkages. The cytosine residues at nucleotide positions 3 and 16 are modified by 5-methylation.

Study Design

In this multicenter, randomized, placebo-controlled, double-blind, phase 2 clinical trial, patients were randomly assigned to receive one of three doses of mongersen (10, 40, or 160 mg per day) or placebo in a 1:1:1:1 ratio by means of a computer-generated randomization schedule without stratification or block allocation. The placebo and active drug were identical in appearance and taste. The three doses of mongersen and the treatment duration were selected on the basis of preclinical, toxicologic, and phase 1 studies. Patients received treatment daily for 2 weeks and were evaluated at days 15, 28, and 84.

The study was sponsored by Giuliani, acting under contract to Nogra Pharma; employees of Giuliani collected and had access to the data, participated in its analysis, and participated in discussions about its interpretation. The study was designed by the first author, who also wrote the first draft of the manuscript; all authors contributed equally to the gathering and analysis of data, and each author had access to the full data set. Editorial assistance with the preparation of the manuscript for resubmission was received from an editor (from Precise Publications) and from Peloton Advantage; both

were supported by Celgene, which had no additional role in the study. The authors vouch that the study was conducted in accordance with the protocol and statistical analysis plan, both of which are available at NEJM.org. Each author vouches for the accuracy and completeness of the reported data, and each author agreed with the decision to submit the final version for publication.

Efficacy and Safety Assessment

The primary end point of the study was the percentage of patients who were in remission at day 15 (defined as a CDAI score of <150) and who remained in remission for at least 2 weeks. Evaluation of the safety of mongersen treatment was another objective. Clinical, biochemical, and hematologic variables were assessed on days -7, 1, 15, 28, and 84. An enzyme-linked immunosorbent assay (ELISA) was used to monitor the patients for complement activation (a side effect of systemic antisense exposure15). The severity of adverse events and their cause (study drug or procedure) were determined.

Secondary end points included the rates of clinical response, defined as a decrease in the CDAI score of 100 points or more or a decrease of 70 points or more, at days 15 and 28, as well as the percentages of patients with a CDAI score of less than 150 at days 15, 28, and 84. We also assessed the CDAI score before treatment and during the week preceding days 15, 28, and 84, as well as changes in median CDAI scores from baseline to each time point. Percentages of patients who had normalization of C-reactive protein after treatment, had elevated C-reactive protein levels at baseline and reached clinical remission, and were in glucocorticoid-free remission at day 84 were also evaluated. Additional end points included changes in plasma levels of proinflammatory cytokines (e.g., interleukin-8 and TNF-a), measured with the use of commercial ELISA kits (R&D Systems).

Statistical Analysis

Sample size was determined with the use of a one-sided testing framework with an alpha error of 0.1 and a beta error of 0.1, because the prospective primary hypothesis was that 14 days of treatment with the highest mongersen doses (40 and 160 mg per day) would result in a higher proportion of patients in clinical remission than would 14 days of placebo treatment and that the lowest dose of mongersen (10 mg per day) would not be effective. Rates of remission were assumed to be 50% with the highest mongersen doses and 20% with placebo.

It was estimated that 40 patients per group would be needed for the study to have at least 90% power to detect significant differences in remission rates between one of the two groups treated with the highest mongersen doses and the placebo group. All efficacy analyses were conducted according to the intention-totreat principle with all patients who underwent randomization and who received at least one dose of study medication. Patients with missing primary end-point data at day 15 or week 4 were classified as not having a response. Patients who received rescue therapy because of worsening of disease after day 28 were classified as not having a response for the secondary end-point analyses. Missing data for continuous end points and secondary variables were imputed with the use of the last-observation-carried-forward method.

The primary efficacy and adverse-event analyses included all 166 randomly assigned and treated patients. Remission and response rates were compared with the use of Pearson's chi-square test or, when not applicable, with Fisher's exact test. Although sample size was determined with the use of a one-sided testing framework, we present results in the conventional two-sided framework. We compared each of the three treatment groups with the placebo group and each group treated with either 160 or 40 mg per day of the drug with the 10-mg dose group.

Demographic characteristics, rates of adverse events, and proportions of patients who discontinued glucocorticoid treatment were compared with the use of descriptive methods. Proportions of patients with changes from baseline in the C-reactive protein level were also documented. Changes in median CDAI scores and cytokine levels from baseline to each time point were analyzed with the Mann–

MDT Int'l s.a.
Switzerland

Headquartered in Switzerland, **MDT Int'l s.a.** is committed in keeping abreast with market trends and anticipating patients' needs by continuous research and development for further improvement and better products.

MDT Int'l s.a.

- ***observes, comprehends and responds*** *to the markets' expectations and needs*
- ***designs, develops and delivers*** *innovative patented medical devices to enhance the patient's quality of life*
- ***markets and distributes*** *products world wide*

MDT Int'l s.a. strives for excellence in our fields of expertise to make a difference.

www.mdtsa.ch

Whitney test and Student's t-test, respectively

Results

Characteristics of the Patients

Among 188 screened patients, 166 were eligible for participation in the study and were randomly assigned to receive one of three mongersen doses or placebo. Demographic and baseline disease characteristics were generally similar among the groups, with the exception that CDAI scores were higher in the 40-mg group than in the placebo group and Crohn's disease duration was longer in the 40-mg group and the 160-mg group than in the placebo group (Table 1). Of the 166 patients who underwent randomization and received at least one dose of study medication, 6 had protocol violations and missing data at day 15 and were classified as not being in remission (CDAI score ≥150) in the analysis of the primary end point A total of 160 patients (96.4%) completed the 2 weeks of treatment and the day 28 follow-up, and 138 patients (83.1%) completed the day 84 follow-up.

The reasons for withdrawal from the study after day 28 are indicated in Figure S2 in the Supplementary Appendix. In particular, 6 patients (2 assigned to placebo, 1 assigned to 10 mg of mongersen per day, and 3 assigned to 160 mg of mongersen per day) received rescue therapy with biologic agents or immunosuppressive drugs because of a worsening of disease after day 28 and were classified as not having a response (CDAI score ≥150) in the analysis of the secondary end points.

Clinical Remission and Response

The proportions of patients with clinical remission (defined as a CDAI score of <150 at day 15 and maintenance of a CDAI score of <150 until day 28) were significantly higher in the 160-mg group (65%) and 40-mg group (55%) than in the 10-mg group (12%; P<0.001) and placebo group (10%; Fig. 1A). No significant differences between the 160-mg group and the 40-mg group or between the 10-mg group and the placebo group were observed (Fig. 1A).

The proportions of patients who had a 100-point clinical response at day 15 were significantly greater in the 160-mg and 40-mg groups than in the 10-mg group (P<0.001 and P=0.03, respectively, in a two-sided test) and in the 160-mg group than in the placebo group (P<0.001) (Fig. 1B).

No significant difference was observed between the 40-mg group and the placebo group.

At day 28, the proportions of patients with a 100-point clinical response (i.e., a CDAI score reduction of ≥100 points) were significantly higher in the 160-mg group (72%), 40-mg group (58%), and 10-mg group (37%) than in the placebo group (17%) (Fig. 1C). The percentages of patients with CDAI score reductions of 70 points or more at days 15 and 28 were significantly greater with the higher mongersen doses than with the lower dose or with placebo.

The proportions of patients who had a CDAI score of less than 150 at days 15, 28, and 84 were significantly higher in the 160-mg group and 40-mg group than in the 10-mg group and the placebo group. We found no significant differences between the 160-mg group and the 40-mg group or between the 10-mg group and the placebo group.

Changes in Clinical and Inflammatory Measures

The median changes in the CDAI score in the 40-mg and 160-mg groups were significantly greater than the change in the placebo group at each time point. No significant difference was seen between the 10-mg group and the placebo group at any time point.

Overall, 102 of 166 patients (61.4%) had an elevated C-reactive protein level (i.e., >3 mg per litre) at screening; among the patients who had elevated C-reactive protein levels at baseline, the proportions with normalization of these levels at day 15 were 4% in the placebo group, 22% in the 10-mg group, 18% in the 40-mg group, and 18% in the 160-mg group. Among patients with an elevated C-reactive protein level at baseline, neither placebo nor mongersen treatment significantly reduced the median C-reactive protein level at days 15, 28, or 84.

Table 1. Baseline Demographic and Clinical Characteristics.*

Characteristic	Placebo (N=42)	Mongersen		
		10 mg (N=41)	40 mg (N=40)	160 mg (N=43)
Mean age (range) — yr	41 (19–74)	43 (20–71)	43 (19–69)	43 (22–70)
Male sex — no. (%)	23 (55)	17 (41)	21 (52)	20 (47)
Female sex — no. (%)	19 (45)	24 (59)	19 (48)	23 (53)
Mean BMI (range)†	23.2 (15.8–39.8)	22.2 (15.9–29.9)	23.6 (18.3–38.4)	23.6 (15.1–36.4)
Median Crohn's Disease Activity Index score (range)	264 (222–392)	246 (221–399)	240 (223–368)‡	243 (221–396)
Median C-reactive protein level (range) — mg/liter	5.1 (0–102)	4.3 (0–78)	4.9 (0–47)	4.6 (0–51)
Glucocorticoid-dependent disease — no. (%)	36 (86)	32 (78)	38 (95)	36 (84)
Glucocorticoid-resistant disease — no. (%)	6 (14)	9 (22)	2 (5)	7 (16)
Taking glucocorticoids at enrollment — no. (%)	9 (21)	7 (17)	13 (32)	9 (21)
Taking concomitant immunomodulators — no. (%)	12 (29)	6 (15)	10 (25)	12 (28)
Current smoker — no. (%)	14 (33)	18 (44)	13 (32)	17 (40)
History of Crohn's disease–related intestinal resection — no. (%)	14 (33)	21 (51)	15 (38)	19 (44)
Duration of Crohn's disease — yr	10.9±1.4	12.3±1.6	7.0±1.3§	9.3±1.5¶

* Plus–minus values are means ±SE.
† The body-mass index (BMI) is the weight in kilograms divided by the square of the height in meters.
‡ P=0.04 for the comparison with the placebo group.
§ P=0.01 for the comparison with the placebo group.
¶ P=0.02 for the comparison with the placebo group.

In the subgroup of patients with baseline elevations in the C-reactive protein level, the rates of remission in the 160-mg and 40-mg groups were significantly greater than the rate in the placebo group; there were no significant differences between these two higher dose groups or between the 10-mg group and the placebo group. The response rates were similar among patients with an elevated C-reactive protein level and patients with a normal C-reactive protein level at baseline. The proportions of patients with baseline elevations in the C-reactive protein level who had remission (defined as a CDAI score of <150 and a normalized C-reactive protein level) at day 15 were 17% (1 of 6) in the placebo group, 0% (0 of 4) in the 10-mg group, 18% (2 of 11) in the 40-mg group, and 25% (5 of 20) in the 160-mg group.

No significant differences in the median dose of glucocorticoids were detected among the groups at baseline (Table 1). One patient in the placebo group and 1 patient in the 10-mg group were taking 25 mg of prednisone per day, and 1 patient in the 40-mg group was taking 5 mg of prednisone per day. Budesonide was taken by 8 patients in the placebo group (median dose, 6 mg per day), 6 patients in the 10-mg group (median dose, 6 mg per day), 12 patients in the 40-mg group (median dose, 6 mg per day), and 9 patients in the 160-mg group (median dose, 7.5 mg per day). At day 84, the percentage of patients who had a glucocorticoid-free remission was significantly greater in the 160-mg group than in the placebo group (6 of 9 [67%] vs. 1 of 9 [11%], P=0.04), and there was no significant difference

between the 10-mg group (3 of 7, 43%) or the 40-mg group (6 of 13, 46%) and the placebo group (1 of 9, 11%).

Treatment with 40 mg or 160 mg of mongersen per day but not with 10 mg per day significantly reduced the mean concentration of interleukin-8 and TNF-a in plasma. This effect was evident at day 15 and day 28.

Safety and Adverse Events

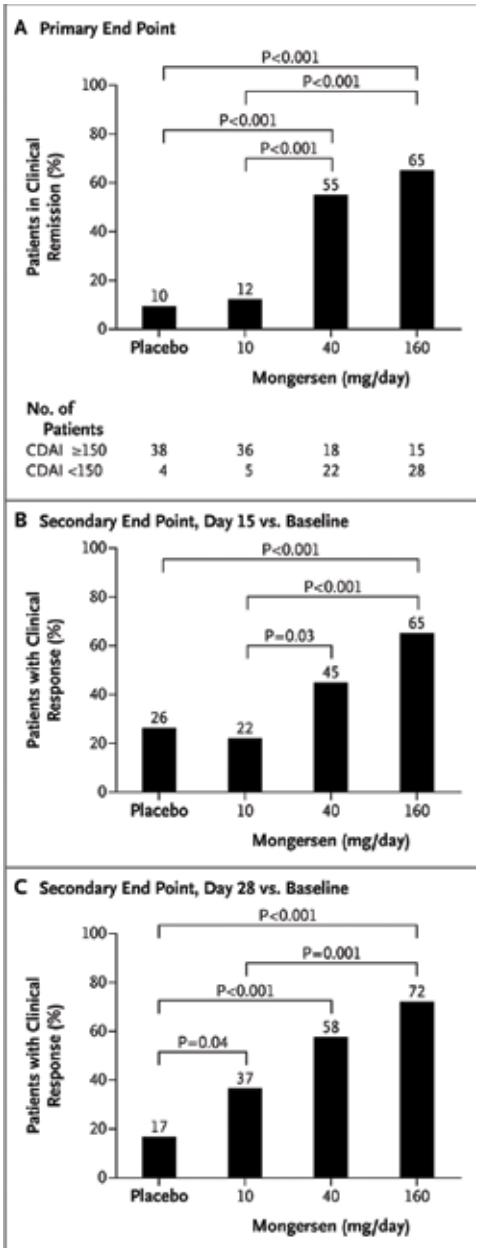
Nine serious adverse events were reported, in six patients. Most serious adverse events were hospitalizations for complications or symptoms of Crohn's disease. There were no deaths. Adverse events occurred during or after treatment in more than 5% of patients. Most adverse events were mild (64% in the placebo group and 65% in the combined mongersen groups). We did not observe changes in the levels of serum complement factors.

Discussion

Targeting SMAD7 with mongersen was of clinical benefit for study participants with active Crohn's disease. The effect was rapid in onset and durable in many patients. The rates of re- mission were greater in the groups of patients treated with 40 mg or 160 mg of mongersen per day than in the groups receiving 10 mg per day or placebo and were similar to the remission rates achieved in some other phase 2 trials of new drugs for the treatment of Crohn's disease,4,16 which range from 16% to 48%, as well as to re- mission rates in phase 3 trials of existing thera- pies.17,18 All three groups receiving mongersen had a significantly greater rate of clinical response than did the placebo group, which suggests that even a dose of 10 mg per day may be therapeutic in a subset of patients. Direct head-to-head stud- ies are required to ascertain the benefit of mongersen relative to other currently available drugs in inducing and maintaining remission in Crohn's disease.

Normalization of C-reactive protein levels was more common in each of the three groups of patients treated with mongersen than in the placebo group, although the differences in the numbers of participants in whom normalization was achieved were not significant. Although the absence of an association between improvement in the CDAI score and normalization of the Creactive protein level in all the patients treated with mongersen remains to be clarified, it is conceivable that healing of tissue lesions, normalization of C-reactive protein levels, or both require treatment for longer than 2 weeks.

Nearly 40% of patients had normal C-reactive protein levels at baseline, possibly because our study population included only patients with inflammatory lesions restricted to the terminal ileum and right colon. Although Crohn's ileitis is frequently associated with low or normal C-reactive protein levels, patients with elevated levels at baseline had a superior



response with 40 mg or 160 mg of mongersen than with placebo. Our findings also indicate that the induction of remission was not affected by the baseline level of C-reactive protein.

A diminished ability to mount an efficient counter-regulatory TGF-ß1 response to inflammatory stimuli is believed to be instrumental in the pathogenesis

of Crohn's disease. This role of TGF-ß1 in intestinal immune homeostasis is dramatically evident in studies in mice. Mice lacking TGF-ß1 or expressing a functionally inactive form of TGF-ßR II on T cells have excessive activation of effector T cells and spontaneous development of gut inflammation. Neutralization of endogenous TGF-ß1 in wild-type mice also leads to severe colitis. Conversely, boosting of TGF-ß1 activity is associated with complete protection from the development of colitis or a reduction in the severity of colitis. The dosage effects that we observed are probably related to the amount of active compound delivered to the gut and thus the extent to which SMAD7 is down- regulated and TGF-ß1–dependent counter-regulatory signals are up-regulated.

The percentages of patients with a CDAI score of less than 150 at week 4 were greater than those seen at the end of the treatment period (i.e., day 14), and the clinical benefit induced by 2 weeks of treatment with mongersen persisted over time; at the end of follow-up, 29%, 62%, and 67% of patients treated with 10, 40, and 160 mg per day of mongersen, respectively, had CDAI scores of less than 150. We have no data on the intestinal distribution of orally administered mongersen in persons with Crohn's disease, but because orally administered mongersen disappears quickly from the gut of mice with experimentally induced colitis, we suggest that the durable effect is unlikely to be related to drug accumulation in the gut.

Moreover, intact mongersen was evaluated in tissue and plasma samples from mice and cynomolgus monkeys with the use of a hybridization-type assay. On oral administration of multiple, large clinical doses, mongersen was detectable in liver and kidney (the known major organs of oligonucleotide up-take when doses are given systemically) but at levels that were hundreds of times lower than when mongersen was administered by intravenous or subcutaneous injection. This is consistent with the very low plasma levels of mongersen reported in an earlier phase 1 study. The therapeutic effect of mongersen requires not only knockdown of SMAD7 but also reestablishment of TGF-ß1–dependent suppression of multiple mucosal cell types.

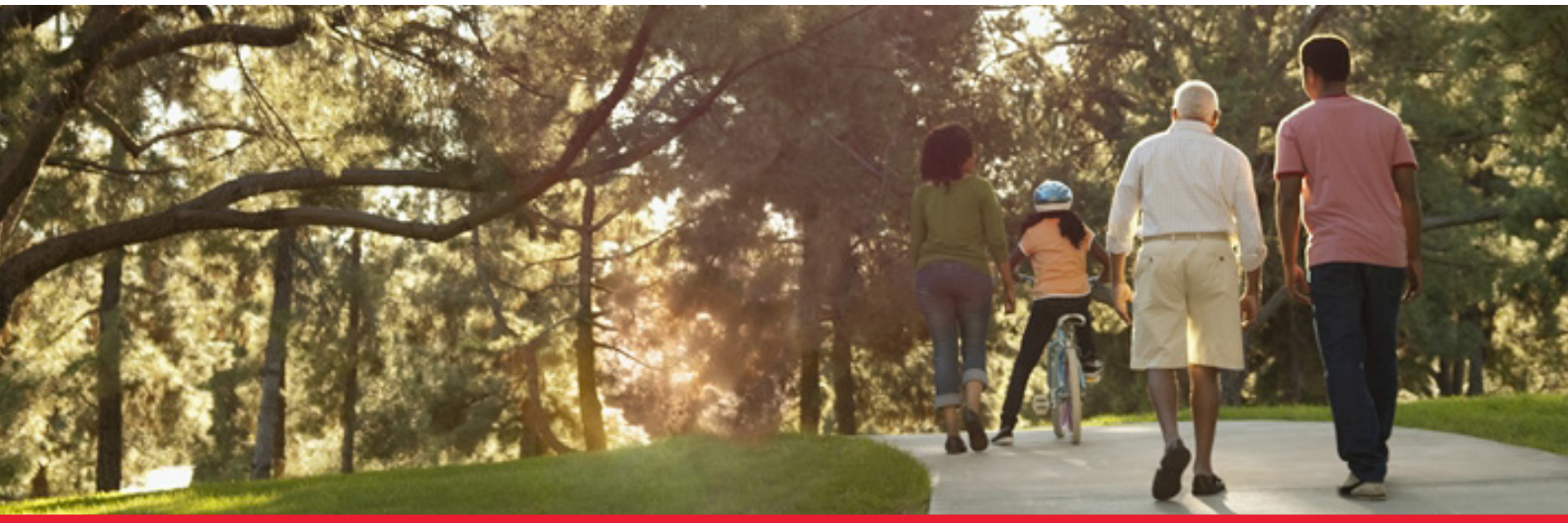
We did not identify safety issues with the oral administration of mongersen in patients with active Crohn's disease, to the extent that a 2-week trial of the drug in 124 persons can determine safety. The majority of serious adverse events reported were related to complications or symptoms of Crohn's disease.

Ideally, further clinical study of mongersen for Crohn's disease should determine the most beneficial clinical dosage regimen, test longer durations of treatment, and assess mucosal healing on the basis of endoscopic analyses of the study participants. Ileocolonoscopy was optional in the current study, and no patients agreed to undergo ileocolonoscopy at the end of the study. Longer-term studies of the efficacy and safety of mongersen, its comparison with existing therapies, and its effect on mucosal healing are needed. Further work will also be needed to determine whether longer-term treatment with or higher doses of mongersen increase the risk of fibrosis, given the profibrogenic role of TGF-ß1 in many organs.

Antisense oligonucleotides targeting mRNA have been used to treat chronic inflammatory diseases. Antisense oligonucleotides against mRNA encoding the intercellular adhesion molecule 1 (ICAM-1), administered intravenously, have been tested with no success in patients with Crohn's disease. Perhaps oral formulations with local activity are more effective than systemic formulations (i.e., subcutaneous) in allowing the anti- sense compound to reach the diseased tissue.

In conclusion, the data from this phase 2 study provide evidence of the efficacy and adverse-effect profile of mongersen in active Crohn's disease. Our results support earlier work showing that SMAD7 has a role in the inflammatory reaction of Crohn's disease.

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