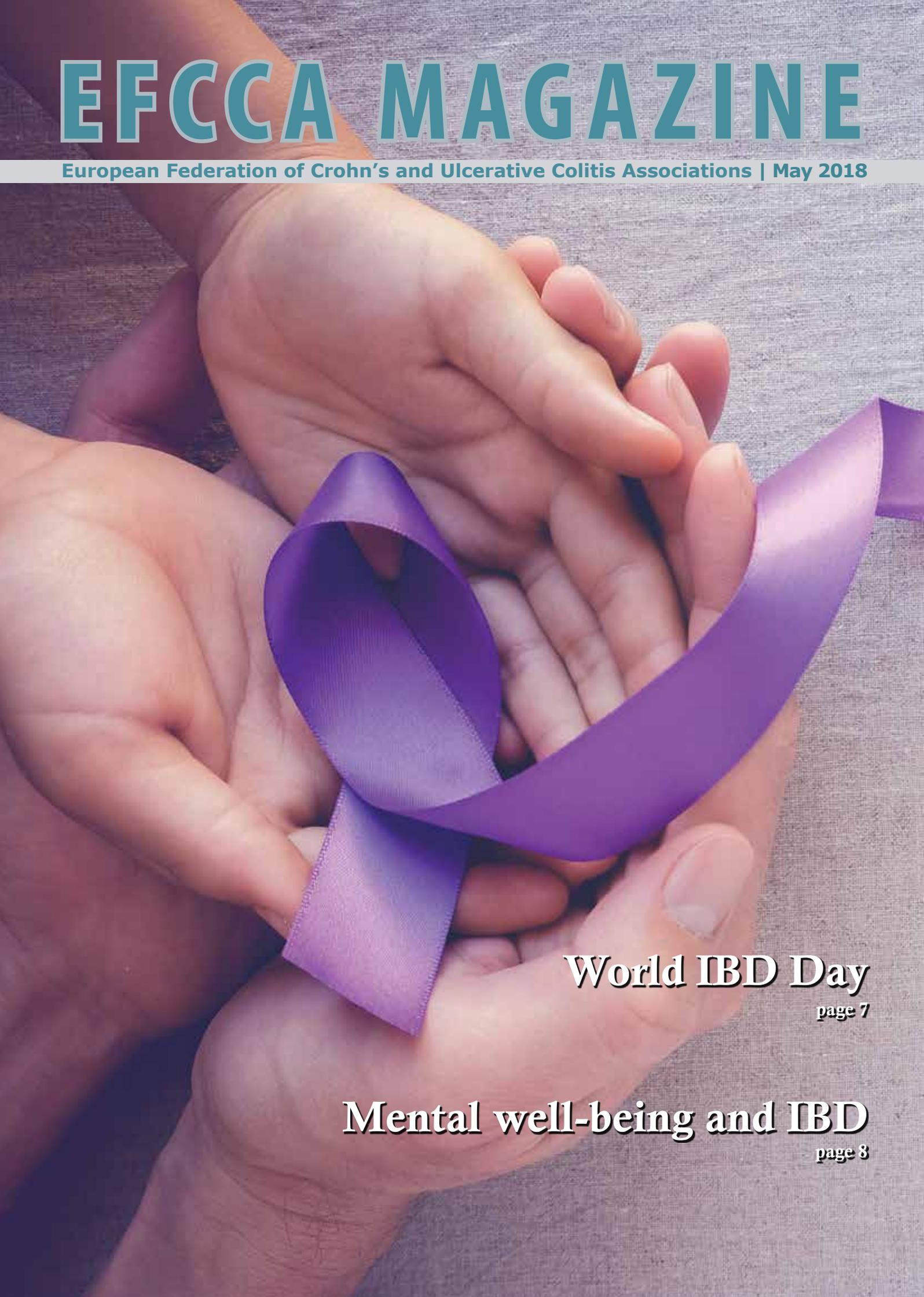


# EFCCA MAGAZINE

European Federation of Crohn's and Ulcerative Colitis Associations | May 2018



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# EDITOR'S EYE

## Paving the way for a better future



By now you are all aware that the month of May is very special to EFCCA as the 19th of May is dedicated to unite people around the world in their fight against Crohn's disease and ulcerative colitis (UC). We are currently coordinating the global campaign for World IBD Day and we look forward to the many activities that our members and other organisations are planning around that date!

We are also happy that this month we are distributing our magazine at the ESPGHAN (European Society for Paediatric Gastroenterology, Hepatology and Nutrition) Congress that will take place from 9-12 May in Geneva. EFCCA will be there, for the first time, with its stand and material and we believe this is a further sign of our growing networking and collaboration with medical societies. And for us this represents an important achievement seen the investment of our EFCCA Youth Group in the transition project from paediatric care to adult one and the increased attention to young and newly diagnosed patients.

The past trimester saw some important achievements for our community: the preparation of the General Assembly and the International Symposium on IBD Research supported by patient organisations to take place end of May have absorbed lot of our energy but in the meantime we are happy to announce that the EFCCA Academy pilot training is taking shape with a first meeting planned in mid- June.

The Academy is a new path that EFCCA is taking and we hope to offer strategic capacity building on issues that are relevant to the IBD community. The training will make use of the patients own experiences as well as outcomes and findings of several surveys such as for example the IMPACT<sup>1</sup> survey.

The full project, programme and content will be presented at our General Assembly and we are confident that after the pilot phase this very important service we are offering to our members will become a regular activity to better support our members advocacy activities and allow our first group of "Certified Patient" to share their skills and knowledge in their national associations.

In February we have been involved in the ECCO congress not only, as usual, by ensuring our presence

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with a stand but also participating in conferences and symposia: our CEO and Vice President have been very busy in giving voice to the IBD patient perspectives and unmet needs and we have to warmly thank our members attending the Congress for their support and commitment. Our stand is becoming the meeting point for our members and a recently established tradition is reinforcing our relationships and exchange of information: for the second year we spent a lovely evening with our delegates and friends from several countries, an enjoyable way to feel united!

Our Board met on March and, alongside the usual management activities, we took the occasion to organise a team building set of exercises to reinforce the group and start working on the EFCCA future scenario after our General Assembly and Symposium.

The EFCCA Youth Group is working hard to prepare the Annual Youth Meeting that will take place in Iceland end of July and we welcomed the youngsters' representatives early April in Brussels and had the chance to talk with them on their next strategy plan and projects.

Finally, we are delighted to announce that a new round of the BAB survey will be presented at our General Assembly whose purpose will be to see the evolution of patients perspectives on biosimilars seen the fast changes of the overall scenario in Europe and beyond. Like the previous one the survey will be supported by Professor Biroulet and Dr Danese and we hope to have new data and information to shape our further activities around patient safety.

My last words are to say goodbye to Martina Jovic, our policy officer who moved to France for a new job. We all enjoyed working with her and we wish her all the best for her future challenges.

**UNITED WE STAND!**

Martin Kojinkov  
EFCCA Chairman



# EFCCA Academy is ready to start!

**We are pleased to announce that the kick off meeting of the EFCCA Academy will take place from 15-17 June 2018 at the offices of EFCCA in Brussels, Belgium.**

The idea of EFCCA Academy was born in 2017 as the result of two “From IMPACT to IMPACTFUL” focus group meetings. The goal of the Academy is to train Certified Patients, skilled IBD patient advocates, who will be trained in strategic topics and given tools to successfully raise awareness about IBD in different settings.

After some scheduling difficulties, the EFCCA Academy is now ready to kick off. The pilot group, approximately ten IBD patients, will come together on June 15-17 in Brussels. The pilot group has been combined from the participants of the original focus group who “invented” the Academy and IBD patients who were not involved in the development; this way, EFCCA will be able to get feedback from both patients who have been involved in the Academy from the beginning and know background and the aims of the Academy, as well as patients who haven't been involved and don't know what to expect.

All of the pilot participants are active within their national patient associations and have a strong interest in joining the Academy. This is crucial, as their feedback will help to improve and optimize the curriculum, after which the application process will be opened to further EFCCA members. After their Certified Patient training, the participants will be able

to take their new knowledge and skills back to their home country and work at the local level in raising awareness about IBD.

The pilot group participants will learn, for example, the basics of medical language and how to effectively use the outcomes of EFCCA's surveys in advocacy work; they will be trained in communication skills and public speaking, in patient rights, work discrimination, life management with IBD from different healthcare provider's point of view etc. The faculty of the EFCCA Academy will consist of teachers experienced in their topic and experts in the field, who are committed and interested in working with patient advocates.

The EFCCA team is excited and looking forward to the kick-off of the Academy, and the project has raised a lot of interest within the EFCCA membership as well. The plan is to offer the EFCCA Academy training at least once every year. The EFCCA Academy is a pioneer project and a big step for EFCCA into a new direction, and it will benefit IBD patients in Europe and beyond.

Sanna Lönnfors  
EFCCA Research & Project Coordinator



## ECCO Congress

This year EFCCA had another successful participation in the 13th ECCO Congress, which took place from 14-17 February 2018 in Vienna, Austria. It was visited by over 6000 representatives of the medical profession and provided an excellent opportunity for networking.



*From left to right: Krisztina Gecse, Frank Behrens, Antonino Spinelli, Luisa Avedano and Claudio Fiocchi.*

As usual EFCCA was kindly provided with a booth in the exhibition hall and the EFCCA staff and EFCCA Vice President, Salvo Leone, had the chance to meet many IBD physicians, nurses and sponsors in order to discuss cooperation on potential common projects. We were also pleased to welcome several delegate from the EFCCA network and for the second year running EFCCA organised a networking dinner on 15 February with EFCCA members including representatives from France, UK, the Netherlands, Slovenia, Israel, Poland, Austria and Italy. It was a great opportunity to exchange information and talk about future projects, but also to relax together after a busy day at the congress.

During the ECCO Congress EFCCA CEO, Luisa Avedano, participated in the roundtable discussions at the Symposium organised by Sandoz on 'Delivering precision medicine and patient-centered care through a multidisciplinary approach' alongside Claudio Fiocchi, Antonino Spinelli, Krisztina Gecse and Frank Behrens.

EFCCA Vice President, Salvo Leone, gave a presentation on the "accumulated experience with biosimilars from EFCCA" at a Symposium organised by Celltrion and he also participated in an Advisory Group Meeting organised by Celltrion on the patient perception on biosimilars and how to offer adequate information around the topic.

Prior to the Congress, the pharmaceutical company organised an internal meeting to which our EFCCA General Secretary, Ciara Drohan and an Austrian patient were invited. The purpose of the meeting was to educate employees on a patient's perspective of living with perianal Crohns disease and how patients' quality of life and life in general is affected by it. It was a great opportunity for a patient to explain what life is like and also for an EFCCA board member to explain how similar and yet different life can be for patients across Europe.

Finally, on the last day of the Congress and on Sunday, Luisa Avedano, Salvo Leone and Sanna

Lönnfors attended the second face to face meeting of the project UC Narrative, a project based on a survey co-designed by the patients' organisations involved whose results will be presented on the occasion of World IBD Day. The other member countries involved are Finland, Italy, Spain, France and Canada. The meeting also included renowned IBD gastroenterologists from the different countries involved.

*EFCCA Vice President, Salvo Leone during ECCO Congress*



## World IBD Day 2018

**In its eighth year of running World IBD Day is becoming an important global event which brings together people living with IBD, patient advocates, healthcare professionals, family, friends and other stakeholders to show their solidarity with the 10 million people that are living with IBD and to raise awareness about the disease which includes Crohn's disease and Ulcerative Colitis.**

The European Federation of Crohn's and Colitis Associations (EFCCA) is coordinating again this year a global campaign aimed at raising IBD awareness by highlighting famous landmarks in the colour of purple alongside the organisation of local events on either the 19 of May (the official date of World IBD Day) or around that date. In some countries the whole month of May is used to raise IBD awareness.

EFCCA's 34 patient association members as well as other IBD sister associations, healthcare providers and IBD activists from five continents are joining this campaign and many are coming up with creative and exciting events. To find out more about these please visit the World IBD Day website ([www.worldibdday.org](http://www.worldibdday.org)) where you will find detailed information about what's happening around the globe.



# Mental-well being and IBD

*Chronic disease, such as Crohn's disease and ulcerative colitis (known as IBD), impact both physical and emotional well-being. People with IBD are at risk for developing the following mental health problems such as depression, anxiety and/or low self esteem. We want to open the debate around this subject as we believe it's an important issue but too often ignored.*

## The Gift - by Jorge Ascenção, psychologist, APDI (Portugal)

One of these days you find yourself with a Gift. You don't really know how you got it, you don't know who left you this "Gift" and, to tell the truth, initially, you didn't even knew you "have it".

You just noticed that you feel more tired than usual, or, it seems like the food you ate didn't "agree" with you. You even tried to use the elevator more and someone told you that you should exercise more, someone else that you should rest a little more... "Make up your minds!" – you thought then.

You've tried some healthier dishes. Cutting on fat, decreasing the sugar intake but from out of nowhere, some nausea, diarrhea, stomach ache, and other symptoms, put you on some sort of permanent "diet" "I can't eat anything anymore". Symptoms come and go. When you finally forget about them, there they are! Your doctor already told you it's all "ok". "Nowadays a lot of us suffer from excess stress from work and from issues at home. The digestive system is the first one to develop some symptoms. "Take a few days off and you'll be as good as new."

But your not. As a matter of fact, today, for the first time ever, you're sure you saw some blood in your feces. "There you go with your nonsense... don't you think you're getting hypochondriac? The doctor told you that everything was good. Take that idea off your mind!"

Sometimes you even doubt if they really care about you. On other occasions you're the one that doubts yourself. "It's all in my mind?" What's really going on? What kind of "Gift" is this, that no one can see, and only you can feel it?

You know that it's there, even if everyone tells you "it's ok". You didn't imagine these pains and that tiredness that comes out of nowhere... or did you? But you were sure today, the pain is too strong and the blood is no joke and it's too much time suffering. Even if the doctor looks at you with that "here he comes with the usual complaints" face – you're not leaving his office not knowing what's really going on.

New blood tests, some more medical exams, a new appointment next week. Finally! I'll know what's wrong with me. What kind of "Gift" this is, but do I really want to know? Opening this "Gift" could be terrible, surgeries? Cancer? The internet has some horrible sites and Facebook "speaks" very badly of these symptoms, it really can be lots of things! If my days are "numbered" do I really want to know how many there are? What about my plans? My family? The appointment is only next week? Can't it be tomorrow?

Can't I cancel it and just don't know? Just stay like this? "Some days I feel better, and some days I feel worse, lately it has become unbearable. But some times I can handle it". How can I be sure that I'm making the right choice? Should I open the "Gift" or not?

Worse than making the wrong choice is not making any choice at all... just to stay in place. In your (dis)comfort zone. To procrastinate. Just let the symptoms and your imagination take their way. Just imagine the stress of the unknown and the monsters of your adrenaline roaming free in your bloodstream. Having a daily emotional catastrophe being unloaded without boundaries to your digestive system...

sharing the future of digestive health



## UEG Week Vienna 2018

October 20-24, 2018

Venue: Austria Center Vienna

Ahead of UEG Week Vienna 2018, UEG President Professor Paul Fockens discusses why he is looking forward to one of the world's premier digestive health meetings.



With more than 13,000 attendees from across the globe, UEG Week is one of the largest gastroenterology and hepatology meetings in the world. This year's congress will take place at the heart of Europe in Vienna, the home of UEG.

A world-class programme has been carefully pieced together by my colleagues in the UEG Scientific Committee, featuring the latest advancements in clinical management and the best new research in digestive health. The programme boasts a variety of symposia and session types to ensure that a comprehensive offering is provided for all attendees, whatever their specialty may be.

The congress kicks-off with the Postgraduate Teaching Programme, comprising of two days of excellent medical education and state-of-the-art sessions. The interactive session formats will include tricky clinical cases, controversial debates and exciting video cases, supplying a perfect mix for both gastroenterologists in training and established physicians.

UEG Week will once again host the hugely successful 'Today's Science, Tomorrow's Medicine' initiative and this year's theme will focus on regenerative medicine in digestive diseases. This symposium series is constructed through a combination of invited speaker and Free Paper sessions, ensuring the world's leading scientists and young researchers unite to help shape future developments in our dynamic field.

Science is at the forefront of UEG Week and we are constantly looking to attract the best science and research to our congress. The meeting provides a fantastic opportunity for researchers around the world to submit and present their latest research findings and, to support the quality of submissions, UEG offer a number of awards, including the Top Abstract Prize and the UEG Rising Stars Awards.

I am anticipating a very exciting week of scientific advances and updates from leading digestive health experts and, along with my fellow colleagues, look forward to welcoming new and returning delegates to UEG Week Vienna 2018.

Late breaking  
abstract submission  
opens August 20,  
2018

Benefit  
from early bird  
fees before May 17,  
2018

# 2018

To find out more,  
visit [www.ueg.eu/week](http://www.ueg.eu/week)



To run away? That's one way to deal with it. But how can you run away from yourself? Won't you take the pain, the tiredness and everything else with you? Isn't there a chance of finding a Cape of Good Hope behind that Cape of Storms you're in now? A path to pursue? A way...

"I'm sorry... what you have is a chronic illness. It's called ulcerative colitis and it's part of the inflammatory bowel diseases (IBD). There isn't a cure yet, but we have some good treatments that can, mostly, control the progression of the disease..."

And, suddenly, your vision of the world and your life shrinks. The diagnosis clears you from the "hypochondriac" label, but it suffocates you in the knowledge that you are in fact ill. You don't feel like you're falling down an unknown darkness, but you're not feeling the ground beneath your feet. You don't understand what the doctor says after "there isn't a cure yet..."

"Now I am a sick person. I shouldn't have gone to the doctor. I was better off suffering without knowing why. Now I'm suffering not knowing what for. This illness is not going away any time soon..." "It doesn't kill me, at least that's out of the way" But what about the despair, the feeling of impotence with this "Gift" that apparently you didn't catch anywhere and no one gave it to you. It just wanted to show up in your life, with no apparent justification.

This threat to the destiny you've planned for yourself, this "reality crash" that you thought happened "only to others".

The chronic nature of the disease, the unpredictable prognosis, your own experience and previous knowledge about chronic illnesses and even about IBD, as well as the kind of relationships that you've established before and now with doctors, nurses and other health caregivers, will put your defences to the test, in a storm of emotions.

You're not really sure where you're heading to, nor if you're doing your path the right or the wrong way. "I'm just going with the flow and see what happens"

– but, if you think about it, you're not standing still anymore. You're not blindly walking through those strange symptoms with that "I don't know how to deal with it" fear.

The "why me" anger left you on a path. A hard path to pursue, but one that you now know you're not walking alone. There are doctors, nurses, and other people that got the same "Gift" you have on that road. You've already met them at the patient association, and they don't leave you with that "no one understands me" feeling. "After all, there are so many people that have this disease and with symptoms similar to mine."

You're not who you used to be, you've learned and keep on learning about a new image of yourself. A suffered one no doubt, but also a more complete and stronger one too. You now know your weaknesses and strengths.

Finally you've stopped looking for blood in your feces. You've learned that you can eat everything as long as you respect the disease flares and the "bad temper" of that "Gift". And after all, inside the "Gift" there was just a game, a game that you learn to play better each day that passes, discovering, step by step, some new rules, getting some "bonuses" when the medical exams bring some good news and little by little the pain and the suffering have gone from permanent to "once in a while".

You're growing with each battle with the IBD rebellion. Smarter, more conscious, in a more secure and complete relationship with yourself, with your family, your friends, and your doctors.

So far away is that person standing at the crossing not knowing what he or she felt, not knowing what to do or where to go. So much that you've climbed and accomplished. You now take better care of yourself, you like yourself more. You're stronger and you live your life the best you can although you have IBD.

Clearly, this kind of "Gift" only happens to the strongest...

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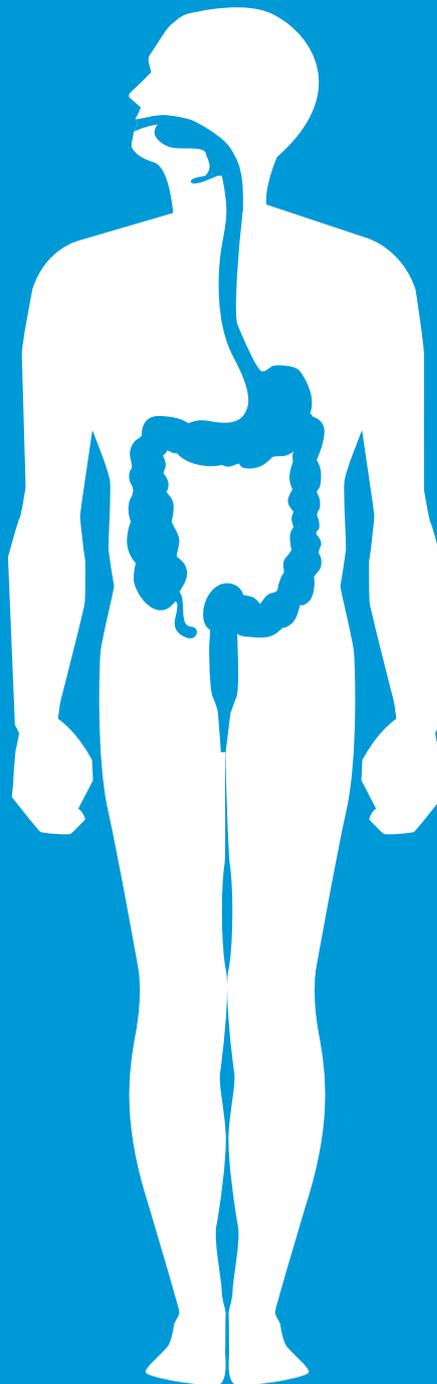
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# IBD and Taboos: “Moon face” effect of IBD treatment

**A recent social media story by famous UK magician Dynamo sparked the hashtag #moonfacefordynamo with people from across the globe sharing their experiences and highlighting the effects of Crohn’s Disease and ulcerative colitis and how the side effects can impact lives.**

Dynamo, whose real name is Steven Frayne, a British celebrity magician recently posted a video on his social media accounts explaining he became “really sick” in 2017 due to his previously diagnosed condition of Crohn’s Disease.

In the video he explained his medication regime since then has caused him to “put on quite a lot of body weight” and develop a rash.

He said he is also unable to shuffle cards because his hands are in “so much pain” due to developing arthritis.

Dynamo thanked people for their “kind support,” following a selfie he posted online showing the change in his appearance, including the extent of the rash on his head.

This then sparked the hashtag #moonfacefordynamo with people from across the globe sharing their experiences and highlighting the effects of the conditions Crohn’s Disease and Ulcerative Colitis and how the side effects can impact lives.

## Leanne’s story

My name is Leanne and I was diagnosed with Crohn’s Disease when I was 15. The first step in my treatment was to have an 8 week course of steroids at a reducing dose which worked amazingly but had such tough side effects to live with.

I had lost a lot of weight before I had been diagnosed as shown in the picture of me at my prom but you can also see the effects the steroids had given



*Dynamo’s social media post sparked a debate on the effects of IBD*

Many commented on the magician’s appearance, noting his weight gain and adding negative connotations to this so as the EFCCA Youth Group we wanted to take the opportunity to talk about this and encourage more people to share their stories to help battle the taboos of the condition.

We hope that our work towards breaking taboos around IBD, by sharing such stories, will reassure sufferers and their families and friends that they are not alone as well as possibly providing answers to questions they might not have been able to ask anyone before.

me a “moon face” which you can see in the picture with my friend. People saw this as negative weight gain and saw me losing a lot of weight and then gaining it again as me having an eating disorder rather than the side effects of the condition or medication.

Following on from the first course I then was put on a second course of steroids for another 8 weeks, which continued to amplify the side effects.

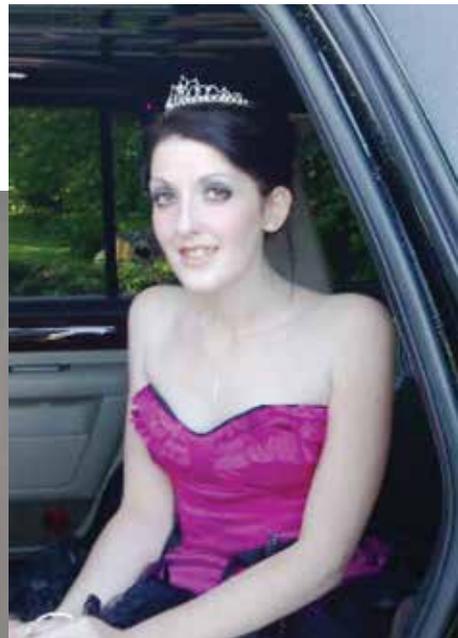
At the time these side effects were difficult to come to terms with but I also was seeing the difference in my health and the improvements they were having so it was a bittersweet feeling.

I always try to remember that “Every day may not be good but there is something good in every day.” and I can’t illustrate the point any differently than that you have to remember the positives even if you are having a bad day.

Remember that even though the treatment may be making you feel bad in some ways it is also helping in

many positive ways and it is about learning to balance those feelings to help you feel better than get stuck in a dark place.

The whole point of these articles and sharing our stories is to make more people aware of the side effects so more and more people feel less alone and isolated by them but also to empower and equip people with the facts.



*Leanne (above) during her prom celebrations and left after being treated with steroids for her condition*

## Kat’s story

My name is Kat and I was diagnosed when I was 14. I already had to take cortisone but not longer than a couple of weeks. I didn’t get that many side effects but since October I have to take it again, at first I was on 32mg then 24mg but for 7 months. I began to feel better, of course, but I also begin to develop the side effects.

One of the most common side effect is: the moon face, where your body retains water and you look

bloated, at first I didn’t notice this immediately. But one day in January I took a picture with friends and I didn’t even recognise myself!

My face had swollen that much, I felt like It wasn’t mine anymore. I just looked like someone else. It was really hard to accept. And it still is.

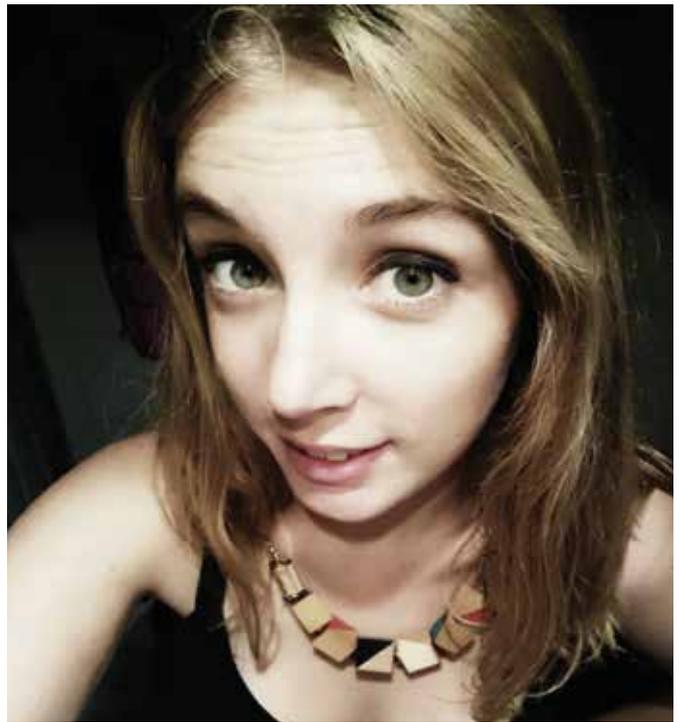
I felt like I looked like a hamster and found myself fat. I gained weight of course, but not enough to look

that fat. But I had to buy clothes in different sizes because my belly was also swollen and I couldn't wear my "normal" clothes anymore.

I had my cousin's wedding and it made me so sad when I saw how I looked on the pictures we took that day. I still can't even recognise myself.

Now I just wait to lose it. My cortisone has now been reduced but my moon face is still here. It will of course take time to get my appearance back to how I know it but I can't wait to stop it and to get back to shape.

Even though I haven't had many negative comments directly regarding the changes in my appearance, it did effect my confidence and as a young person that can be tough to deal with. I hope sharing my story will help others and help to break down taboos on this subject.



*Kat still struggling from the effects of her treatment*

## European Youth Meeting, Iceland, July 2018

**Time is approaching fast for this year's annual youth event of the EFCCA Youth Group known as the European Youth Meeting or in short EYM. This year it will be held on the weekend of 26th – 29th July and will be organised and hosted by CCU samtökin in Reykjavík in Iceland.**

The EYM is EFCCA's Youth Meeting and it is an annual meeting held in different countries around Europe every year. Delegates come from different Crohn's and Colitis associations from across Europe and join together in this meeting to meet new people with the conditions, who are also passionate about raising awareness. This event also allows participants to gather information for themselves and for their association's youth groups in their own countries.

The purpose of the meeting is to help those young adults who attend to make a network around Europe, to get new ideas for their youth groups or associations and gain information to be able to support or improve the services in their own country.

During this year's EYM the attendees will have workshops and lectures on Mental Health Wellbeing

as well as Transition from Paediatric care to adult care. There will also be a sporting event in the city of Reykjavík, a surprise trip, Gala dinner and election for the EFCCA Youth Group for who will continue the great work and projects for the following year. This weekend has always been very successful and this year will hopefully be no different.





## 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.



## France

# Founder Honoured at 35th Anniversary GA

**Sunday, 24th March 2018 was a very special day for the members of AFA CROHN RCH France, (the new name for Association François Aupetit). The General Assembly was held at the Ministry of Health auditorium with 150 participants who unanimously approved the 2017 Activity, Moral and Financial Reports.**

The CEO of the Ministry of Health, Professor Jerome Salomon, rendered a very positive and enthusiastic homage to all of the work, all the input and action AFA has produced over the years and without a doubt for many years to come.

But what was so special was the recognition given to the Founders of AFA throughout the past 35 years. Janine Aupetit, who passed away in 2017, had promised her son, François, to find the financial and scientific means to fight Crohn's Disease and Ulcerative Colitis. In 1983, following François' death in 1982, Professor Yves Le Quintrec took on the task alongside Janine Aupetit. Together with others, they pushed every door they could find....a bank to start

with and the foundation of GETAID, in 1983, to do research on IBD, especially related to the use and prescription of the few treatments available at that time. Thirty years ago, the largest IBD registry in the world today, EPIMAD, was created by the Professors, gastroenterologists, doctors, researchers, all involved in the objective of finding ways to stop the effects of IBD and help patients to stabilize their disease: a major activity in the life of AFA!

The annual distribution of grants totaling € 250 000, to eleven research teams selected by the Scientific Committee and the Board of administrators is a very precious and emotional moment which took place along with the photos of each one with Afa President

*From left to right: Prof. Yves Le Quintrec , Prof. Jean-Pierre Gendre, Anne Buisson (Afa Assistant Director) Prof Jean- Frédéric Colombel, Chantal Dufresne (Afa President), Prof. David Laharie, Prof. Laurent Beaugierie and Prof. Laurent Peyrin-Biroulet*



Chantal Dufresne and the President of the Scientific Committee, Prof. David Laharie.

35 years for AFA, but also 35 years for the Scientific Committee of AFA, whose members and presidents are among the most notable professors and researchers in Gastroenterology, specializing in IBD, in the world today: Prof. Yves Le Quintrec (1983-1996), Prof. Jean-Pierre Gendre (1997-2009), Prof Jean- Frédéric Colombel (2010-2013), (now practicing at Mount Sinai Hospital in New York, where Dr. Crohn had discovered IBD), Prof. Laurent Beaugerie (2013-2014), Prof. Laurent Peyrin-Biroulet (2015) and Prof. David Laharie (since 2016).

They were all present and each one gave a testimony of what AFA had done at each stage of its development, each one having given their free time and energy to make AFA the reference in France and a reference in the world of IBD. The most recent action is the foundation of a new association AFEMI, to promote therapeutic education to patients, and the election of its president, Dr. Jacques Moreau, member of the Scientific Committee as well.

For the final touch, Prof J.F. Colombel was asked to speak and he gave a conference on “From the first symptom to remission, how to optimize patient care,



*Prof Jean-Frédéric Colombel addressing the assembly*

today and tomorrow?” The silence in the room says it all. New outlooks, different diagnosing techniques, new care organization and so much more to insure the hope and well-being of patients everywhere were just a few of the topics this eminent professor so generously shared with the audience.

All were invited to share a glass and toast to a memorable and moving celebration.

Madeleine Dubo e, AFA CROHN RCH France

## Italy

# Collaboration between doctors and patients reduces social costs by 20%

**AMICI Onlus presents a research carried out together with the University Cattolica del Sacro Cuore on the quality of care from the point of view of both patients and physicians, along with a research on the social and economic impact caused by Inflammatory Bowel Diseases (IBD).**

Amici WE Care is a project created by AMICI in collaboration with the University Cattolica del Sacro Cuore in Milan which aims to define the quality of care of people with IBD.

The research led by professor Guendalina Graffigna, coordinator of the research center “Engageminds Hub” at the University Cattolica del Sacro Cuore in Milan, highlighted the different

perception of the patient quality of life and how it improves with a higher involvement of the patients in their treatment procedures. Treating IBD is a complex process that must involve multiple specialists and cannot consider the physical side of the disease alone; instead, it must consider the past and the psychological needs of the patients during their treatment.

Most doctors (69%) spoke in favor of actively engaging their patients in the treatment – yet, in a limited way – whereas 20% thinks that the active role of their patients should be limited to their adherence to the medication. There is a positive change (11%) in this tendency represented by doctors with less than 10 years of work experience who truly consider patients as an “active” member of the care team. Only 25% of the patients adhere to the treatment correctly; however, the degree of compliance to the treatment improves according to increased patient engagement.

The results clearly show how actively engaging the patients in their treatment by improving and promoting information generates a better management of the

disease; furthermore, it improves the adherence to the treatments and the patient quality of life while also reducing healthcare costs. Patients with high engagement levels have 20% lower direct healthcare costs (drugs, visits, exams) and 25% lower amount of sick leave days.

The final part of the study looks at the different perception of doctors and patients: there is a discrepancy between the patient’s and physician’s evaluations of the importance and satisfaction regarding the quality of care assessment criteria. For this reason, there are considerable differences between the priorities of these two groups, in particular regarding therapy personalization and the active participation of the patient in his/her own therapeutic choices.

Another study on the economic burden of IBDs in Italy has been carried out in collaboration with the Alta Scuola di Economia e Management dei Sistemi Sanitari at the University Cattolica del Sacro Cuore in Rome. The survey involving 2426 patients estimates for the first time the average annual cost that IBD

*From left to right: Prof. Ruggieri, Dr. Pisanti, Prof. Armuzzi, Prof. Graffigna, Maueri (Journalist), Sen. Granaiola Italian Senate, On. Carnevali Italian Parliament and Enrica Previtali, AMICI President*



patients must pay out of pocket at 746 euro; however, when taking into account the general productivity losses caused by suffering from this disease this average annual cost reaches 2.258 euro.

Therefore, patient engagement is an ethical and practical priority not only for the patients and their families but also for the National Healthcare System.

Guendalina Graffigna, the scientific supervisor of the project, states that “in accordance with the Patient Engagement recommendations recently developed by the University Cattolica in collaboration with the Italian region of Lombardy under the supervision of the Istituto Superiore di Sanità, the We Care project, highlights both the importance of actively engaging patients in their treatment to improve clinical outcomes and the importance of taking care of the work well-being of the doctors and of their education with the aim of supporting the cultural change in the healthcare system towards the centrality of patients and of their needs.”

Alessandro Armuzzi, professor at the Fondazione Policlinico Gemelli Università Cattolica in Milan and IG-IBD general secretary, states that “people suffering from IBD in the world are upwards of 5.000.000. This

disease has now been recognized globally. Its rate of growth has not only spiked in developed countries, but risen in large urban areas of the developing world where it was absent only 20 years ago.

There are between 150.000 and 200.000 IBD cases in Italy. Inflammatory bowel disease is a chronic disease which needs to be considered a social disease in its own right compromising an individual’s work and private life. IBDs must be treated by a multidisciplinary team able to put the patient needs at the center of their focus.”

According to Enrica Previtali, president of the Italian National Association AMICI Onlus, “this study provides extremely useful data to optimize the processes of managing and taking care of IBD patients. Our priorities are the reduction of the economic burden affecting patients, which is represented above all by services that are not included in our recently updated Basic Benefit Package (LEA - Livelli Essenziali di Assistenza), such as screening exams necessary before any treatment with biologic drugs. For this reason, AMICI Onlus wants to open a discussion with the National Healthcare System to change obsolete regulations.”

## Malta

# We have been silent – That means that we were very busy!

**During the AGM of the Malta Association of Crohn’s & Colitis (MACC) which was held on Friday, 16th March 2018, Josef Busuttill – MACC Chairperson – informed the members who attended the meeting that MACC was very busy working on a number of projects during the past year.**

The new MACC Committee is working hard on a number of initiatives, all having the aim to create the necessary awareness of IBD in Malta. These initiatives are being run in parallel and include the lighting up of prominent building on the World IBD Day, the

development of a video clip to be used on various media, including social media, and the organisation of a national informative Seminar for IBD patients and their families which will be held later on this year.

Josef Busuttill also informed the MACC Members that collaboration with other NGOs is underway for better efficacy and success. Informative brochures were recently designed and printed and are being distributed in hospitals and clinics around Malta and Gozo.

During his presentation, Josef Busuttill encouraged the Members present for the meeting to help MACC break the taboo that exists amongst IBD patients and their relatives.

“IBD is just another health condition and there is nothing to be shy or afraid of! If we (the IBD patients) don’t speak about IBD and our experience, no one would know about us and our needs.” Josef contended. “We should be our own ambassadors to help the authorities understand what IBD means and what help we require!” he continued.

Mr Marco Portelli, an MACC Committee member, also explained the importance of creating awareness of IBD in Malta and informed the members that he had the opportunity to speak to students in one of the schools in Malta. Another initiative that was well received and acknowledged by the MACC members since students may find it difficult to explain to their respective school administration staff, teachers and their peers what IBD entails.

Josef Busuttill thanked the new MACC Committee for the hard work and commitment. Following the presentation of Josef Busuttill, an informative presentation by Dr John Schembri was delivered, addressing the role of biosimilars and newer biologics in the treatment of inflammatory bowel disease from a patient’s perspective – a presentation which was well received by those present for the AGM.

by Josef Busuttill, MACC Chairperson

*Delegates during the MACC AGM, 16 March 2018*





## Pfizer Inflammation & Immunology

**Building on a heritage of more than 60 years**, Pfizer I&I is a leader in transforming the lives of people with inflammatory and autoimmune conditions.

The leadership of Pfizer I&I is demonstrated by the development and delivery of medicines to help address the unmet needs of patients living with certain rheumatology, medical dermatology and gastroenterology conditions. Pfizer provides resources to help educate people living with these conditions so they can better understand how to get the most out of their treatment and care. We also provide services to ensure that patients have access to the benefits of our breakthrough scientific advances.

With multiple potential regulatory milestones worldwide, our expansive research program and pipeline will sustain our momentum and strengthen our ability to put more I&I patients first around the world.



**Pfizer**  
Inflammation &  
Immunology

# UK

## Happy holidays! Toilet signage and Can't Wait Cards make travel with IBD a little easier

Thinking about travel can be a worrisome business for those living with IBD. Thanks to good progress in Crohn's and Colitis UK's Travel with IBD campaign, striving to have "Not every disability is visible" toilet signage installed in travel hubs, things should be a little easier this summer.

Around 81% of hubs targeted – including airports and service stations – engaged positively with the charity and 44% have already introduced signs.

“Since we launched the campaign in August 2017, almost 3,000 people have taken part, emailing more than 50,000 times to the 27 travel organisations to encourage them to change their signage,” says Andy McGuinness, campaign manager for the charity.

“We're delighted with the response the campaign has had. Members have really got on board with this and we know the signage is already tackling stigma

and making a big difference to the lives of those living with IBD who need easy access to toilets to support them with their condition.”

Crohn's and Colitis UK also engaged with the travel hubs to train staff to increase understanding of IBD and increase acceptance of the charity's Can't Wait card, which explains that you have a medical condition which means you need to use the toilet urgently. The card can be ordered in 29 different languages, professionally translated and ideal for holidaying abroad. During a holiday in the Hungarian capital Budapest, Paul used his Can't Wait card to



access a toilet in a cafe. He said: “Budapest has very few public toilets so the only options are hotels or independent cafes and bars. I saw a little cafe and asked to use the toilet that says it’s for customers. When I showed my Can’t Wait card ... Bingo! They couldn’t have been more obliging.”

The Travel with IBD campaign began after a survey of 1,776 people with IBD, conducted by Takeda UK Ltd, Crohn’s and Colitis UK and IBD Passport, found that 72% felt IBD limited their travel some to all of

the time, 70% worried about toilet facilities while travelling and 28% had deferred, cancelled or changed a trip because of an IBD-related issue.

### THE NEXT CAMPAIGN

Crohn’s and Colitis UK will focus on encouraging high-street food and drink chains such as McDonald’s to adopt the signage and accept the Can’t Wait card. Keep an eye on [crohnsandcolitis.org.uk](http://crohnsandcolitis.org.uk) for more information.

## Access to benefits

Crohn’s and Colitis UK has been working to make sure people with Crohn’s and Colitis have access to the benefits they need. By delivering training for health assessors who complete Employment and Support Allowance (ESA) assessments, the aim is to improve health assessors’ knowledge about the challenges of living with IBD. There have been four training sessions in Bristol, Manchester, Edinburgh and London.

Crohn’s and Colitis UK commissioned Disability Rights UK to research the barriers in the system for people applying for ESA and Personal Independence Payment (PIP).

“We know that our members struggle to go through these assessments due to the fluctuating nature of IBD,” says Lauren Phillips-Brighthouse, Helplines Manager at Crohn’s and Colitis UK. “By improving the knowledge of these health assessors about what it’s like to live with IBD, we hope that people will have better outcomes when applying for benefits.”

The successful ‘Crohn’s, Colitis and Me’ poster also enjoyed a makeover fit for a Queen, to enable supporters to share their story of what it is like to live with Crohn and Colitis.

## BAKE IT for World IBD Day



Crohn’s and Colitis UK will celebrate World IBD Day on 19 May with a wedding theme as it coincides with the royal wedding between Prince Harry and Meghan Markle.

Supporters are encouraged to hold their own royal tea party or bake sale to raise awareness of IBD and funds for the charity. The successful ‘Crohn’s, Colitis and Me’ poster also enjoys a makeover fit for a Queen, to enable supporters to share their story of what it is like to live with Crohn and Colitis.



# Belgium

## Campaign for a legally enforceable toilet access pass

### Hidden camera reveals how patients are refused access to toilets

The following scenario will sound familiar to many IBD patients: you are in a mall or city center when you suddenly feel the urgent need to go to the toilet. You know that if you don't find your way to a toilet right away – sometimes even within a minute – you'll risk having a very embarrassing 'accident' in public. So you rush to the nearest store, bar or restaurant, explain your illness to the staff as briefly as possible, and ask if you can use the bathroom. And then the staff says no...

Although a lot of Belgian shops, bars and restaurants do help IBD patients in these situations, CCV-vzw and Association Crohn-RCUH decided they'd had enough of the unacceptable behavior of the other establishments. So these Flemish and French-speaking IBD patient organizations, together with Takeda, launched a campaign to turn their toilet pass – which already existed but had no legal power – into an enforceable document. Another goal of the campaign was to make the general public aware of the enormous impact of IBD on patients' personal and professional lives.

The campaign was launched in March 2018, with a website that showed a hidden camera video and an online petition. The video unequivocally revealed IBD patients being denied access to the toilets in popular stores in various Belgian cities, and invited viewers to sign the petition. The Belgian press quickly jumped on it, resulting in numerous publications in the most popular newspapers, and significant attention on the main TV and radio stations. The number of signatures went through the roof, reaching the 5,000 mark within two days. A few days later more than 11,000 people had signed the petition and many more had read or



*The video available on the [www.supportIBD.be](http://www.supportIBD.be) website shows how patients have been refused access to toilets*

joined the conversation on social media and forums on media websites.

It's empowering to see how Belgian IBD patients have taken matters into their own hands to make a change. And with success, because they've taken a major step towards mainstream acceptance of their disease. The commotion they generated even prompted patient organizations for other intestinal diseases to join in. As we speak, they are forming an alliance to create a single toilet pass and to convince the government to make it legally enforceable.

To be continued...

You can watch the video (only available in Flemish/Dutch or French) on [supportIBD.be](http://supportIBD.be). For the purpose of this being a Belgian campaign, may we ask you not to sign the petition unless you are Belgian?

If you have any questions about the campaign, please contact [supportibd@lvtptr.com](mailto:supportibd@lvtptr.com)

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# Cyprus

## Appointment of paediatric gastroenterologist at Nicosia Children's Hospital

After years of intensive efforts by the Cyprus Crohn's and Colitis Association (CYCCA), as well as the Paediatric Liver, Gastroenterology and Nutrition Centre of Archbishop Makarios III Hospital and Kings College Hospital, the Celiac Disease Patients Association, the Association of Children with Liver Disease and other stakeholders, for the opening of a position in a Public Children's Hospital for a Paedogastroenterologist, we witnessed, at last, the appointment of Dr Elena Savvidou in this position as of January, 2018.

Strange as it may sound, this is considered a major step, as for many years there has been no such specialisation in the public or private sector in Cyprus and the situation was very difficult for the suffering children and their families. What has been arranged in the meantime and specifically since March 2014, is a very fruitful cooperation between our local hospital and Kings College Hospital of England. This includes the presence of a Specialist Doctor from

this Hospital in Cyprus 3-4 times a year, to examine and help suffering children, in cooperation with local doctors and nursing staff. In addition, local doctors and nursing staff are in continuous communication with Kings College Hospital, exchanging ideas and deciding on a course of therapy for individual patients.

CYCCA will support this effort of strengthening the local team with the addition of a local



*Dr Savvidou (in the middle) with Dr Andreas Hadjidemetriou on her right and Dr Panayiota Protopapa on her left, two Doctors who have played a major role in working out and implementing the cooperation with Kings College Hospital. The other persons are the President and members of the Board of Directors of CYCCA*

paedogastroenterologist, with all available means, for the purpose of improving the efficiency, speed and the level of service offered to the children. The close collaboration with Kings College Hospital, however, will continue and expand in the future, in order for

Cyprus to have a high level of medical care which will minimise the suffering of children and their families and the need to send children abroad for this vital treatment.

## Romania

### Patients Forum project - 2018

**Our association, ASPIIR, and the medical team of the IBD dedicated center, I.C. Fundeni, Bucharest, started the project “Be Patient of 10!” – a series of monthly meetings of IBD patients and ostomates with doctors focused on the needs of patients and answering their concerns and questions.**

We invited specialists from gastroenterology, surgery, psychology, oncology and other fields related to IBD and colon surgery in order to answer questions from patients. The first meeting of this series took place in November 2017, in the same venue where 8 years ago our association had its first meeting for setting up the association. The meeting gathered patients from the Gastroenterology Department of the Fundeni Clinical Institute, coming from Bucharest and the surrounding area.

We continued in January 2018 with a new Forum focused on two specific topics, namely “Peri-operator management in IBD” and “Nutrition” and were honored with the presence of two well-known surgeons and a stoma care nurse.

In February, the patients could find out about the extra-intestinal manifestations in IBD, such as rheumatic reactions that may occur in IBD as well as osteoporosis and what we have to do to relieve rheumatic pain, the benefits of swimming and so on.

A dermatologist informed about the risk of psoriasis associated with IBD (as a complication of IBD, but also as an anti-TNF-alpha adverse reaction); about the fact that properly diagnosed and treated even severe forms of pyoderma gangrenosum can be solved with minimal scars and with recommendations for the high-risk patients (Crohn’s disease) regarding perianal abscesses. We could also find out from an



ophthalmologist about the frequency of episcleritis in IBD, and other ophthalmologic manifestations.

March came with a new Forum theme: “ The management of tuberculosis risk in IBD Patients “ and physicians from Elias University Emergency Hospital, Bucharest and National Institute of Infectious Diseases “Matei Bals” joined us and answered questions about TB manifestations that may occur in untreated patients; about the risk of severe infections in patients undergoing biological therapy or of reactivating dormant infections, the perspective on the vaccinations in the patient under biological treatment and many others.

The Patients Forum will be extended in 2018 to other major cities and dedicated centers to IBD and we do hope that it will be a great support for patients.

Isabella Grosu, ASPIIR

# Spain

## Artificial intelligence for people with Crohn's disease and ulcerative colitis

**ACCU Spain presented its information and guidance service to people affected by Crohn's disease and ulcerative colitis at its General Assembly with the addition of an artificial intelligence bot that will be able to answer users' questions 24 hours a day, 7 days a week.**

A chatbot is a guided conversation with an artificial intelligence robot that interacts with the people who talk to it.

So, when a patient or any other person related to inflammatory bowel disease, be it a family member or healthcare professional, has a question and wants to make a query, they can access this new tool anytime, anywhere using Facebook. It is therefore a multi-device solution that is perfectly suited to the growing trend of mobile phone use.

With the incorporation of this artificial intelligence into the work of ACCU Spain, the organization will provide an added value service to users by offering immediate answers to any type of query related to IBD and its management. Thanks to the knowledge provided by ACCU, the robot will be able to independently guide the user and provide him with all the information he needs on various topics. As the conversation progresses, the user can focus on the points of greatest interest.

The range of topics you can ask the bot about is quite broad: identifying symptoms, lifestyles, myths about IBD, finding and learning about medical facilities, information about IBD-related drugs and their side effects, or information about legal issues related to the disease.

The decision tree has been defined and validated by ACCU Spain and follows existing user response protocols. Likewise, as with the way in which the service responds to users, it will be improved in accordance with the conversations that take place.



*ACCU España President, Julio Roldán (right), and ACCU Director Roberto Saldaña (left) during the General Assembly*

In addition, being a machine, the chatbot gives the user the confidence to ask questions on other topics that may cause social embarrassment or fear, such as incontinence or other topics that are often considered taboo, and that perhaps the user would not dare asking another person.

The bot's assistance to the user of the guidance and information service may go beyond the chat conversation since, if the user accepts, he or she may enter contact details to receive from ACCU Spain periodic advice, news, events and information.

Another important aspect is that the implementation of the bot not only brings advantages to users by facilitating access to quality information

but the ACCU's AI platform will, with the help of aggregated data, make continuous improvement, visualize the steps followed by the user, identify common questions and know the real needs and desires of users. This will be a key to success in the conceptualization and design of channels and digital assets which results in a user with greater satisfaction. Under no circumstances will ACCU recognize or identify users of the service, with the exception of

those persons who expressly request it.

The chatbot will first be integrated into ACCU's Facebook profile and then into the ACCU website.

The project is sponsored by Takeda, a pharmaceutical company involved and concerned about the quality of life of patients with inflammatory bowel disease.

## Poland

### Contest for scientific theses on IBD

**The Polish Association "J-elita" is the one and only patient organization in Poland that organizes a contest for scientific theses in the field of IBD. The contest is dedicated to authors of Ph.D., MA and BA theses from public and non-public Polish universities.**

The prizes in the contest are not high. Basically, it is an equivalent of an average monthly Polish gross salary. But it is not the money which is important here!

The aim of the contest is to direct the interest of young students of science towards IBD and motivate them to share the results of their researches. "We encourage people to submit their thesis not only in the field of gastroenterology but also from other fields, for instance: genetics, biologics, psychology or even economics" said Malgorzata Mossakowska – Honorary President of the Polish IBD patient association "J-elita" as well as founder and Secretary of Chapter of the contest.

In the jury there are: prof. Grazyna Rydzewska, prof. Witold Bartnik – honorary members of "J-elita" and also prof. Andrzej Radzikowski. All of them are authorities in the field of IBD and at the same time people that enjoy trust and respect of patients.

There was a record number of theses submitted to the 4th edition of the contest, including 11 doctoral theses defended at the Polish universities from all over the country. Among laureates were: Ph.D. thesis: Katarzyna Tonecka, MD (Medical University of Warsaw) "The role of CD200-CD200R signal path in the murine model of intestine colitis" and Ewa

Stawowczyk, MD (Jagiellonian University Medical College) "Economic analysis of biological medicines in the treatment of UC in Poland"; MA thesis: Kamila Sarkowicz "An assesment of a frequency of fiber consumption in IBD patients and the level of knowledge about a role of a diet in the treatment" and Maryla Turkot "Results of home parenteral nutrition in the treatment of patients with severe form of IBD"; BA thesis: Dagmara Cwiertniewicz "A role of a low-FODMAP diet in the treatment of IBS" and Karolina Dombkowska "A proposition of a new methodology for CD and UC treatment".

In the previous editions of the contest the prizes received young scientists and graduates from the different universities across Poland. Some of the laureates were IBD patients that chose for their thesis a subject close to their hearts and related to IBD, like: cosmetology, obstetrics or health science.

It has been years since „J-elita Association”, with its over 2000 members and 4600 observers on Facebook helps scientists and young students of science to collect data particularly for their MA and BA thesis.

„J-elita” Association

## An unexpected experience

***My name is Inken. I'm 30 years old and was diagnosed with Crohn's Disease at the age of 11. I study Health Management in Germany and I also work as a volunteer for the German Crohn's & Colitis Association (DCCV).***



With my diagnosis at the age of 11, my life changed but the world around me did not stop. I had Crohn's disease and I had to cope with everything – severe pain, diarrhea, always being tired. The following years have been very erratic and I did not have a long period of remission.

My fascination with spending some time in a foreign country came while learning English and French, and later Spanish as well, at school. Despite still having trouble with my bowel, I never stopped dreaming of it.

With the help of the 'Stiftung Darmerkrankungen' (German IBD foundation) where I got a scholarship for doing an internship in a foreign country, and the support of the German Crohn's & Colitis Association (DCCV), here I am now – in Dunedin, New Zealand.

I am doing an internship for 15 weeks at the University of Otago, where I am working on a comparison study concerning IBD at the Medical Department. Furthermore I got to know the NZ

Health System, especially Crohn's and Colitis New Zealand (CCNZ).

Although I had lots of help, I also had lots of work and preparations to make before my planned departure to New Zealand: Booking flights, applying for a visa and looking for a suitable accommodation. Collecting all the medication I needed to bring (many prescriptions for every medicine necessary). Finding a health insurance (for foreign countries) which also covers patients with chronic disease. Asking my GP for different documents which confirm that I do need this medication. Asking Abbvie (Pharma company) for a Humira ID pass/card, many cooling packs and two cooling bags. Scheduling routine appointments with my specialists (Gastroenterologist, Urologist, ...) at home to have an overall check-up before traveling and finally getting routine blood tests and B12 injections

The biggest problem I've had so far: How to transport my 10 cooled Humira injections for a period of more than 40 hours? I got many cooling packs from Abbvie as a first step, however in the planes the

flight attendants were not allowed to refreeze them. Instead they had to give me ice cubes. I had to change them every few hours because the temperature had to be between +2 and +8 Celsius in the two cooling bags. I put a bigger one I bought myself around the others to help them stay cold longer.

But how to check the temperature? Open the bags every time and risk that it is getting warmer inside? My boyfriend suggested to me to try using a Bluetooth thermometer. First, I ordered both Bluetooth and normal thermometers to see if they could get reliable readings, and took notes and recorded results. I then ordered a second pair and did a few new tests.

Before my departure I was still a little anxious and



*My cooling back*

nervous if everything would work with controlling temperature and regularly getting new ice cubes. Very expensive injections and a very long flight - not really the best combination.

...but everything arrived intact in the end and even going through the security check was no big deal.

After my very long flight I was jetlagged and tired for 2-3 weeks but after that time I got used to it. For my entire travel period and the time of the internship I checked the availability of bathrooms in general everywhere. All in all, my bowel has stressed me out a



*Meeting colleagues from Crohn's and Colitis New Zealand*

little but nothing major happened (flights were good, but once when watching penguins and once in the middle of my Christchurch trip I had some very hard situations which I could fortunately manage in the end). On the North Island my bowel wanted to test the bathroom in a bus – not very comfortable but it worked out. In general there was always a solution for every Crohn's problem.

I got to know very friendly people everywhere socially and in my field regarding the disease. For instance I went to a local CCNZ group meeting in Dunedin and had the chance to attend to a board meeting in Wellington. In my opinion a very important point is communication between ourselves (as IBD patients), also in an international context.

Although several weeks ago a blood test was necessary because of feeling tired and exhausted, and I also had some bowel pain, but it did not reduce the enjoyment of my stay.

I don't regret this trip at all; the internship and travelling around New Zealand has helped me and changed my life in many ways I hadn't considered before. I would recommend it to everyone regardless of illness or money. Give it a try – there is always a way. If you have any questions or you want to contact me: [Inkenkanbach@web.de](mailto:Inkenkanbach@web.de)

I look forward to hearing from you!

# An earthquake

*by Jorge Ascenção, APDI, Portugal*

An earthquake inside any room, in any building, in any city of the world. It's something that can happen anywhere and that can have greater or lesser destructive effect. Such as Inflammatory Bowel Disease (IBD).

And, just like in IBD, it has an epicenter. A central point at the surface, where you can register the maximum intensity of that seism from where the shockwaves depart ...

Our first mistake, sometimes, is to think that we can isolate that earthquake in a room. Well closed. Really isolated from all the adjacent rooms. From all the buildings around. You can't contain an earthquake with the magnitude of IBD only inside "your room". You can't even contain it inside you own "personal and family building". Its vibration can start in the first symptoms of the disease, or at full throttle when you know your diagnosis. But be sure it will shake the world of some one with IBD, and, with no doubt, reach the people around you.

Tell me something, if you were sitting in a room, and your child in the room next to yours, and suddenly, beneath your feet, an earthquake "blasted through" ... do you really think you could stop the shockwaves from hitting your child in the other room? Then, why do some of us want to (or try to) keep IBD just for themselves? "I can control it", "I dont need to bother anyone." "They wouldn't know how to deal with this disease ..."

We need time. You're right. It's important. We don't have to immediately accept this new reality that was imposed called IBD and for the same reason, time will be useful to integrate these new "rules" in life.

But, as you go forward and comply to the prescribed drugs, doctor appointments, exams, as you take those abdominal pain crisis, and panic attacks when you see blood in the feces ... as you take that injustice ... are

you really going to let your children "in the dark"? "Imagining" the reasons?

You can deceive yourself, thinking that they don't see, or hear or don't understand something ... but they already know that something is wrong. They just don't know what! "Why is dad in pain everyday?" "Why is mom always in the bathroom?" "Why is daddy always shouting at me and never has any patience at all?" "Why do you keep going to the hospital?" "Why don't you tell me what's going on? Don't you trust me?"

And, at this point, without knowing the real reason, they make one up and sometimes these made-up stories are worse than reality ... they start to fill the "gap" of your lack of trust in them, with doubts if the disease is even worse than it looks "My mom is in the hospital for over two weeks and they don't let me see her! Is she going to die?"

And, back to the earthquake "story" if it was in your child's room, wouldn't you feel it, in your own room? Or get your child not to realize what was happening in their own room? With their own health? Your child also will need time to "get it". And it's so unfair to "get" this kind of diseases. "I thought only old people got diseases like mine" a patient was telling me just a few weeks back in a session.

In some age groups we don't really understand what a disease is. And a disease that "lasts forever" no less. And "what did I do to get it?" "Why do I have to take all those meds?"

How can you tell if its a child's tantrum, the sulkiness of a teenager, or the petulance of that pain that simply doesnt go away? All of your children's friends can eat "junk", drink soda, and he or she can't? Or can they? Why not? How do you negotiate this with them?



“Later” or “never” are issues hard to explain or even to find out on your own. Your children don’t come with an instruction manual even if they don’t have IBD. But you already have some kind of “your own IBD manual”, right?

It’s not complete. We know where the earthquake is coming from, but we don’t know the “why”. We can better manage the disease, but we don’t have full control of it, or of its symptoms. And we can’t fully stop the “earthquakes”. Yet!

The first step is to inform your doctor or nurse that you would like to bring your children to the next appointment. Ask them to address some questions that they asked back home. “But then how do I deal with all those questions?”- By being the great dad and the great mom you always were. Trust yourself!

And, maybe the doctor, the nurse, the nutritionist or the psychologist have already seen this kind of “earthquake” ... maybe they even have some ideas on how to overcome those questions, the pain, the conflicts, maybe they need to hear your thoughts

about your own IBD or your children’s IBD. Communication!

And how about exploring some new strategies with a psychologist? Give your children some space to ask all the questions, unleash that anger, the injustice, and explore fear and hope, about his/her own IBD, or about mom or dad’s IBD. And guess what? You have the right to have a space of your own too!

When you talk to your children or your relatives, learn to start some sentences with “I need”, or “I feel that”, or even “I’m afraid of”. And be available to listen. To be there ... and ask them to be there for you. Do you really know a better role model than this for your children? Wouldn’t you be there for a friend? Well, right now we need available people in our own “room” during these “earthquakes”. And our children need to know what’s happening in their “room” and to know that they can count on us. Transparency!

It’s our responsibility to learn, enlighten, and overcome that huge earthquake. Together!

## Declaration for Patient Safety

**Health First Europe(HFE) is urging patients, healthcare workers, and all citizens to sign a declaration on Patient Safety. Governments must act now to stop preventable harm and guarantee a safer healthcare in Europe.**

The World Health Organisation (WHO) estimates that patient harm is the 14th leading cause of the global disease burden, alike illnesses such as tuberculosis and malaria. In some European countries, the burden of patient harm is comparable to that of chronic diseases (e.g. multiple sclerosis and some types of cancer). Statistics show that strategies to reduce the rate of adverse events in the European Union alone would lead to the prevention of more than 750 000 harm-inflicting medical errors per year, leading in turn to over 3.2 million fewer days of hospitalization, 260 000 fewer incidents of permanent disability, and 95 000 fewer deaths per year.

The Declaration for Patient Safety aims to call upon health authorities, policymakers, healthcare professionals, providers and patients to join hands to prevent unnecessary harms in healthcare by promoting safer health systems and high quality standards on patient safety across Europe.

You might find references and further info on the Declaration for Patient Safety at <http://declaration4patientsafety.eu/> - now available also in French – German – Italian – Spanish.



### About Health First Europe

Health First Europe (HFE) is a non-profit organization bringing together patients, healthcare workers, academics and medical technology industry. HFE has consistently been part of building policy aimed at better patient safety in the EU. HFE's key priority is to promote the development of a truly patient-centred healthcare, a system where all European citizens could benefit from the best medical treatments available. As part of that effort HFE has created a set of recommendations, sponsored numerous events and developed patient safety indicators.

## Crohn's and Colitis Australia to develop National Action Plan for IBD

**The Turnbull Government has engaged Crohn's & Colitis Australia (CCA) to develop a National Action Plan to identify the priorities to improve quality of care for more than 85,000 Australians affected by inflammatory bowel disease (IBD).**

The IBD National Action Plan will be jointly developed by the government, medical and other health care professionals and CCA, who will receive \$150,000 in funding to undertake this work.

The Plan will seek to identify and consolidate a blueprint for improvement of the quality of care for Australians living with IBD.

It is estimated that one in 250 Australians are

living with Crohn's disease and ulcerative colitis (collectively known as inflammatory bowel diseases) – a chronic and largely hidden bowel diseases in which the intestines become inflamed.

CCA has lobbied government for a change in IBD services and met with Hon. Greg Hunt, Minister for Health to discuss the importance of improving IBD health care in 2017. The National Action Plan will build on the evidence gathered as part of the national IBD audit and Australian IBD Standards developed by CCA.

Francesca Manglaviti, CEO of Crohn's & Colitis Australia, said she was delighted to have the opportunity to lead the development of the National Action Plan.

“This Plan will provide guidance and direction on key goals and priorities for IBD health care, and help us ensure that people with IBD receive the best possible IBD care in Australia.”

The Turnbull government, stakeholders in IBD care and people living with IBD will work together with CCA to develop the National Action Plan. The first step will be a round-table meeting to identify gaps and consider actions.

The National Action Plan will be a public document published on [www.crohnsandcolitis.com.au](http://www.crohnsandcolitis.com.au) upon completion.

## Employment and social inclusion of persons with disabilities

**The European Disability Forum has adopted a resolution to promote employment & social inclusion of persons with disabilities.**

After EDF first reaction to the European Commission's proposal for the European Pillar of Social Rights (the Social Pillar), and ahead of the Social Summit for Fair Jobs and Growth on the 17 November, EDF Board adopts a resolution in the same context. Through this resolution, EDF Board addresses Heads of States and Governments to call for a strong commitment towards the right to employment, social inclusion and social protection for persons with disabilities and all people in the European Union (EU).

To apply the principles of the Social Pillar and achieve higher employment rate, better working conditions and adequate standards of living and social protection for all EU citizens including persons with disabilities, national governments should commit to its implementation at national level.

To this end, EDF resolution:

- reminds EU Member States of their obligations under the United Nations Convention on the Rights

of Persons with Disabilities (UN CRPD), as well as under the 2030 Agenda on Sustainable Development and the Sustainable Development Goals (SDGs);

- calls for adequate financial resources to be allocated to promote better employment conditions and social protection for persons with disabilities;

- calls for the adoption of a strong directive on Work-Life Balance for Parents and Careers which recognizes both the perspective of carers of persons with disabilities and of parents with disabilities.

EDF and its members will advocate to bring the messages of the resolution at the attention on Heads of States and Governments during the Social Summit on the 17 November 2017 and during the Social Platform side event in Gothenburg on 16 November 2017. Follow the discussion on social media using the hashtag: #SocialSummit17

Contact: Simona Giarratano, EDF Social Policy Officer: [simona.giarratano@edf-feph.org](mailto:simona.giarratano@edf-feph.org)

# New treatment options for inflammatory bowel diseases

**Bram Verstockt, Marc Ferrante, Séverine Vermeire, and Gert Van Assche**

The landscape of IBD treatment is widening rapidly. As more biologic and small molecule therapies become available, patients and clinicians alike will be faced with selecting the right drug. The mechanisms of action and perceived tolerability of new treatment options will increasingly drive clinical decisions. Head-to-head comparative trials are desperately needed to facilitate these important choices.

## Abstract

The advent of anti-TNF agents has dramatically changed the treatment algorithms for IBD in the last 15 years, but primarily and more importantly secondary loss of response is often observed. Fortunately, new treatment options have been actively explored and some have already entered our clinical practice. In the class of anti-cytokine agents, the anti-IL12/IL23 monoclonal antibodies (mAbs) have entered clinical practice with the anti-p40 mAb ustekinumab in Crohn's disease (CD). Also, more selective anti-IL23 agents (anti-p19) have shown efficacy and are being further developed, in contrast to agents inhibiting IL-17 downstream which have failed in clinical trials despite their clear efficacy in psoriasis (Verstockt et al. in *Expert Opin Biol Ther* 17(1):31–47, 2017; Verstockt et al. in *Expert Opin Drug Saf* 16(7):809–821, 2017). Following up on the efficacy of the anti-adhesion molecule vedolizumab, etrolizumab (anti-beta-7 integrin) and PF-00547659, an anti-MadCam mAb, are being developed (Lobaton et al. in *Aliment Pharmacol Ther* 39(6):579–594, 2014).

Oral anti-trafficking agents, such as ozanimod, targeting the S1P receptor responsible for the efflux of T-cells from the lymph nodes, have also shown efficacy in patients with ulcerative colitis (UC) (Sandborn et al. in *N Engl J Med* 374(18):1754–1762, 2016). Oral agents inhibiting cell signaling have been explored successfully in IBD. Tofacitinib, a non-selective oral Janus kinase (JAK) inhibitor, is effective in patients with UC and several other more or less selective Jak1, 2 and 3 inhibitors are being developed for the treatment of CD and UC (Sandborn et al. in

*N Engl J Med* 376(18):1723–1736, 2017; Vermeire et al. in *Lancet* 389(10066):266–275, 2017; De Vries et al. in *J Crohns Colitis* 11(7):885–93, 2017). Finally, despite initial disappointing results with systemic administration of mesenchymal stem cells, Alofisel, adipose tissue derived, allogeneic mesenchymal stem cells, locally injected in perianal fistula tracts, induce long-lasting beneficial effects and the drug has been approved in Europe (Panés et al. in *Gastroenterology*, 2017). In summary, the quest for new treatment options in IBD is very active and justified by the high medical need and unresolved problems patients are facing.

## Anti-IL12/IL23 agents

The non-selective anti-IL12/23 mAb ustekinumab (Stelara®, Janssen) has been tested in four large phase II/III clinical trials in patients with IBD, and has been proven to be efficacious to induce and maintain clinical remission in CD [9–11]. This treatment has been approved before to treat psoriasis and psoriatic arthritis, and is now also approved in Europe and the US to treat patients with Crohn's disease. The long-term safety in a large prospective cohort is reassuring, but it has to be said that patients with IBD comprised only 3% of that cohort. Most were patients with psoriasis or rheumatologic conditions [12]. The results of a phase III, randomized, double-blind, placebo-controlled multicenter study to evaluate the safety and efficacy of ustekinumab induction and maintenance therapy in subjects with moderate-to-severe UC (UNIFI, NCT02407236) are expected

The role of ustekinumab pharmacokinetics is

unclear at this moment, but cohort data suggest that endoscopic healing is related to ustekinumab trough levels [13], which was also observed in a post hoc sub-analysis of the phase III program [14]. In contrast to infliximab, the immunogenic profile of ustekinumab is very limited (2.3% of all 1154 patients included in the UNIFI trials developed auto-antibodies against ustekinumab, measured via a drug-tolerant assay) [11]. This might explain why immunomodulators do not seem to influence ustekinumab pharmacokinetics [14].

Though the efficacy and safety of blocking p40 has been established, it is not clear if direct modulation of the IL12 axis via p40 contributes to the efficacy or has potential risks related to IL12's role in tumor immune surveillance and in host defense against intracellular pathogens [2]. Hence, selectively blocking IL23p19 might offer important differentiation in efficacy and safety.

MEDI2070 (AMG-139, Amgen and MedImmune) is a fully human IgG2 monoclonal antibody, which selectively binds p19. The results of a phase IIa induction study recently demonstrated clinical efficacy in 121 patients with moderate-to-severe CD, who previously had failed anti-TNF therapy [15]. After administration of 700 mg MEDI2070 intravenously at week 0–4, clinical effect ( $> 100$  drop from baseline CDAI-score OR CDAI  $< 150$ ) at week eight was achieved in 49.2% of patients, compared to 26.7% of patients receiving placebo ( $p = 0.010$ ). Through week 12, no increased rate of adverse events (AE) with active treatment was observed compared to placebo. Similarly to MEDI2070, risankizumab (BI-655066, Boehringer Ingelheim and Abbvie) potently binds to p19 and prevents its binding to the IL23R.

The results of a phase II trial in moderately-to-severely active CD were favorable [16]. Selective blockade of IL23p19 with risankizumab was superior to placebo in achieving clinical remission (30.5% vs 15.4% respectively,  $p = 0.049$ ) and clinical response (39.0% vs 20.5% respectively,  $p = 0.027$ ). Ninety-four per cent of all included patients had been exposed to anti-TNF before, with approximately one-third (30%) experiencing primary non-response and another third (28%) secondary loss of response,

reflecting a very refractory population. In addition, significantly more patients achieved endoscopic remission with risankizumab compared to placebo (17.1% vs 2.6%, respectively;  $p = 0.002$ ) at week 12. So far, risankizumab shows a favorable safety profile with fewer severe or serious AE reported compared to placebo. Although ustekinumab and risankizumab have not yet been compared head-to-head in IBD, a phase II randomized-trial in patients with psoriasis showed superiority of risankizumab compared to ustekinumab [17].

LY3074828 (Eli Lilly) is actually being studied in patients with moderate-to-severe UC (NCT02589665). Tildrakizumab (MK-3222, Sun Pharma and Merck) will potentially be studied in active CD, after the first positive results of a phase IIa trial in psoriasis [18]. Finally, guselkumab (Janssen Biotech) showed efficacy in a recent phase II trial in psoriasis [19, 20], and early trials in patients with IBD are underway.

Targeting IL17, a key cytokine secreted by TH17 cells and downstream mediator of IL23 signaling, is logical as an increased expression of IL17A and IL17F has been reported in active CD, scattered throughout the submucosa and muscularis propria [21, 22]. Brodalumab (AMG827, Amgen) is a fully human antibody against the IL17-receptor A (IL17RA), studied in a phase II trial in moderate-to-severe CD. The study was terminated prematurely after an independent review of unblinded safety data from 117 of 216 planned subjects demonstrated an imbalance in worsening CD in active treatment groups [23]. Secukinumab (AIN457, Novartis) is a fully humanized selective anti-IL17A antibody (Fig. 1), studied in CD after increased expression of IL17A mRNA was reported in the intestinal mucosa of CD patients [24].

Phase I-II trials in psoriasis and rheumatoid arthritis showed clinically relevant responses and a head-to-head comparative trial in patients with plaque psoriasis showed superiority for secukinumab over the anti-p40 ustekinumab [25]. Nevertheless, an RCT in moderate-to-severe CD demonstrated blockade of IL17A was ineffective and secukinumab may even worsen disease in patients with a certain genotype. In

addition, higher rates of AE, mainly serious infections (mucocutaneous candidiasis) were noted compared to placebo [26].

The fact that blockade of either the ligand (secukinumab) or its receptor (brodalumab) causes worsening disease, suggests this is not merely coincidence but probably a true biologic effect. The worsening comes not entirely unexpected, as IL17A has been claimed to show both a protective and exacerbating effect in preclinical murine models [2]. Both RCTs clearly point out that blocking IL17/IL17R may interfere with a protective function of IL17 in the intestine.

### Anti-adhesion molecules

Vedolizumab (Entyvio©, Takeda), a mAb targeting  $\alpha 4\beta 7$  integrins resulting in a gut selective mechanism of action, has been approved for the treatment of moderate to severe Crohn's disease and ulcerative colitis worldwide. Natalizumab, a non-selective anti- $\alpha 4$  integrin mAb, had been shown to be effective in Crohn's disease before, but is only available to treat Crohn's disease in the US and Switzerland. Other jurisdictions have not approved this drug since it carries a risk of a potentially deadly viral brain disease, progressive multifocal leukoencephalopathy [3]. The long-term risk in patients with multiple sclerosis treated long term is estimated at 1/300. With vedolizumab, no cases have been reported so far in over 72,000 exposed patients.

Etrolizumab (Genentech-Roche) is a slightly less gut selective mAb targeting the  $\beta 7$  integrin subunit and thus both  $\alpha 4\beta 7$  and  $\alpha E\beta 7$ . This could potentially increase its efficacy as  $\alpha E\beta 7$  integrins, through their binding to E-cadherin, are responsible for retention of lymphocytes in the diseased tissue. On the other hand, this broader mechanism of action may result in a loss of gut selectivity and thus in more systemic side-effects. Etrolizumab was proven to be efficacious in a phase IIb trial in moderate to severe ulcerative colitis [27]. The remission rates in the 100 mg and 300 mg SC group combined were significantly better than placebo (10% 300 mg, 21% 100 mg, 0% placebo,  $p = 0.048$  and  $p = 0.004$  respectively). Of note, etrolizumab at either dose of 100 and 300 mg was not more effective than placebo in patients who

had already been treated with anti-TNF agents before. A large phase III trial is currently recruiting patients.

Inhibiting mucosal addressin cellular adhesion molecule 1 (MadCAM-1), the ligand of  $\alpha 4\beta 7$  integrin, also is a gut-selective anti-adhesion molecule strategy. The anti-MadCAM-1 mAb, PF-00547, 659 (Pfizer and Shire) has been tested in both Crohn's disease and ulcerative colitis, but clear significant improvements over placebo of clinical disease activity have not been shown yet [28].

Fingolimod, an oral anti-adhesion molecule targeting the S1P receptor, is used in clinical practice in patients with multiple sclerosis. The binding of S1P to its receptor, guides lymphocytes out of the lymph nodes and therefore, interfering with this mechanism, results in a sequestration of lymphocytes in the lymph nodes. Ozanimod, an S1P receptor antagonist, has shown efficacy in patients with moderate-to-severe ulcerative colitis. Ozanimod 1 mg, but not the lower dose of 0.5 mg, was significantly superior to placebo (ozanimod 1 mg 16.4%, ozanimod 0.5 mg 13.8%; placebo 6.2%;  $p = 0.048$  and  $p = 0.14$  respectively) [4]. Both doses were better than placebo at inducing mucosal healing. Other similar molecules are being developed to treat IBD. S1P receptors carry a risk of systemic infections, including JC virus induced brain infections, and bradyarrhythmia, but this risk may vary based on the S1P receptor subtypes targeted by the different compounds.

### Janus kinase inhibitors

The Janus kinase (JAK) enzymes, named after the two-faced Roman god Janus, are crucial in the signaling of a variety of cytokines through their receptor and always occur in heterodimers. Different combinations of JAK 1, 2, 3 and Tyrosine kinase (TYK) 2 are involved in the signaling of key inflammatory cytokines. The specificity of a molecule for the different JAK subtypes therefore will determine its efficacy and safety profile. The non-selective JAK inhibitor tofacitinib (Pfizer) is approved in Europe and other parts of the world for the treatment of rheumatoid arthritis. Also, in moderate to severe ulcerative colitis, tofacitinib at a dose of 3 to 15 mg BID is more effective than

placebo to induce clinical remission [5]. The results of two large phase III trials (Octave 1 and 2) confirm the efficacy at inducing remission in ulcerative colitis, and the results of the maintenance phase of these trials indicate that tofacitinib is also effective at maintaining remission throughout one year [5]. On the other hand, tofacitinib failed to show clinical efficacy in Crohn's disease [29].

Other compounds, such as the more JAK1 selective filgotinib (Galapagos/Gilead) and upadacitinib (Abbvie) are being developed to treat Crohn's disease and ulcerative colitis. Filgotinib is more effective than placebo to induce clinical remission and mucosal healing in patients with moderate to severe Crohn's disease [6]. Results from a phase II RCT with upadacitinib are also showing dose dependent favorable outcomes in patients with Crohn's disease [30]. JAKinibs are associated with an increase in herpes zoster infections and potentially with other systemic infections, serum lipid disturbances and anemia [7]. Ongoing phase III trials may elucidate whether the safety profile is determined by the selectivity of compounds for JAK1,2,3 and Tyk2 respectively.

### **Fecal microbiota transplantation**

Treating IBD with fecal material has been tried for more than 2000 years. All data available until recently, were uncontrolled [31]. However, the renewed interest in the intestinal microbiome as a modifier of human disease, has led to randomized controlled trials using fecal transplantation in patients with ulcerative colitis. Most of the fecal mass is comprised of microbiota, and therefore the term fecal microbiota transplantation (FMT) has been used. In total, 3 out of the 4 RCTs with FMT which have been performed in recent years, show a significant and favourable effect in inducing clinical and/or endoscopic remission in patients with UC [32–35]. Nevertheless, more research is needed on the ideal microbiome composition and FMT conditions, such as mode and intensity of administration, to treat UC and CD.

### **Nucleotides**

The oral anti-sense small oligonucleotide Mongersen (Guliani/Cellgene) is directed against the translation of SMAD7. This is a key inhibitory protein

that downregulates the signaling of Transforming growth factor-beta (TGF- $\beta$ ). When SMAD7 protein is suppressed, TGF- $\beta$  will be able to resort its anti-inflammatory effects on the mucosa. The first RCT with Mongersen indicated that this molecule is efficacious to induce clinical remission in patients with Crohn's disease. Mongersen at the higher doses of 40 and 160 mg given daily for 14 days was better than placebo at inducing Crohn's disease remission [36]. In addition, Mongersen induced a long-lasting response off therapy [37]. However, a confirmatory randomized control trial was stopped prematurely because of lack of efficacy and the further development of this drug has been halted.

### **Mesenchymal stem cells**

Stem cell therapy has not been successful in IBD until the advent of mesenchymal stem cell therapy to treat perianal Crohn's disease. Cx-601, Alofisel (Tigenix/Takeda) has proven to be efficacious to induce and maintain fistula closure, when applied locally close to the tract in conjunction with surgical preparation of the fistula track [8]. Of note, a high placebo effect was noted in this trial, which could have been due to the background therapies including anti-TNFs and the surgical preparation of the fistula track with closing of the internal orifice in both treatment arms. The drug received approval in Europe and a second phase III trial is being conducted.

### **References:**

Please visit: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5910475/>

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