

# EFCCA MAGAZINE

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

A young boy with dark hair, wearing a dark blue t-shirt and blue patterned pants, sits on a kitchen counter. He is looking off to the side with a thoughtful expression. The background shows a kitchen with white cabinets and a decorative tile border. A box of cereal is visible on a shelf above him. In the foreground, there is a chocolate cake on the counter.

## Castigado y sin comer

A short film about a boy with Crohn's disease

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## Symposium on IBD Research

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# EDITOR'S EYE

## Empowering patients



Dear Readers,

I am very pleased to share our news about some of the exciting initiatives that we, as EFCCA, are planning for this year. Notably the organization of our second International Symposium on IBD Research supported by patients, which will take place at end of May in Bucharest, Romania and which will reinforce the patient's role and voice in research.

We will be gathering patients, physicians and other healthcare related stakeholders in order to promote the debate on research in IBD and to expand our know-how. A structured cooperation and exchange of information will allow us to strategically develop research based on patients unmet needs and priorities.

This a very important meeting for the IBD community worldwide especially for those patient organisations that are investing human capital and financial resources in research to finally find a cure for patients with IBD. We believe this is the main pathway that will lead to a better future for people with IBD and we also expect that this symposium will lay the foundations for a

permanent observatory on IBD Research

Another good piece of news is that we have now completed the mapping project on innovative medicines and devices. 32 members of EFCCA participated in this project giving us a widespread overview of the current state of affairs as concerns access to and availability of innovative medicines such as biologics and biosimilars as well as other devices. The outcomes show that there are significant differences between countries and can put IBD patients in very unequal positions in terms of access to care, in some cases even if they live in the same country and within the same health care system.

The results of the mapping project will allow us to highlight existing health inequalities and to advocate both at national and European level for a better European healthcare system that provides equal access to treatment.

This project would not have been possible without the active participation of our members and the committed volunteers and staff that have been working hard in collecting and analysing the relevant information. A huge

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

thank you to all!

As far as our partnership with international medical societies is concerned I'm pleased to inform that ECCO has involved us in the new elaboration of the ECCO Guidelines on Crohn's and that 4 patient representatives will be involved since their design phase in partnership with physicians and nurses. I am also happy to share with you that we are strengthening our collaboration with the United European Gastroenterologists (UEG), which resulted in the participation of our CEO, Luisa Avedano, during the closing session of the UEG Week allowing her to provide the patients' perspective to a wide scientific audience.

In Barcelona, the day before the UEG week our CEO was also invited in the first patient parent meeting organised by ESPGHAN, the paediatrician European society, a strong sign of our increasing visibility, in particular on the importance of the transition phase between child care and adult one.

We are also opening up new horizons and have started collaborating with stakeholders that have previously been unknown "actors" to us such as for example Microsoft. We all know that Microsoft plays an important role in data collection and the debate around "Big data" is presenting new challenges but also new opportunities. So therefore we are pleased that EFCCA forms part of the debate on how to maximize the potential of health data for society. You will find more information about this and the previously mentioned initiatives in the EFCCA News section of this issue.

In other stories and articles of this issue you will find plenty of evidence of the commitment and hard work of our members, our youth group and other partner organisations in serving the interests of the IBD patient community and to ensure that our voice is heard and our concerns are being addressed.

I am always amazed to see how much courage, energy and enthusiasm people can muster when they are so deeply challenged. We all know that IBD is a hard battle, but we can and we will overcome this fight against IBD as long as we work together and stay united!

Martin Kojinkov, EFCCA Chairman



# Biologics and Biosimilars: Regional Patient Advocacy Workshop

**Delegates from 17 patient associations representing immune modulated disease groups in the Mediterranean area gathered at the Patient Advocacy Workshop in Rome from 10-11 November 2017 in order to discuss experiences and local best practice around issues concerning Biologics and Biosimilars.**

The workshop was organized by the Global Alliance for Patient Access (GAfPA) in cooperation with EFCCA and forms part of 3 regional seminars that were held throughout 2017 as a follow up to our main workshop in Barcelona 2016.

At the Barcelona workshop more than 60 representatives from a variety of immune modulated disease groups treated by biologic therapies decided to create greater awareness amongst patient communities regarding the issues impacting access to biologic and biosimilar treatments and to provide and improve basic understanding of the science and issues associated with biological medicines and biosimilars.

During the Rome workshop presentations built on previous discussions by bringing together

patient representatives primarily from Southern Europe to consider the outstanding policy questions around patient access, use of biologic and biosimilar medicines, and how to most effectively ensure that the patient voice can be heard in policy decisions.

The 17 patient delegates from 9 different countries represented specialties from across rheumatology and gastroenterology, including several members of EFCCA.

Luisa Avedano, Chief Executive Officer of EFCCA formally opened the workshop and encouraged attendees to engage in a frank and open conversation about the way in which biologic and biosimilar medicines are used in their own countries and how they feel about this as patients. Dr David Charles,

*Participants at the Regional Patient Advocacy Workshop, Rome 10-11 November 2017*



Chairman of GAfPA, provided an introduction to the topic by explaining the manufacturing process behind biologic and biosimilar medicines. He welcomed the development of biosimilar medicines as offering additional treatment options, bringing down prices by increasing competition, and overall helping to increase patient access. However, Dr Charles did urge caution around treating biosimilars in the same way as generics.

### Discussion on Pharmacovigilance (PV)

The group agreed that one of the most crucial aspects of a robust PV system is to be able to track any patient response to a switch of medicine, whether this is between biologics or to a biosimilar. Attendees all recognised that their healthcare systems are under increasing pressure to deliver quick financial savings by switching patients to biosimilars. Participants

concluded that patients should have the right to an informed discussion with their physician about their options, and their right to choose to remain on a treatment if they are stable.

### Regional Best Practice for Advocacy

Several EFCCA members shared their specific experiences on advocacy work which was followed by a good debate and exchange of ideas and the group came up with some concrete examples for successful advocacy work.

More details can be found in the reports of all 3 regional workshops (Munich, 5-6 May 2017, Warsaw 15-16 September 2017 and Rome 10-11 November 2017). The reports are available on our website. For further information please contact the EFCCA office.

## Symposium on IBD Research

**EFCCA will organise its second Symposium on IBD Research funded by patients to take place on 27 May 2018 in Bucharest, Romania bringing together representatives from patients groups from 5 continents, gastroenterologists and other healthcare providers as well as relevant stakeholders in order to reinforce patients' role and voice in research.**

It will build on the first Symposium on IBD Research that was organised by EFCCA in 2012 and which gathered evidence and information from IBD patient associations that directly fund or promote research into the causes and treatment of IBD and provided a unique platform for IBD associations from around the world to exchange and get new ideas in developing research-support strategies.

This year's Symposium in Bucharest will lay the grounds for an information model that allows patient associations, individuals and/or researchers to know what subjects are being investigated, to evaluate or develop cross frontier co-operations, to create synergies and to better strategize research.

It will be structured into 3 clusters. Every cluster will focus on a specific topic chosen according to the outcomes of consultations among EFCCA members

and prominent International Medical Societies.

Cluster 1: "New challenges beyond originators and biosimilars".

Cluster 2: "Patients' priorities and unmet needs in research

Cluster 3 "Patient centered research and clinical trials: what do patients need?"

The Symposium aims to boost the debate on research in IBD, reinforce relationships and know-how within the IBD community and support a more robust exchange of information worldwide. It will ensure stronger and more structured collaboration between patients' associations and researchers/scientists based on unmet needs and priorities.

For more information please contact the EFCCA office.

# The social impact of a chronic disease

**Understanding how a disease impacts our social roles, personal relations, our productivity, employment and contributions to the society, as well as the effects of the disease on society has to be part of our overall understanding of the disease.**

Medical costs in chronic disease are significant. But what are the implications for us who are part of the society, and for the society as a whole? A couple of years ago, EFCCA and national patient associations carried out a first ever study in an effort to identify and describe the impact IBD has on the quality of life of Europeans living with it. Many reported absence from work, underperformance in education, and an array of discrimination in employment, educational and social context. This has helped us broaden our understanding of the extent to which we as individuals and as society can be affected by the disease.

Another face of the social impact of disease is seen in the way social actors change. With the effect of the disease both individually and collectively, we are also interested to look (and measure) how our employers, schools, government institutions and services change in response to our needs which stem from our disease?

Do employers adopt new regulations to support employees with IBD? Have there been awareness raising campaigns in schools on needs of youth living with IBD? And can we say that services which are available to us have better knowledge of our needs? The change which occurs at the level of society actors should equally contribute (albeit in longer term) to better health outcomes for us as individuals and a group, and ultimately less cost for the society. We as the patient community are best positioned to measure that change, assess it and advocate for increased public commitment.

A recent analysis carried out by a group of US experts (BCG, Inflammatory Bowel Disease: Today's Burden, Tomorrow's Opportunities, 2016) on the burden of the disease shows that people living with IBD are faced with degraded quality of life and difficulties in social context. Besides this, indirect



*Marko Perovic is member of the Serbian IBD patient association UKUKS as well as member of the EFCCA Executive Board. He has long term work experience on social issues and civil society organisations.*

costs of IBD (those incurred as a result of leaves, sick days and under-productivity) significantly increase the IBD-related costs, in addition to the costs directly related to treatments and health-related costs (which in turn account to as little as one fifth of all costs).

The fact that IBD, as a chronic disease may and does have effect on patients, on public health, as it does on the society, bearing a strong social impact helps us place the focus of our attention to mid and long-term effects of the disease, and requires us to expand our area of interest to better understanding the new IBD realities, in which people are not mere patients isolated in medical settings, but members of the society to which they contribute with their productivity, participation and social investment.

Marko Perovic, EFCCA Board member

# More Trust, More Data, Better Health

## How does Europe grasp the innovation opportunity?

**Last November Séan Kelly MEP, hosted the launch of a one-year ‘roadshow’, organised by Microsoft, bringing together key stakeholders including patients, regulators, data protection authorities, innovators, researchers and industry to take part in a discussion on maximising the potential of health data for society.**

The main objective of the roadshow is to develop a paper with concrete policy recommendations for policy makers and interested third parties at European and national level.

MEP Kelly emphasized the need for all relevant stakeholders to come together and find meaningful answers to the challenges faced in this area. Besides MEP Kelly, MEP Pilar del Castillo Vera, MEP Peter Liese and MEP Michal Boni also participated in the meeting and provided their own views on how health and data interact for the better good. Topics discussed included: how to tackle uncertainty in innovation, the factors which influence patients’ and citizens’ willingness to share their health data, and the importance of building trust as a task for all stakeholders.

EFCCA’s CEO presented the patients’ perspective on data sharing, highlighting that, whilst patients are generally willing to share their information if it can help save lives, they want to first be made ‘owners’ of their data. Hence, patients should be able to easily find where their data is being stored and who has access to it. They also need to be better informed about what rights they have and rules governing data protection need to be transparent and should be a common agreement between all stakeholders, with clearly defined roles and responsibilities. Likewise, systems processing health data need to be transparent and should provide feedback to patients on how and where their data is being used. Finally, sharing success stories of where these goals have already been achieved will be a key step, and can help to further raise awareness around the benefits of digital health.



*MEP Sean Kelly during the opening of the event organised by Microsoft on Big data*

Mr. Martin Seychell, Deputy Director-General at the European Commission’s health and food safety department, outlined several initiatives which the Commission is pursuing in relation to its Digital Single Market objectives.

The conversation will continue at regional meetings that will focus around research, clinical need and patient-centricity, examine the health systems impact of health data, and provide a wider societal framing for the digital transformation of healthcare.

Finally, an event at the European Health Forum in Gastein will provide the link between ethical frameworks and health systems reform at national and regional level, before the roadshow is concluded at an event in November 2018. The ultimate aim of this ‘roadshow’ is to develop and launch a policy document, with specific recommendations.



# UEG WEEK

**This year UEG WEEK, celebrated its 25th Congress which took place in Barcelona from 28 October until 1 November 2017 and was attended by more than 12 000 healthcare professionals and stakeholders from 118 countries.**

As usual EFCCA was present with an information stand at the exhibition hall giving us an excellent opportunity to network, meet stakeholders and inform about our activities.

We are very proud to say that our cooperation with the United European Gastroenterologists has strengthened over the years, one outcome of this close cooperation is that our CEO, Luisa Avedano, has been invited to talk at the closing session of the Congress alongside physicians about patient empowerment and IBD care. This session generated some interesting insights and discussions and showed the importance of patient involvement in such events allowing stakeholders a better understanding by providing the patients' perspective.



*EFCCA CEO, Luisa Avedano, speaking during the closing session of UEG WEEK 2017.*

## “Patient Voice” Workshop

**The “Patient Voice” project was launched in January 2017. Its mission is to empower IBD patient organisations and provide them with a digital platform to collect patient-reported data that could leverage internationally standardised and medically endorsed metrics for the purpose of advocacy towards improved IBD treatment.**

By providing an IBD digital platform patient organisations will be able to:

- Track and compare their patient-reported outcomes in a specific region and country
- Share the data with Health Care Professionals
- Collect, aggregate and analyse data

On 6-7 December 2017 EFCCA CEO, Luisa Avedano attended the “Patient Voice” Workshop which took place in Brussels. Alongside EFCCA, some patient organisations agreed in being part of the Patient Voice pilot phase: our Swedish member Mag-

Och Tarm Förbundet and Crohn's and Colitis Canada, that presented the first outcomes of their trial period, while AMICI Italia and ACCU Spain were still in a pre-launch phase and shared their experiences on the issues they were facing and trying to overcome.

During the day participants worked on reviewing output from pilot countries, reaffirmed the strategic direction and aligned on the project governance structure. Dr Alissa Walsh facilitated the discussion on feedback and related technical issues based on the reactions and advice from the patients involved in Sweden and Canada.

It was a very fruitful meeting since we had the chance to approach different issues and better define further actions. EFCCA believes that the “Patient Voice” Project could represent an

important step forward and deeper awareness on the importance of patient data collection and ownership.

The project is sponsored by Takeda.

## EFCCA’s mapping project is completed

**National health systems and access to treatments tend to be unequal in EFCCA’s member countries, in particular when dealing with new/innovative treatments and devices. Some countries have no national registries of IBD patients available that would assist in obtaining information about IBD patients. To reduce such inequalities, EFCCA carried out a thorough mapping of all innovative treatments available in its member countries.**

The outcomes of the survey provide an overview of the situation and will support the exchange of knowledge and experience among EFCCA countries, promote a better understanding of European healthcare systems, improve the mobility of people with IBD in European countries and facilitate the access to treatment in other countries. The outcomes will be used to display discrepancies to European policy makers and to stress the importance of equal access to treatment.

Thirty-two national patient associations from thirty-one countries participated in the survey. In most participating countries, patients are covered by a state insurance that is same for all, combined with a possible voluntary private insurance, and in most countries health care is financed by employers, employees and/or the state together. Reimbursement policies varied from the patient paying nothing as insurance covers everything to the patient paying everything at the point of care and getting reimbursed later. In most countries, the patient can freely choose his/her health care provider, but in some the provider is defined by the system based on e.g. where the patient lives.

Although most associations reported no regional differences in their country, some pointed out that there are variations within their countries due to the country’s federations making up their own laws or having their own insurance systems. Access to health care can also vary due to geographical reasons and distribution of specialists. Such variations can put

IBD patients in very unequal positions in terms of access to care. The outcomes also showed that access to new innovative therapies is far from equal between countries. Only Humira (adalimumab) was approved and available for IBD patients in all participating countries; on the other hand, only five of the participating countries (Czech Republic, Finland, Hungary, Ireland and Switzerland) could offer all of the five biologics and two biosimilars in this survey to IBD patients.

Other issues of unequal access brought up by the participants were better access to those with private insurance coverage, slow and bureaucratic approval procedures of new medicines coming to market and into the patients’ reach, certain therapies only being available in bigger cities, lack of IBD nurses and specialists and limited access to psychological support, mental health services and specialist dieticians. The availability and source of a precise number of IBD patients or prevalence of IBD varied greatly in the participating countries. In very few of the countries there was a patient registry available, and most countries were only able to provide a very wide estimate on the number of IBD patients.

EFCCA is working on providing recommendations for different stakeholders for tackling the issues of unequal access and lack of patient registries based on the outcomes of the mapping survey.

Sanna Lönnfors, EFCCA Scientific Adviser

At MSD, we work hard to keep the world well. How? By providing people all around the globe with innovative prescription medicines, vaccines, and consumer care and animal health products. We also provide leading healthcare solutions that make a difference. And we do it by listening to patients, physicians and our other partners — and anticipating their needs.

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The recent merger between MSD and Schering-Plough expands and strengthens our capabilities to help make the world a healthier place. Our goals are clear and our commitment is fierce. We are dedicated to solving problems and pursuing new answers.



# Breaking down taboos: IBD and mental wellness

Happy New Year from all of the members of the EFCCA Youth Group. We hope it is a happy, healthy and successful year for you.

We are looking forward to another fun packed year of continuing to break taboos, raise awareness as well as ensuring young people living with IBD don't feel alone living with the conditions they have.

As a youth group we have many work streams we are focusing on and hope these will support our success again throughout 2018. We hope you continue to enjoy our stories and shared experiences this year and can join us in celebrating the changes that are happening to the level of awareness of IBD.

As ever as a group we discuss various topics as seen in previous EFCCA Magazines and we try to "Break down taboos" which come with daily life and IBD.

Something we have found to be very important to many sufferers of IBD is mental wellness. It has become apparent that the focus of mental wellness hasn't been a priority but more and more studies across Europe are showing how much it is actually impacting people living with IBD and their lives.

With this article we want to share with you some facts that have been discovered regarding mental

wellness but as well what is starting to happen across Europe to support those with mental wellness needs.

We encourage you all to read these stories, remember them and tell them to your friends, relatives, doctors and whoever is willing to hear your story.

Another great development across Europe is the recognition from organisations around this topic and tailoring services to meet the demand.

The rise in mental health concerns over the last few years has seen a sharp increase; this might be because more people are talking about the problem but also because of more people being diagnosed.

A lot of people suffering with IBD need extra support with this when they are having a flare and the rest of the time they have no symptoms but many studies being completed conclude that the rates of anxiety and depression are high in this cohort for various reasons including coping with a chronic illness as well as the thought of having surgery, and that IBD-focused psychological services should be a key component of any holistic IBD service, especially for those identified as having active IBD.

Late autumn last year the association in Sweden organised a mental wellness weekend to support the youth group. It was great success and we wanted to share it with you.

## Mental Wellness Youth Weekend in Sweden

One weekend in September the youth group in Sweden organised a youngster weekend with the theme of "mental wellness". A study made by the head of the association and Kairos Future showed that 44% of the patients with IBD in Sweden suffers from mental illness. It's an important subject that's

often hard to talk about. We believe that we need to talk about it to be able to break the stigmas.

We welcomed 16 youngsters from all over Sweden in the age of 20-30 to the castle of Lejondal outside Stockholm. The environment around the castle was



*Participants of the Mental Wellness Youth Weekend*

amazing and the autumn leaves colored the trees around us.

During the weekend we had a lot of different activities to empower mental wellness. We tried medical yoga, coloring with an artist, had a conference about mental wellness and some different workshops. The same study that was referred to before shows that 46% of patients with IBD are often worried about the need of having surgery in the future.

This kind of worrying can also be a part of why so many patients suffer from mental illness. That's why we decided to have one of the workshops about living with an Ostomy. We wanted to break stigmas and prejudices about it. Several of the delegates told us that the workshop helped to reduce a lot of worries about a potential surgery.

Many people living with chronic stomach-diseases feel alone and embarrassed. Our main goal during the weekend was to show our solidarity and that you shouldn't have to feel alone.

We noticed during the weekend that the youngsters

appreciated the activities and shared their own stories. The weekend resulted in new friendships and a feeling of hopefulness.

Thanks to everyone who helped this weekend be a success and we hope that our success can be repeated across Europe so that together we can make a difference. Just keep fighting!

We hope you have enjoyed reading about our mission and the success that's already started across Europe – look out for more stories throughout 2018.



## Romania

### Inauguration of second IBD Center

**ASPIIR Association is continuing its initiative started in May 2017 in Bucharest regarding the recognition and implementation in Romania for centers dedicated to IBD patients. On 10 October 2017 we inaugurated the second Center dedicated to IBD patients – at the Regional Institute of Gastroenterology and Hepatology “Prof. Dr. Octavian Fodor” in Cluj-Napoca.**

The Association of People with IBD in Romania (ASPIIR), in partnership with the Romanian Club for Crohn’s Disease and Ulcerative Colitis (RCCC) and the Regional Institute of Gastroenterology-Hepatology “Prof. Dr. Octavian Fodor “Cluj-Napoca (IRGH) met on 10th of October in the Blue Hall of IRGH Cluj for a debate focused on the recognition and implementation of criteria for IBD dedicated center and for the inauguration of the second dedicated Center for IBD patients. The topics discussed include the training and accreditation of centers dedicated to the care of patients with inflammatory bowel diseases, patient-centered care, the importance of long-term disease control and optimization of monitoring, increasing quality of life, and reducing the burden of the disease (direct and indirect costs related to the disease).

By founding and getting accreditation of IBD dedicated centers we can ensure the optimization of

medical care and the improvement of the quality of life of IBD patients. Therefore ASPIIR advocates that for the success of this approach at national level, it is necessary to collaborate with patients, doctors and the relevant authorities.

The event was attended by IRGH physicians, professor Marcel Tantau, associate professor Alina Tantau, dr. Rozana Zaharie – who designed the overall image of the medical team and the services available at this time in the IBD dedicated Center IRGH; Prof. Mircea Diculescu and Prof. Dr.Liana Gheorghe – who came with their expertise related on the first dedicated patient center opened at Fundeni Clinical Institute in May last year; other important voices of the medical system – Attila László, president of the Health Commission of the Senate of Romania; officials – Emil Boc, the mayor of Cluj-Napoca; representatives of the ASPIIR Association; patients of the IRGH and other civil society stakeholders.

## Romania elected to the board of the European Ostomy Association

**We are proud to say that Isabella Grosu, Director of ASPIIR, was elected to the Executive Committee of the European Ostomy Association during its XV Congress which took place in Copenhagen, Denmark from 5-8 October 2017.**

Often, IBD patients or those with colon cancer have to cross a surgical intervention that ends up with a stoma

(ileo or colostomy). Although in the past this situation was a major trauma or an unpleasant complex, both



*Newly elected Executive Committee of the European Ostomy Association*

for the patient and their family and friends; nowadays, ostomates have a reasonably normal and even more permissive life in terms of day-to-day social activities, family, job, nutrition etc.

ASPIIR wants to address the needs of people with stoma by providing information about stoma devices, stoma care, even offering some stoma products; by engaging those interested in participating in courses supported by stoma therapists; providing pre-operative and post-operative counselling on quality of life as an ostomate.

We want to align Romanian ostomates facilities to European standards. In this respect, a lot of lobbying and advocacy activities are required in relation to the decision-making authorities in the sphere of medical devices and the management of the related budget, but also a constant visibility and active presence in the European Ostomy Association (EOA).

In this context, as a result of ASPIIR's activities and involvement in European projects, at the 15th Congress of the E.O.A., Romania was elected member of the Executive Committee of the European Association, alongside Denmark, Sweden, Germany and Iceland. From this position, we want to get the approval from the National Health Insurance for an increased monthly amount for stoma devices, reimbursements (now there is an insufficient amount of about \$ 55 per month), which would also lead to the possibility of importing better quality devices, compared to those in the Western European market.

The Congress gathered representatives from European and African countries and created a proper platform for the establishment of new organizations of ostomates in African countries (where they do not exist yet) and to support the improvement of facilities needed for those in the lower or medium developed European countries.

# Slovakia

## New SCC Board

**The Slovak Crohn's Club is based in Bratislava and since its foundation in 1993 it has undergone many changes and updates in order to support people with IBD in Slovakia**

We are bringing together specialists and people with IBD to talk about latest news in IBD treatment and to provide psychological support for living daily with IBD. What's more, we are organizing conferences and talks with doctors on particular issues related to IBD giving advice on various topics.

This year, we have changed our management and have now some new and young members whose enthusiasm and dedication to help could be visible from the numerous new activities such as for example a photo shoot IBD campaign (see image) or educational afternoons on particular topics.

We have successfully cooperated with professionals from a gastroenterological company and together with the Ministry of Health discussed the reduction of costs for important medicines of IBD patients. Our main activities are organized in the capital city, Bratislava, but our educational afternoon sessions or camp for kids are based in various cities across Slovakia, so more people from the whole of Slovakia can participate.

*Our recent photo shoot to raise IBD awareness in Slovakia*

Despite the fact, that in Slovakia there are approximately 14.000 diagnosed IBD patients, there is widespread lack of knowledge of IBD. We are happy to say that our efforts to raise more awareness have been successful and we have appeared in shows on TV and in various articles in printing media.

This year in May 2018 we will be celebrating our 25th anniversary so we are very much excited about the planned conference connected with a rich program full of entertainment and activities for our members. Furthermore, we would like to be more involved in activities regarding campaigns or charity work and be more visible to a wider public to provide relevant information about our function and IBD patients. Of course, all other annual efforts such as entertainment for kids or educational sessions are planned too but the main focus is to take care of our members, give them all important information and show them how to live even with IBD a happy and successful life.

Veronika Ivancíková, Slovak Crohn Club







## 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.

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# New Zealand

## Reducing the growth of IBD

Presentation of the 69 page report entitled, “Reducing The Growing Burden of IBD in New Zealand ” - the findings of a year-long study carried out by Crohn’s and Colitis NZ Charitable Trust.



*CCNZ Junior Ambassador, Nicole Thornton speaking at Parliament*

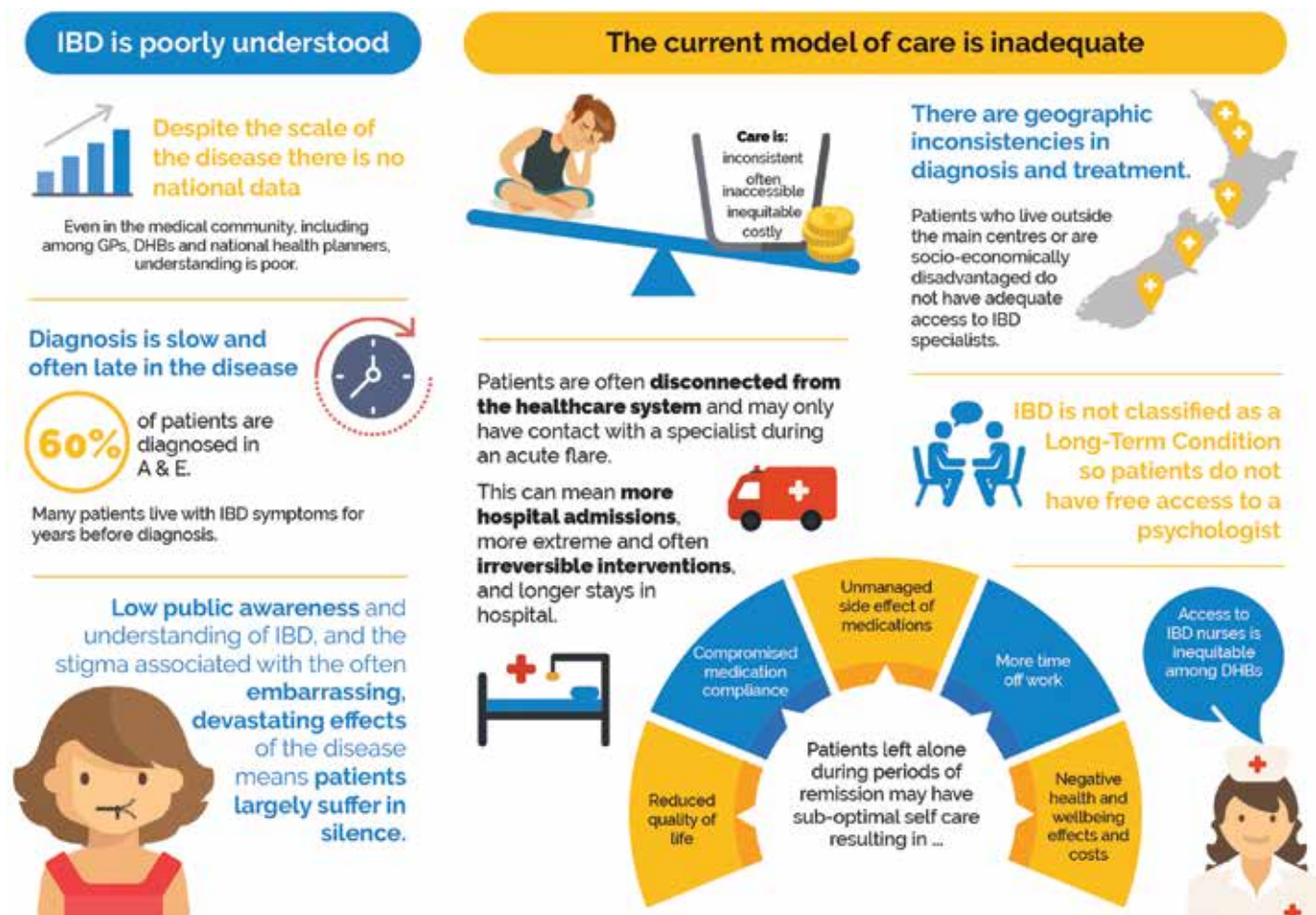
On 2 November, at a breakfast meeting at the New Zealand Parliament, affectionately known as the “Beehive”, eighty people, including Members of Parliament, business leaders, and health care professionals, listened intently to a twelve year old girl talk about her personal journey with Crohn’s disease. The next speaker was a Police Detective, another Ambassador of Crohn’s and Colitis NZ, who shared her story of completing police academy, interrupted by hospitalisations and surgery.

The purpose of the meeting was to present the 69 page report entitled, “Reducing The Growing Burden

of IBD in NZ”, the findings of a year-long study in NZ.

In December 2016, Crohn’s and Colitis NZ Charitable Trust was the recipient of a \$40,000 NZD unrestricted grant to study the burden of inflammatory bowel disease on our small country of 4.5 million people. The findings were shocking to those in the audience, but were not at all surprising to those involved in the care and treatment of people with Crohn’s disease and ulcerative colitis.

The study was led and authored by well-known



*Infograp summarizing the findings of the report , part 1*

NZ health economist Suzanne Snively. Health data was reviewed and analysed from hospitals and national databases. Additional information was drawn from patient surveys and interviews. Workshops were held with health professionals, patients, their families, health statisticians, pharmacists, and psychologists.

These were the findings:

- New Zealand has one of the highest IBD rates in the world.
- Approximately 20,800 New Zealanders have IBD (1 in every 227 person) and the numbers are increasing at a rate of 5.6% every year.

- There is inequity in access to services throughout the country
- There appears to be a significant delay in recognition and diagnosis of IBD in the primary care sector
- It costs NZ an estimated \$245 million in health care expenditures and lost productivity every year which is a staggering amount for so small a country.

Presenters at the meeting included the report's author Suzanne Snivley, Co-Chairs of CCNZ Dr. Richard Stein and Brian Poole, QSM, Nicole Thornton, the twelve year old girl with IBD and

CCNZ ambassador, IBD nurse Megan Mackay, Becs Parker, a CCNZ ambassador and Police Detective, and President of the NZ Society of Gastroenterology, Dr. Michael Schultz. Also speaking was the host of the Parliamentary breakfast, Speaker of the House, the Rt. Hon Trevor Mallard.

The report will be the seed of future work as, in addition to raising awareness of IBD in NZ, the report recommended:

- 1) the establishment of an IBD National Working Group to address shortcomings in diagnosis, access to treatment, and standards of care.
- 2) research to develop guidelines for treatment and ongoing management
- 3) development of a nation-wide database of

IBD patients

- 4) clinical trials on the impact of timing of pharmaceutical interventions
- 5) promotion of a national discussion to promote greater understanding, care, and support, or IBD patients.

Moving forward, we will report on the long term impact of this important report.

CCNZ, an affiliate member of EFCCA, is grateful to Janssen Pharmaceuticals for their unrestricted grant which made this report possible.

By Dr. Richard Stein, Co-Chairman, Crohn's & Colitis New Zealand

*Infograp summarizing the findings of the report , part 2*

### Solutions

Proactive coordinated care with earlier, timely interventions, would significantly reduce costs and improve quality of life for IBD patients.

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The study establishes a clear imperative for:

- 1 An IBD National Care Working Group - to address shortcomings in diagnosis, access to treatment, and standards of care
- 2 Research to develop guidelines for a 'New Zealand Standard of Care for IBD Patients' - building:
  - a nation-wide evidence base
  - clinical trials on the impact of the timing of pharmaceutical interventions
  - evidence to afford IBD priority status as a long-term condition
  - specification of the pathways of care for IBD
- 3 Information and communication
  - developing the knowledge base on IBD across the health sector
  - a national discussion to promote greater understanding, care and support for IBD patients



*Reducing the Growing Burden of Inflammatory Bowel Disease in New Zealand* was commissioned by Crohn's & Colitis New Zealand (CCNZ) to identify and shed light on the scale and personal, social and economic costs of IBD in New Zealand, and to make recommendations on how this burden might be reduced. The study has been authored by economist Suzanne Snively ONZM.

The report is a first step towards an informed national discussion about the growing problem of IBD in New Zealand. In the absence of national data, the report has drawn on estimates and studies carried out over 16 years within specific DHB regions, as well as patient surveys, case studies and international data.

Crohn's & Colitis New Zealand (CCNZ) exists to bring visibility to this difficult, invisible condition. We provide support, advice, resources and information about Crohn's disease and ulcerative colitis to patients and their families. Our organisation includes individuals affected by Crohn's and colitis, and medical specialists who are active in the treatment of these chronic diseases.

  
The study was made possible through an unrestricted education grant by Janssen New Zealand.

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To download a copy of the report visit  
[www.crohnsandcolitis.org.nz](http://www.crohnsandcolitis.org.nz)



Reducing the Growing Burden of Inflammatory Bowel Disease in New Zealand

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IBD affects an estimated **20,792** New Zealanders

**1** in every **227**

and it is increasing at a rate of **5.6%** every year

**NZ has one of the highest IBD rates in the world**

Our IBD rate is comparable in incidence to Type 1 diabetes

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It costs NZ an estimated **\$245m** in healthcare costs and lost productivity every year

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It is a chronic, debilitating, lifelong disease, with onset typically in early adulthood.

IBD has a profound physical, social and psychological impact on those living with the disease.



# UK

## Press Play

Some people prefer to keep their Crohn's or Ulcerative Colitis diagnosis to themselves or a small circle of trusted friends and family. Others, such as 23-year-old Rhiannon Jenkins, are happy to open up and tell others how it has affected their lives.



*Scene from the video on how young people tackle living with IBD*

In one of five videos created by Crohn's and Colitis UK showing how young people tackle living with their condition, Rhiannon talks candidly about studying at university while coping with UC. The series of films highlight the challenges younger people with IBD face and how they are coping with issues relating to their disease, such as leaving home, schooling, telling others about your illness, relationships and transition into adult care.

It's not the first time Rhiannon has publicly shared her experience of the disease. In fact, two pieces of work towards her drama BA at De Montfort University were artistic representations of her life with UC. "My second-year performance was about how doctors can treat you like a bit of meat and so I literally used a piece of meat on stage during that," she says. "Then, in my third year, I made myself into a superhero who

was battling my disease and I got people up from the audience to play parts.

"One got to be my sidekick – my medication – and someone else got to be the enemy, which was my disease. Then we had a big battle with mashed potato, glitter and bubbles." She laughs, adding: "It was a big visualisation of what it is actually like to have the disease, to have so much thrown at you."

Rhiannon was keen to share her experiences of being a young person living with IBD as part of Crohn's and Colitis UK's film project. Leaving home for university, she says she was "mega scared" and full of anxiety about whether she could manage. She told herself: "The only way you are going to find out if you can do it is by trying." Her parents Colin and Julie were very supportive. "They weren't worried about

me and said ‘if you want to do this then don’t let your illness stop you from doing it’” says Rhiannon.

See the films at [www.crohnsandcolitis.org.uk/young-person](http://www.crohnsandcolitis.org.uk/young-person).

The films were created by Crohn’s and Colitis UK and supported by the People’s Postcode Trust, a grant-giving charity funded by players of People’s Postcode Lottery.

## Toolkit for GPs unveiled

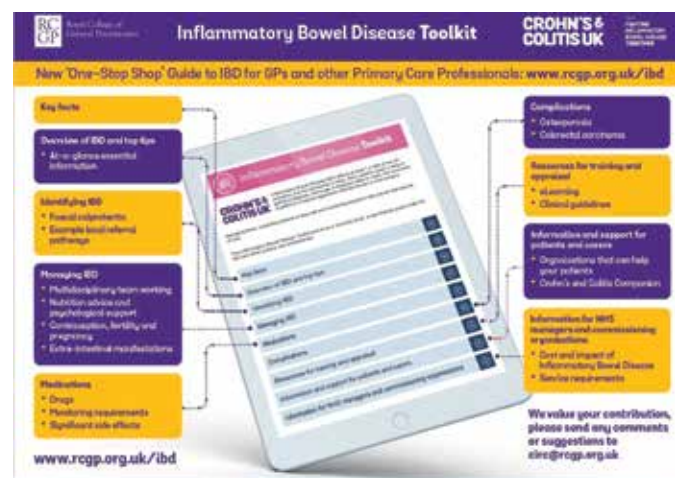
**A new toolkit to help General Practitioners and other primary health teams better support patients with Inflammatory Bowel Disease is now being used by medics across the UK.**

The online resource, developed by Crohn’s and Colitis UK and the Royal College of General Practitioners, has been produced as part of a year-long RCGP ‘spotlight project’ that aims to raise the profile of IBD among healthcare professionals. The toolkit is a ‘one-stop shop’ of information to help general doctors identify people with IBD and to refer, support and treat them appropriately, working with their specialist team. Patients can also access the information free of charge. It includes:

- Key facts about Crohn’s and Colitis
- An overview of IBD and top tips about the conditions
- Clinical guidance (for example, from NICE)
- Information on identifying and managing IBD
- Advice on medication and flare management
- Details of complications that may arise
- Resources for training
- Information for patients and carers
- Information for NHS managers and commissioning organisers
- Podcasts

In one of the podcasts, Dr Kevin Barrett talks to Crohn’s and Colitis UK patient champion Rachel Fowler about her experience and the kind of support that she needs from her GP. In the other, Kevin speaks to an IBD nurse about how primary and secondary care can work together to provide the most effective care for IBD patients. A 30-minute e-learning module about IBD is also available.

Amanda Quincey, Crohn’s and Colitis UK trustee and patient adviser on the spotlight project, says she



welcomes the new toolkit. “It’s helpful to have this information all in one place. When a patient with possible IBD symptoms goes to see their GP, the doctor will be able to access lots of useful and detailed guidance on what to do next in terms of treatment or tests.

“We wanted to make it clear in the toolkit that while there are red-flag symptoms for IBD – such as passing blood or mucus – a lot of people don’t have those signs, so they may have continual gastro problems with no known cause. I have heard of countless patients with this experience. I myself had an IBS diagnosis for 15 years before I was diagnosed with Crohn’s four years ago. It’s important for GPs to know that atypical symptoms are common, and that they can refer patients for the faecal calprotectin stool test to differentiate between IBS and IBD, which is a common misdiagnosis.”

The toolkit is available at [www.rcgp.org.uk/ibd](http://www.rcgp.org.uk/ibd)

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delivering affordable quality  
therapeutics for patients

## Spain

# “Castigado y sin comer” - a short film about the life of a boy with Crohn’s disease

ACCU España presents a short film that shows daily life of Julén, an 11-year-old boy with Crohn’s disease. Launched in June 2017, the short film has already got more than 40,000 views in Youtube. *Castigado y sin comer* has been realized thanks to the collaboration of Pfizer, Enusa, Puerto Real City Council, Grupo Lansys and the school El Trocadero.



*Jesús Paya López playing Julén, a boy who has Crohn’s disease*

*Castigado y sin comer* (Punished and Hungry) is an emotional fictional story based on real facts that shows how complicated it can be for a child with Crohn’s disease to undertake some common activities that could be effortless for other children, such as going to school or playing with peers, especially when enteral nutrition (A way to provide food through a

tube placed in the nose, the stomach, or the small intestine) is the treatment. It is estimated that in Spain there are approximately 150,000 people with inflammatory bowel disease. Of these, 10% are under 20 years old. The disease is especially difficult and complex when children suffer from it because it can affect their physical and social development. In fact,



up to 35% of people diagnosed during childhood suffer from stunting and 50% of children with IBD cannot adequately socialize or complete their studies due to the high percentage of school absenteeism because of the complications of the disease. ACCU Spain wants to improve the quality of life of these children and believes that the first step to do it is to portray their reality in images to make it known by the general population.

The director of the film, Almudena López Vázquez, has been able to successfully capture the drama that some families experience when they have

to face the Crohn's disease of one of their children. For López Vázquez, it is not the first time she has dealt with issues related to childhood and illness, something that the viewer can appreciate. The sensitivity is present throughout the 8 minutes of the short film.

Jesús Paya López is the main actor who plays Julén. His maturity stands out and astonishes. Castigado y sin comer has also had the collaboration of a young professional actor, Ramón San Román performing the role of a psychologist.

Watch the movie (with subtitles):  
<https://youtu.be/b-pAGaZWPIE>

## France

# MICI Connect (IBD Connect) : A digital Tool to the Real World of IBD

**The development of an internet platform to help IBD Patients and their families and friends seemed like a MUST in view of all the problems patients face in real life, with so much inequality in care due to geographic inaccessibility to information, advice, support. If there is something worthwhile in the use of digital, making access to help channels right nearby is one of them.**

AFA Crohn RCH France made this dream come true by bringing the patient closer to the answers to particular needs. What makes the platform original is the fact that this tool was designed and built by the patients themselves, in answer to their own individual problems and needs in everyday life.

As close as you can come to the patients' needs, MICI Connect, although digital, offers concrete, practical information, an immediate answer to ongoing preoccupations as they appear for each individual patient. MICI Connect is just one more way to improve daily life with IBD.

It's an interactive progressive tool where each one can bring in his or her personal experience to improve the feedback, offer ideas on the contents, comment on the way they use the platform as explained below.

This new internet platform designed by AFA offers services and a support program from patients, for patients. Several paths are proposed allowing each user to progressively assimilate the information needed daily with the disease. The patient may also follow his or her progression with the disease through some useful scores for consultations with health professionals: fatigue, quality of life, number of stools, etc. and add this data to his or her health journal.

Truly original is the option to chat with peers and soon with health professionals, but also to be able to participate in surveys aiming to optimize patient care in general through better knowledge on patient daily life.

MICI Connect is an ensemble of tools to better understand and manage your disease between two medical consultations, thereby improving your

daily life. There are a wide range of modules such as for example « Comprendre » (Understand) to be informed, « Communauté » (Community) to share with other patients and their family and friends and « Événements et actualité des MICI » (Events and News about IBD) to stay informed about current events and news.

There are also Patient experiences, videos, computer graphics and a module « Quiz ». Even health professionals can use this platform to keep up with their knowledge about IBD and better communicate with their patients.

Marion Windels – Community Manager, AFA

## Portugal

# First APDI Congress

by Luisa Avedano, EFCCA CEO

**The Portuguese IBD patient association APDI organised its first APDI Congress on “The relationship between patient and physician and quality of life of patients with IBD” which took place on 25 November 2017.**

Over 100 participants (patients, their families, medical students, hospital administrators and health professionals) attended this important event that was opened by Ana Sampaio, APDI president who stressed the importance of the proposed topic and then gave the floor to a representative of the Northern Regional Council of the Order of Physicians.

After this institutional part Candida Cruz, APDI Vice President presented the conclusions of a Workshop held in May on “Doctor-patient relationship “ that gathered over 30 participants representing all players involved, including IBD patients, general practitioners, nurses, pharmacists, psychologists, nutritionists, hospital administrators and pharmaceutical industries.

Another important part of the event was a round table involving APDI psychologist, an APDI volunteer, a gastroenterologist, the President of the Regional Health Authority and a representative of the Order of nurses. After lunch I had the opportunity to give a presentation on “IBD in the World” offering the audience an overview of EFCCA mission, activities and priorities that was translated into Portuguese by Diogo Barros, a medical student that has been already involved in EFCCA activities in the past. Other topics presented in the afternoon, such


as “new therapies in IBD”, “New Therapeutics and scientific advancements” contributed in feeding and widening the debate.

Finally, APDI President Ana Sampaio presented the results of the “Impact of IBD in Portugal”, an important survey with more than 500 respondents that gave an in-depth picture of the quality of life and care of IBD patients in the country.

It was a day rich of information and a learning opportunity where inspiring practices, concrete examples and strong involvement of different stakeholders created a great atmosphere where patients, health care professionals and institutional representatives had the chance to debate and better understand the unmet needs of the IBD community in Portugal.

I was honoured by the warm welcome and friendship of our Portuguese member, and I really learnt a lot from the high level of commitment and professional approach of patients and stakeholders. I’m sure that this first congress will pave the way for further and equally successful activities soon.

A last word to thank Candida, Ana, Diogo and Norberto for making me feel at home in the beautiful setting of the “Casa do Medico” in Porto. United we stand.



## 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.



# The power of working together

*Interview with Inge Vandelannoote and Liesbeth Moortgat, two amazing women, one IBD patient plus one IBD nurse, who decided to cooperate together in order to spread a positive message to newly diagnosed patients and patients who have to deal with all the physical and emotional consequences of the disease.*

## ***Inge, what was it like when you were diagnosed with IBD?***

I was diagnosed in 2000 with ulcerative colitis. I had medical problems for over two years before my diagnosis, so I was actually happy when I finally found out. I got medication and could carry on with my studies. Then I got married and had 2 children. Since then, for 15 years I had ups and downs, but I didn't show anyone around me that I was suffering.

## ***Why is that?***

I behaved like this because of the way I was brought up. I remember my father told us as children that we should not complain and that we should not feel sick. He told us to be strong kids and that working was the key in life.

## ***What changed your attitude?***

It was back in 2015 when people started telling me that it wasn't ok how I lived my life. I always had a smile on my face pretending everything was fine even though they could see that I was not well. Around that time my neighbour was diagnosed with colon cancer. As he was always at home, we somehow started talking and he convinced me to see my gastroenterologist.

Seeing my gastroenterologist was quite hard as he asked me where I had been all those years. I had to admit that I wasn't very keen on taking my medicines and that I thought I was smarter than everyone else. I thought I had to live my life with "my" IBD and that it was "my" illness and "my" IBD journey... We started a new course of treatment but for a long time no single treatment seemed to work efficiently.

After one of my many visits to the doctor, my IBD nurse, Liesbeth Moortgat, started talking to me as she saw that I was not well at all. It was then when I broke down into tears. I gave her my diary, which I was carrying with me that day and which described in details how I really felt. I was surprised because she read my whole story and it was an eye opener for her as she could see what was going on behind my mask.

## ***How did the talk with Liesbeth affect you?***

I decided I wanted to do more with my life and I became involved with the Belgian IBD patient association CCV-vzw ([www.ccv-vzw.be](http://www.ccv-vzw.be)) with the idea to share my experiences and to help fellow-patients. I want people to know that their illness does not define them and that they don't need to hide.

Life can be taken positively but one should be honest with oneself. To be honest is to tell others that you have a disease but in the first place you have to be honest with yourself and accept your disease. That's my advice to young people. It's not a shame to have a chronic disease like IBD. If I had accepted my disease sooner, life would have been much easier for me.

Together with Liesbeth we have been doing awareness raising work, I write a blog, we have done a Tandem talk about our experiences and we recently were on the radio talking about my IBD journey.

## ***Liesbeth, how do you see your relationship with Inge?***

Well, what links us is that we are both humans. I remember when I met with Inge she was not well, her disease was very active and when I explained things to



©Stefaan Beel

***Inge*** (left) is a 37 years old mother with two kids, working in a small family business. She is also an active volunteer and Executive Board member of the Belgian IBD patient association CCV-vzw.

***Liesbeth*** (right) is a 44 years old mother of 2 daughters with an active life outside work. She has been working as an IBD clinical trial nurse from 2002 to 2010 when she changed to teaching nurses. Since 2016 she is working as an IBD nurse at the AZ Delta Hospital and is also a member of the N-ECCO Executive Board.

her she was always smiling saying “yes, yes...okay”. I didn’t believe that she was okay and I told her “Inge, you can be yourself, just tell me”. I think that was the moment when she finally could talk about her complaints and worries knowing that it would be confidential.

Through my work I know a lot about IBD. I learn and read about it daily, I give advice every single day but I never experienced how it really feels like to deal with IBD every day. When I sit together with Inge: me

sharing what I know as IBD nurse and as a person just like Inge and Inge sharing what she feels as patient and as a person; I get a better image and I can better guide and coach her through her IBD journey.

***You found the time to read Inge’s diary, how did you manage with your workload?***

I always laugh when people say that we don’t have enough time to talk with patients. We can talk and connect with our patient while we are doing things



©Dries Luytten, Inge and Liesbeth during a Tandem talk

related to their treatment. I am really convinced that if you invest time in your patient in the long run you will win time. If you really listen to your patient and help them the way they want to be helped then you have a win-win situation. When you don't listen to the patient, he/she will still call you every day, still ask questions.

### ***What's your advice to other healthcare professionals?***

A lot of people say “treat patients in the way you want to be treated yourself” but that's absolutely not true. I would say treat patients as **THEY** want to be treated. It's important not to adapt but always ask questions to your patient, for example ask them “what does fatigue mean for you?”. It's so easy as a nurse to think “oh fatigue for me is that and that ... and I can give some information to the patient based on that adaptation of myself. In that way you don't always help your patient because you inform them of something they don't need.

I give you an example, I see a lot of patients with problems about fatigue. One day I was talking to a patient about it and the solution we came up with was horse-riding. For me, personally, that would not have

been a solution but the patient, since she has taken up horse riding, is feeling less fatigue. What I am saying is, that if you don't talk to your patients you would never come to that solution.

So my advice is listen carefully to your patient what they need, coach them, give them the information they need to cope with their problems. This is about patient empowerment. Working together to find a solution suitable for the patient.

### ***What are your plans for the future?***

We have a lot of dreams, we want to write a book, we want to do more tandem talks, also at the European level. We have already been on the radio to share our thoughts and experience and of course we cooperate on Inge's blog. We believe it's important to get all stakeholders on board and to start working together, especially as concerns patient education and newly diagnosed patients.

If you would like to follow Inge's blog please visit the link below:

<https://ingevdln.blog/>

# Living a purposeful life



**My name is Daan Hekking, I am 24 years old, born in Raalte, The Netherlands and five and a half years ago I was diagnosed with Crohn's Disease after four surgeries in nine days. At the moment I live and study in Umeå, northern Sweden. In June 2018 I will graduate and obtain my master degree in Advanced Product Design at the Umeå Institute of Design. For my final master degree, I decided to focus on paediatric Inflammatory Bowel Disease (IBD) patients and come up with a solution for a child or parent that makes it easier to cope with their condition..**

Five and a half years ago I was 18 years old and I was in my third year of the bachelor's programme, Industrial Design Engineering at the University of Applied Sciences Windesheim in Zwolle, The Netherlands. I was doing perfectly fine and as part of my programme, I decided to study abroad for six months in Auckland, New Zealand. A visa was granted, flights were booked, the accommodation was arranged and paid for and a day before I would fly to New Zealand for six months; an infected appendix. Of course a big bummer, but with my optimism, I expected to fly to New Zealand a week later when the situation was more stable.

Unfortunately, two days later my bowels got perforated for the first time, three days later for the second time and four days later for the fourth time. Undergoing surgery this often in such a short time makes you end up in the intensive care unit. It took

me seven weeks to actually leave the hospital, but left me severely underweight, physically and mentally scarred and tube fed. Furthermore, I had a lifelong management of Crohn's Disease ahead. Though it sounds very negative, these intense periods also showed me how amazingly supportive and unconditionally loving my parents, brother, family, friends, colleagues, neighbours and school staff were for me at that time. When you are healthy, you often take this for granted. Obviously I would have loved to have missed this whole period with surgeries, rehabilitation and shame, but in the long run, I believe it has changed me for the better. It has shown me a side of life I had not seen before; a side that makes you realise life is too short to live without purpose and joy.

Six months later I was at my normal weight, felt fairly strong again, not dependent on tube-feeding anymore and decided to continue with my studies

in Zwolle. The staff at the University was extremely helpful and understanding and promised me they would arrange everything for me if I decided to give my study abroad in Auckland a second chance. A year and a half after my first surgery I flew to Auckland with one of my best friends to study for six months in New Zealand. It was the time of my life and I am forever grateful that the University staff offered me this second chance.

Even though I am diagnosed with Crohn's Disease, I can luckily live a life without limitations. At the moment I am in the second year of my master programme, in northern Sweden. Between my first and second year, I paused my studies to obtain work experience and decided to intern in Stockholm and New York City, each for six months. Travelling is and stays a big part of my life and so far I have not experienced many issues.

Every six months I meet up with my gastroenterologist in Zwolle, The Netherlands to chat about my health status and upcoming plans. Whenever I come back home to visit family and friends, I also pick up medication for six months and bring this back to Sweden or America, together with my medical passport. This way I can keep the same pharmacy in my hometown and don't have to deal with setting up connections with new pharmacies, foreign policies, insurance issues and it saves me time. Whether I will keep ordering medicines this way after graduating, which will be in June this year, is something I have to discuss with my insurance and gastroenterologist.

### **Advocating for paediatric IBD patients**

As mentioned before, my Crohn's experiences have changed me and make me live a life with more purpose. When I was sixteen I started with my bachelor in Industrial Design Engineering and until now I still love what this profession has to offer me and what it can mean for the world. Industrial Design, Product Design, User Experience Design, Problem finding, Solution creation, or however someone wants to describe this profession, it allows me to advocate for a group of people that is in need of improvement. Being a designer puts me in a position to find and

understand the problems a group of people is struggling with and come up with a solution that improves their quality of life.

I have been very lucky to meet some amazing people at Shire and we have decided to work together during my master thesis in order to come up with a solution that benefits paediatric IBD patients or their caregivers. For children, interruptions caused by IBD can result in absence of school, an absence of sports activities and so on. The more often this happens, the more someone becomes isolated from his or her social environment.

As a child, this isolation can scar him or her, which impacts their personal development. Embarrassment plays a crucial role in their disease experience. Having a conversation about poo or bowel abnormalities is not the most pleasant one, let alone if you are a child. If due to circumstances such as IBD, people do not feel comfortable with themselves, and design has the potential to make a positive impact, I have to explore this!

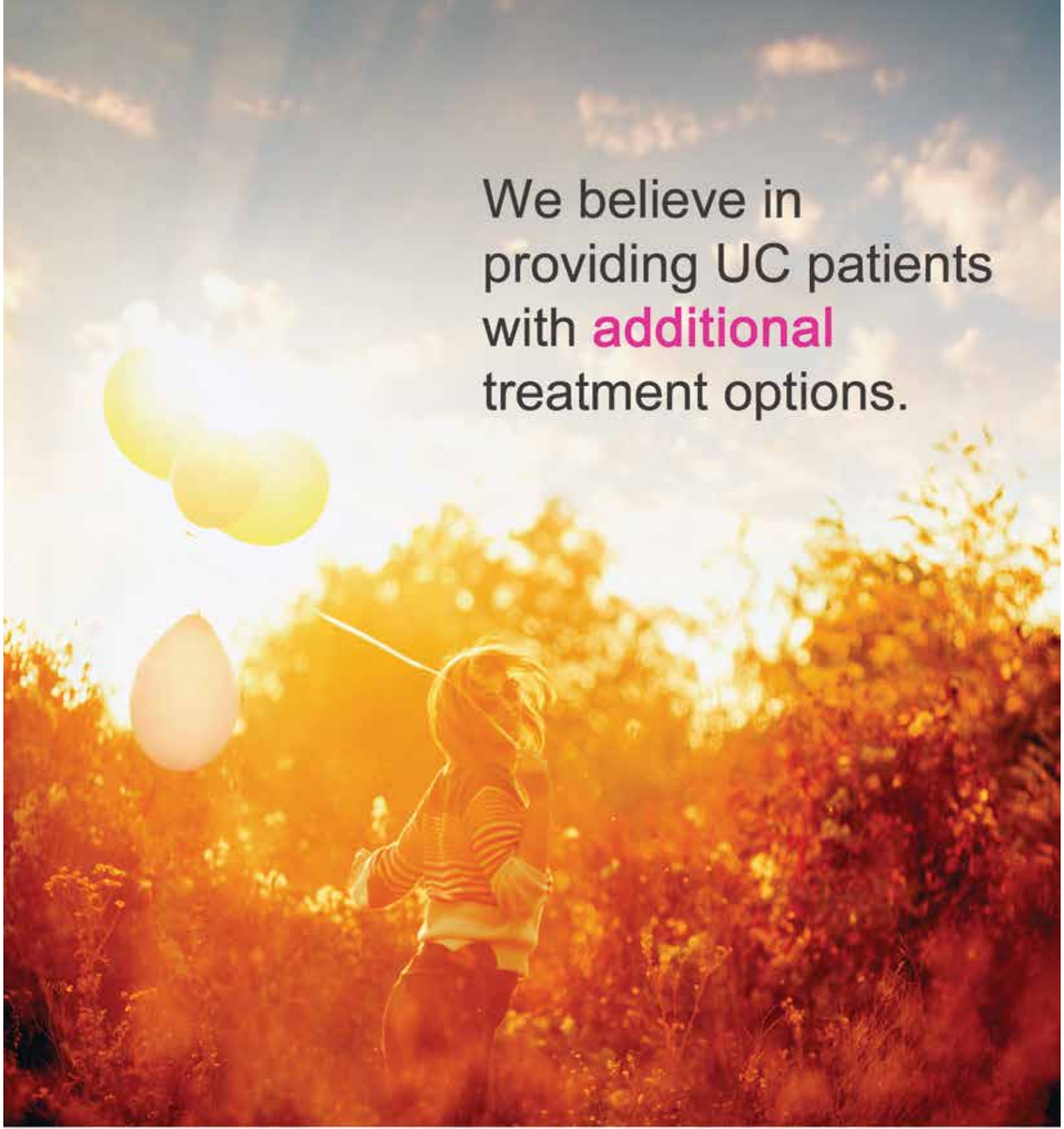
I started with this project in January 2018 and the solution will be presented early June 2018. I am very excited to continue with this project, understand in what other ways children and their caregivers are affected by this disease and see how a design-driven mindset can help make their lives easier and more enjoyable.

A while ago I made animation about IBD which can be viewed on: <https://vimeo.com/236045543>

### **Let's work on this together and combine our forces**

I am extremely eager to hear some of your stories, so if you are reading this and have paediatric IBD experience and willing to chat with me; please reach out to me on [daan\\_hekking@live.nl](mailto:daan_hekking@live.nl) and join me in creating a solution for children or their caregivers that will help them overcome the obstacles that are holding them back from living a life without joy.



A child in a striped shirt and dark pants stands in a field of tall grass, holding a string of three balloons (two yellow, one white) against a bright sunset sky. The scene is bathed in warm, golden light.

We believe in  
providing UC patients  
with **additional**  
treatment options.

Otsuka Pharmaceutical is a global healthcare company with the corporate philosophy: 'Otsuka-people creating new products for better health worldwide.'

The Otsuka Group is comprised of 158 companies and employs approximately 42,150 people in 25 countries and regions worldwide. Otsuka is committed to focusing its research and development on innovative products which address unmet medical needs, particularly in our specialist areas of gastro-intestinal, renal, endocrine, oncology, and central nervous system disorders.

# Patient Journey with IBD

Results of a recent study on the Patient Journey with IBD carried out by ABCD Brazil show that IBD patients in Brazil face many problems. The Patient's Journey is the first quantitative and qualitative study done in Brazil to map in depth the reality of the patient with IBD.

With 3,563 questionnaires the ABCD Patient Journey with IBD study was able to draw a profile of patients with inflammatory bowel disease. The result of the research, which has just been published and is available on the ABCD website ([www.abcd.org.br/jornada](http://www.abcd.org.br/jornada)), is an important document for specialized physicians, representative entities and associations dedicated to IBD, in addition to serving as a parameter for the suggestion of future public policies related to the diseases.

The results confirm that the greatest difficulty of the patients is in relation to the time to obtain an accurate diagnosis. The journey usually begins with the first symptoms and goes on for several months (and even years), with visits to various specialists and emergency rooms. Of the total study participants, 26% took more than a year between onset of symptoms and consultation with a gastroenterologist or proctologist and 43% were at least four times before at the emergency room before receiving a final diagnosis. Of the 41% that took more than 12 months to receive the diagnosis, 20% had to wait more than three years to discover the disease and begin appropriate treatment.

One of the reasons for delay in diagnosis is disease-specific, but the problem may be aggravated by difficulties in accessing specialists who know and identify IBD. In addition, the initiation of treatment does not necessarily mean immediate improvement and requires adaptation and dedication of the patients and the medical staff involved, as it may include hospitalizations, surgeries and complementary tests for the correct staging of the disease. Even patients with many years of diagnosis have told us that the journey is one of constant learning about disease, treatments and how the body reacts to every change.

The results also demonstrate that even adherence to treatment does not mean that there are

no seizures and symptoms. “The answers confirm that each patient’s journey is unique and can follow several and tortuous paths. Some lead to greater acceptance and resilience, others to loneliness and isolation. Some obstacles are also recurring in several stages, such as limited access to medicines and multidisciplinary health teams,” says Dr. Marta Brenner Machado, President of ABCD. The specialist points out that there was no study that sought to understand how patients live and what are the biggest problems they face on a day to day basis.

“From these data, we can better understand the patient’s reality and understand his difficulties in accessing medications, his desire and lack of access to multidisciplinary health teams, especially nutritionists and psychologists. We reinforce ABCD’s objectives to facilitate the exchange of experiences and facilitate the dissemination of information to allow more patients to have access to treatment and a better quality of life,” she emphasizes. The president of ABCD also stresses that the objective of the research is not to indicate the prevalence of the disease or to estimate the size of the IBD population in Brazil, because there are no epidemiological studies to obtain these data. However, the Brazilian Intestinal Inflammatory Disease Study Group (GEDIIB), a partner of ABCD in this project, is engaged in developing further studies that may produce new and additional knowledge to this research.

## Two phrases

To obtain the data, the Patient’s Journey took two phases. In the quantitative survey, whose questionnaire was available online on the ABCD website, participants answered 42 open and closed questions. In the qualitative research, in-depth interviews were carried out with six patients from São Paulo, Rio de Janeiro and Minas Gerais: three women and three men, covered by the Unified Health System

(SUS) or by private agreement with Crohn's disease and ulcerative colitis. No significant disparities were identified between SUS and covenants, except for the ease of scheduling consultation with a specialist.

### **More information**

ABCD: Email: [secretaria@abcd.org.br](mailto:secretaria@abcd.org.br)  
[www.abcd.org.br](http://www.abcd.org.br) | [www.facebook.com/abcd.org.br](https://www.facebook.com/abcd.org.br)

# Supporting patients with arthritis

## *Interview with Mary Vella, president of Arthritis and Rheumatism Association in Malta*

### **What is ARAM?**

ARAM is the Arthritis and Rheumatism Association in Malta which has been set up over 10 years ago. It's composed of patients suffering from various types. We organize educational activities consisting mainly of lectures, symposia and group discussions led by rheumatologists and other associated health care specialists involved in the care of arthritis patients. We also organize self - management courses in collaboration with the Government Health Promotion Unit. The aim of these activities is to disseminate accurate and independent information to patients with arthritis as well as to the general public.

### **Are you involved in European work?**

Yes, we are very active at European level. We have been working with the European League against Rheumatism (EULAR) and have been elected full members of EULAR patient group in 2008. Through EULAR we got in touch with other patient associations that work with immune modulated disease groups, such for example the Psoriasis patient associations and EFCCA and its members associations who we met at the Biologics and Biosimilars Patient Advocacy workshop in Barcelona in February 2016. We also form part of Agora Organization which is an umbrella which gathers southern national organizations/ countries suffering from Arthritis. We also form part of European Patient Academy on Therapeutic Innovations (EUPATI) and Eular Patient Research Partners.

### **Has your European work had a positive effect at the local level?**

Yes it has, through EULAR, Agora and GAFPA workshops on Biologics and Biosimilars we received

important information about the issues involving these innovative medicines. Through GAFPA we learnt about potential concerns of switching and traceability. We realized that our concerns were similar to other patients across Europe.

When we received information that switching from originator drug to biosimilars was taking place locally at the Gastroenterology Unit, we decided to take action before it effects also the Rheumatology Patients. On 13 April 2016 we released our Position Paper, which we had been drafting since October 2015. This Position Paper was sent to all stake holders to voice the concerns of the rheumatology patient community, about potential switching and traceability.

I, as ARAM representative had a meeting with the Ministry of Health where I discussed our position paper and explained our concerns as regards switching in stable patients on Biologics. Once a patient is stable on a Biologic medication, we believe that there is no medical reason to risk a switch, irrelevant of potential cost savings. I am happy to say that we managed to convince the officials and for the time being, Maltese patients that are stable on Enbrel, the major biologic drug used in RA will not be switched to Biosimilar. This was confirmed through a DH Circular sent to all Health Care Professionals associated with the Rheumatology Unit on the 21st November 2017.

### **What are your plans for the future?**

We continue with our regular work in education and supporting arthritis patients in Malta, and lobby for access to new drugs on the market like Jak inhibitors for RA so that we will be at par with our European neighbors.

# Study on switching to biosimilar infliximab in Crohn's disease

## Introduction

Biosimilars are biologic medicines that are highly similar to an already approved biological medicine, known as the reference product. Biosimilars are approved according to the same standards of quality, safety and efficacy that apply to all biological medicines. (1) At the 25th United European Gastroenterology Week Congress, Celltrion Healthcare presented data from the phase III, randomised controlled, switching trial comparing biosimilar and reference infliximab. The data showed comparable efficacy and safety between all treatment groups (maintained and switched) in patients with moderate to severe Crohn's disease (CD) up to one year. (2)

The phase III study in patients with Crohn's disease (CD) is a randomised controlled, double-blind trial containing a main period up to week 30 and a switching period after week 30 up to week 54. The study included 220 CD patients who were randomly assigned to four groups (Group 1: n= 56 for CT-P13 maintenance, Group 2: n= 55 for switch from CT-P13 to reference infliximab, Group 3: n= 54 for reference infliximab maintenance, Group 4: n= 55 for switch from reference infliximab to CT-P13) (Figure 1). The main study period was to demonstrate similar efficacy, safety, immunogenicity, and pharmacokinetics between CT-P13 (Remsima®/ Inflectra®) and reference infliximab (Remicade®) in direct comparison, and the switching period was to evaluate efficacy and overall safety profiles between the 1-year maintenance treatment group and the switching group (3-5).

## What are the findings of the 3.4 study? (3-5)

During the main study period, the study demonstrated similar efficacy between the two treatment groups, CT-P13 and reference infliximab, in terms of Crohn's Disease Activity Index (CDAI)-70, CDAI-100 responses, and clinical remission rate up to week 30. Moreover, the results also showed

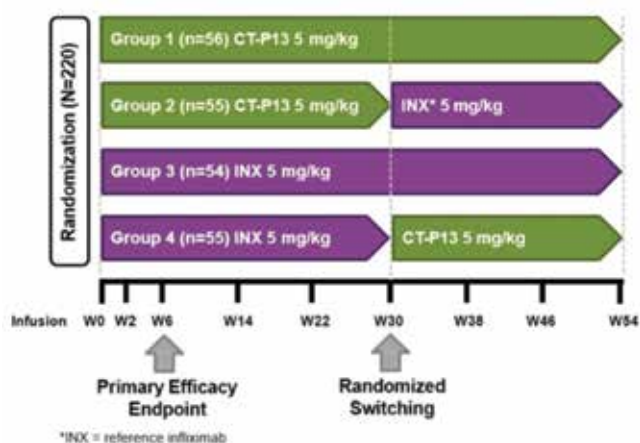


Figure 1. Study design of phase III Crohn's disease (CD) 54 week study

that CT-P13 was well-tolerated and that the overall safety profiles including immunogenicity were similar between the two groups up to week 30.

Similar results were shown after switching at week 30. All efficacy results including Short Inflammatory Bowel Disease Questionnaire (SIBDQ) score, which is a measure of quality of life for people with inflammatory bowel disease (IBD), were similar among all four treatment groups including CT-P13 maintenance, reference infliximab maintenance, and switching (CT-P13 to reference infliximab and reference infliximab to CT-P13) groups in both directions up to week 54, and there was no statistically significant difference between the groups (Figure 2).

The overall safety profiles of CT-P13 were similar to that of reference infliximab considering all safety parameters in terms of tolerability of study drug, adverse events, serious adverse events, infusion-related reactions, and infections. In addition, there were no notable differences of safety profiles between all 4 treatment groups (Figure 3).

The study results confirmed that patients who

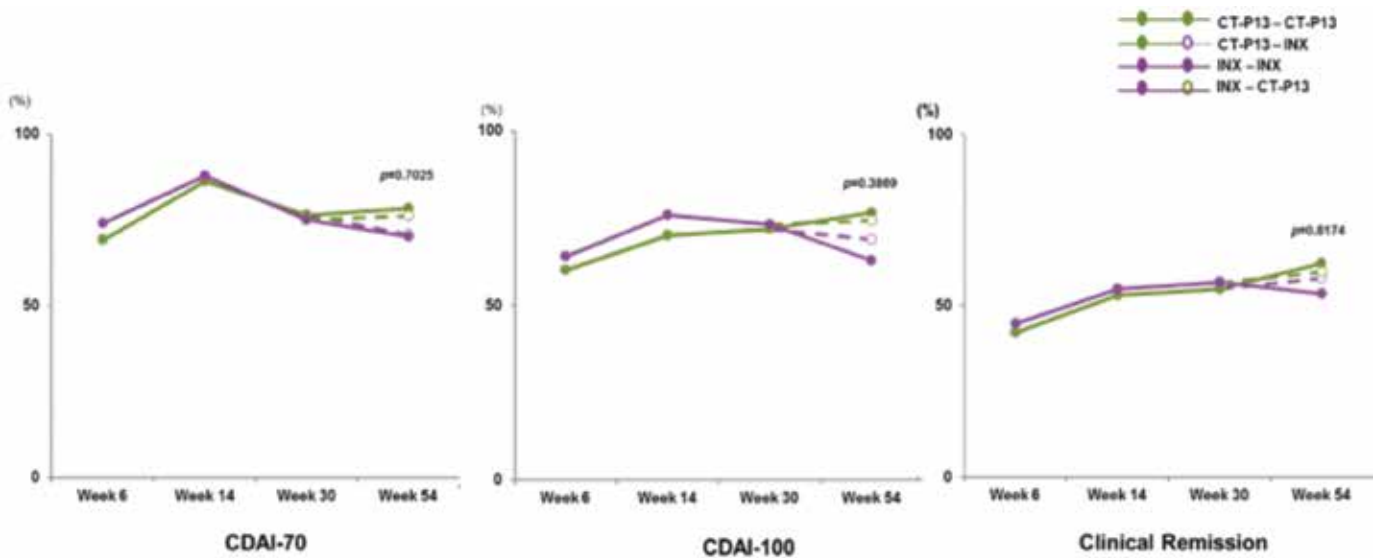


Figure 2. The proportion of patients achieving CDAI-70, CDAI-100 response rates and clinical remission in each group up to week 54

were treated with CT-P13 for a long period of time or switched to CT-P13 from reference product did not result in increased immunogenicity, occurrence of adverse event or loss of efficacy.

### Why is this study so important?

Extrapolation of CT-P13 data to IBD is based on similar physico-chemical characteristics, comparable biological functions, equivalent PK/ PD data, and comparable efficacy and safety in patients with ankylosing spondylitis (AS) and rheumatoid arthritis (RA). While abundant real world

data in IBD indication have already been published, residual concerns on extrapolation remained.(6)

This is another randomised controlled trial following the NOR-SWITCH study in IBD patients using CT-P13 that demonstrates switching is safe. (7) Comparable safety and efficacy were shown between CT-P13 and reference infliximab in all treatment groups and the results of this study provide the clinical evidence for those who have concerns about extrapolation in IBD.

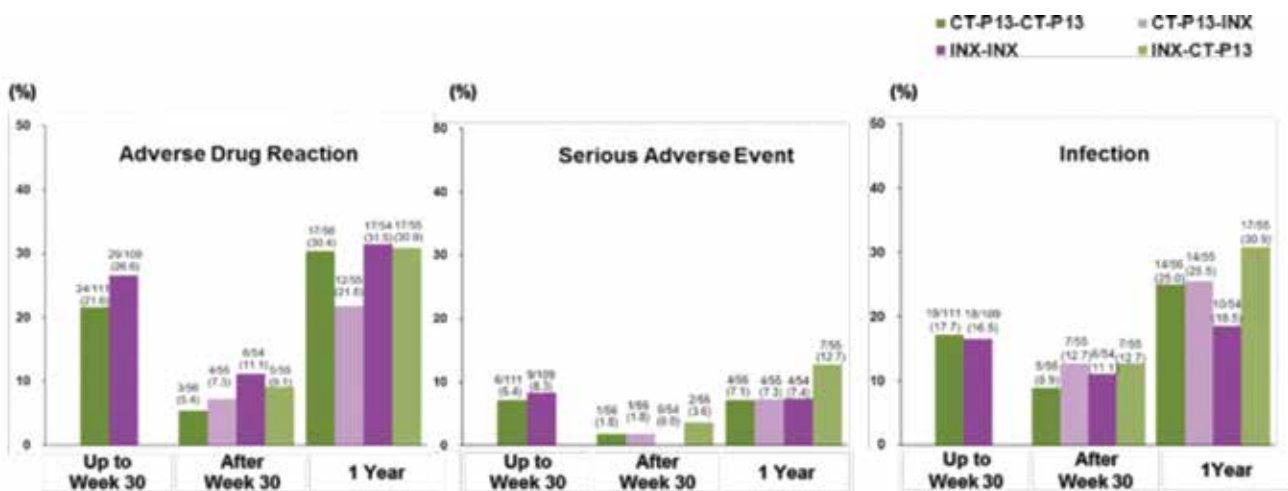


Figure 3. 1-year data of adverse drug reactions, serious adverse events, and infection in each group

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## A European survey on the phenotypic features of IBD in couples with IBD and their offspring

**Maria Pia Costa Santos, Joana Torres, Gastroenterology Department, Hospital Beatriz Ângelo, Loures, Portugal**

Familial aggregation of IBD may be due to genetic factors; however, genetics alone only explains a small portion of disease heritability, highlighting the role of environmental factors that may be shared within a household and between family members.(1,2)

Some small studies have observed that the chances of developing IBD after marrying to an individual with this disease is significantly increased relative to what would be expected by chance alone. (5) This observation is puzzling, and suggests that environmental factors may indeed be involved in the pathogenesis of disease. (5) One of the first studies to address this issue was conducted by Bennett et al., who evaluated 19 couples with IBD (mostly of Jewish ancestry); in 14 cases, the second member of the

couple only developed IBD after marriage.(6) Later on, Laharie et al, in a cohort from Northern France, identified 30 couples with IBD; in 22 couples, both partners developed IBD after marriage, a number greater than expected by chance ( $P < 0.02$ ), and this occurred on average 8.5-9 years after cohabitation.(5)

Importantly, based on these two studies, it is estimated that if both parents are affected by IBD the risk for the progeny to develop IBD is substantially

higher.(5,6) In the study by Bennet et al. the diagnosis of IBD was established in 36% of the offspring from the 19 couples included.(6) In the more recent study by Laharie et al., the prevalence of disease among 54 children from 25 couples with both parents affected with IBD was 17% and the probability of developing disease increased with age, with a 33% risk estimated by 28 years of age.(5) Whether these estimates would apply to different populations remains unknown; however we hypothesize that since both studies were conducted in high risk populations for developing IBD (Jewish ethnicity and in a high-incidence area for disease) it is possible that the risk for progeny maybe actually lower than what originally estimated.

Since these original studies were conducted, there was no further research in this area. However, identification of couples where both members have IBD, could offer the chance to further understand disease pathogenesis. Most importantly, by describing in what frequency disease develops in the offspring of couples with IBD, estimates of risk to prospective parents could be more accurate and pre-conception counselling improved.

We here propose to perform a pan-european survey to identify couples where both members are affected by IBD and describe the circumstances of their diagnosis, retrieve information on their disease type and phenotype, increasing the size of the previous cohorts. In the same survey we also aim to characterize in a larger European cohort, the risk for the progeny to develop disease and to provide more detail on their phenotypic characteristics. This survey was already endorsed by ECCO's Clinical Committee and will be distributed to physicians in ECCO. We are also hoping to have the support from patient's associations, who could be crucial in advertising and distributing the survey link to their associates, allowing patients to self-reply and self-report their disease features and characteristics. All the answers will be kept anonymous and the data will only be used for research purposes.

Hopefully, this survey will provide more accurate risk estimates to couples and prospective parents living with IBD. Furthermore, identifying families at

very high risk for developing IBD could also offer the possibility to create a "high-risk" cohort for future studies. In fact, unaffected relatives of IBD cases not only have a higher risk for developing disease, but they also present some features of subclinical inflammation. Indeed several studies focusing on healthy relatives of patients with IBD have found that a subset of IBD relatives display altered intestinal permeability, elevated faecal calprotectin, positive anti-microbial markers, alterations in markers of innate and acquired immunity, altered gut microbiome, etc (3,9–15).

Therefore, studying first-degree relatives of patients with IBD and families with IBD, offers the potential to greatly advance our understanding on the earlier stages of disease, which could ultimately pave the way for developing prediction tools and preventive strategies.

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## Improved knowledge in IBD starts to be adopted in daily practice

Many patients with Ulcerative Colitis (UC) or Crohn's disease (CD) also known as "Inflammatory bowel disease" (IBD) are still suffering, which has an impact on patient's everyday life, work and education. A European survey of 5000 IBD patients a few years ago, over 85% of patients reported that they have been hospitalised for reasons related to their IBD in the previous 5 years.

The availability of new medicines over the last 15 years has meant that better outcomes can be achieved. Evidence has also revealed that it is better to treat patients as early as possible. However, in day to day practice, proper goals and the path to achieve them are often poorly defined. An example of this is the overuse of steroids when other medications are available.

Physicians know people with Crohn's disease have times when they are feeling great, almost "normal" while at other times feel awful. What has been proven recently is that Crohn's disease can be highly active even when the patient feels "pretty good", this is called subclinical inflammation and leads to damage

to the bowel and more complications like strictures (narrowings). This often leads to surgery because the complications were not felt (feeling "pretty good") and therefore not treated. Surgery often means more disability and an overall poorer quality of life.

Having new medications available means it's no longer considered sufficient to have a short-term focus on symptoms, nor is it sufficient to rely on the patient feeling "pretty good". Physicians and patients must work together to focus on achieving remission.

To do this, monitoring is required. This monitoring ensures that if remission is not achieved, that medication can be modified. By stopping bowel



damage, it can often mean a decrease in the need for surgery and decreased disability.

There are several types of monitoring. For example, testing the blood (specifically the inflammatory marker called CRP) and stool samples (specifically calprotectin) of patients as well as endoscopic procedures, as published in the POCER study (1). You may hear your doctor speaking about “Treat to Target”. Achieving remission is the target and this gives the patient the best possible chance of stopping the disease.

One of the biggest studies, called REACT (2), looked at monitoring in 40 hospitals, over a 2 year period and involved 2000 patients. It was proven that patients who were cared for in a structured way, using monitoring tests and the right medicine had much less need for emergency hospitalisation and surgery.

### **Testing blood and stool samples in everyday life**

After the initial proof about the value of testing stool samples (calprotectin) and blood (CRP) it has also been proved that if these tests were performed appropriately, some patients could avoid having up to half of their colonoscopies (which take 30 to 60 minutes, using a tube and camera through the anus which can be uncomfortable for the patient). Calprotectin stool testing can also predict flares up to 4 months in advance.

This test can now be performed in the comfort of your own home and results sent to your doctor using a mobile phone camera and app. Patients can use this app and the results to help discussions with their doctors and nurses.

In the **CALM study (3)**, it was demonstrated that taking treatment decisions based on monitoring different objective parameters such as CRP and calprotectin, can deliver better disease control than focusing on symptoms only. It is expected that in the future, the adoption of this learning will improve “tight control” of the disease.

### **Using technology to improve care**

In the EFCCA survey of 5000 patients it was discovered that 88% of IBD patients search the internet for IBD information, several times per month. Some 66% of patients also said they would be happy to use their mobile phone to help with their disease.

Mount Sinai hospital in New York has discovered that patients feel that there is often poor communication with their doctor including both about the targets of therapy and possible treatments. Patients seemed eager to get involved to improve communication and increase their own responsibility for their IBD, feeling that this would give them more control.

### **New technologies are now available to allow this to happen.**

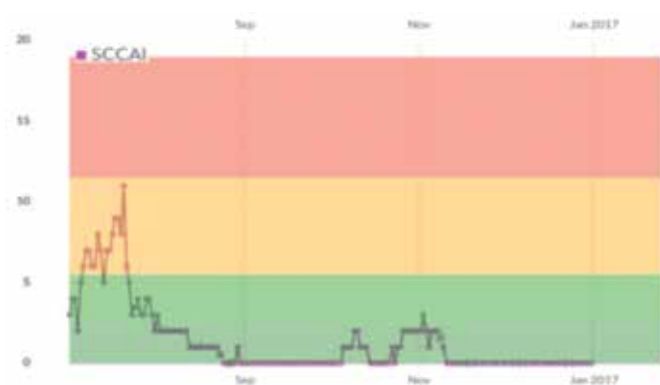
Through using mobile phone apps or a website, patients can answer simple questions about symptoms and quality of life. This information is then available to the individual patient as well as the treating team. These answers provide the treating team with vital, relevant patient information. It also means that patients do not have to remember everything that happened since their last appointment and that the appointment can be focused on the things that really matter to the patient.

At the John Radcliffe Hospital, Oxford, UK, 60 patients have tested a comprehensive, web-based programme. Emails were sent to patients on a regular basis and these emails linked directly to the questionnaires about symptoms, quality of life and important outcomes such as steroid use and need for emergency department visits.

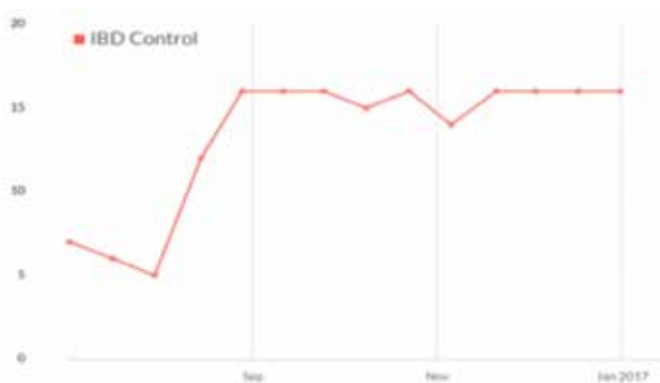
By answering the questions, the programme was then able to graph the results which could be seen by both the patient and the treating team. The symptom graph is colour coded – dark green = remission, light green = mild, amber = moderate and red = severe. An example of one patient’s graphs is shown below.

This patient had a flare of their symptoms (graph enters into the amber area), medication was altered and he returned to the green area. When the symptoms flared the quality of life (shown in the IBD Control graph) went down, and when he improved, this also improved.

**Symptom graph**



**IBD Control graph**



Patients liked using this system, feeling that it made them more empowered. This included improvement in communication with the treating team, improvement in decision making and improvement in awareness about their disease. Many also reported that they felt reassured that there were questions about feeling tired or feeling anxious: topics that they had been reluctant to bring up in normal appointments.

Another aim of this approach is to use this data that patients enter at home to better streamline appointments: that is, to see patients when they need to be seen rather than when they are well.

Another tool developed and recently validated with the focus of improving physician – patient communication is presented as an IBD Disk.

This method also displays the results in graphs for patients and doctors to see what’s happening with their IBD. A group of expert Gastroenterologists selected 10 questions, the most important information to have from patients. IBD Disk includes questions about abdominal pain, body image, education and work, emotions, energy, relationships, joint pain, regulating toilet habits, sexual functions, and sleep. The IBD Disk is another promising tool for patients.

Technology, questionnaires and the role of the patient is proving to be a valuable way of partnering. We still have work to do, physicians need to agree on exactly which questions are best and what technology will be easiest to use and access for patients.

**Comparing patients from different parts of the world**

As we know some patients have better access to treatment because they live in developed countries with better healthcare than other less developed countries. Regardless we need to be able to compare services and to set a standard that the whole world can hope to meet. This will mean for those countries that are more advanced to work towards the same goals as those countries that are less advanced.

To do this you need to agree on the information you compare to measure how good or bad a hospital, region, state, country, continent performs against another. It also sets a minimum standard that it is hoped all countries can reach.

Until recently there was no agreed set of criteria on which things to compare in IBD. An independent group, ICHOM had organized several meetings with

**FIGURE 3. Hypothetical example of how a patient's IBD Disk assessment may change over time with good disease management.**



physicians, nurses and patient representatives and they decided on 14 items that should help to compare patient results and outcomes across different hospitals. In a near future, we should hope that many hospitals will be able to measure their achievement in these

different categories and work together on identifying best solutions, sharing educational programs and advance the lives and outcomes for patients together.

Patients should feel confident that in IBD, there are multiple projects currently looking at improving the way IBD patients are treated.

These projects mentioned are just a few of the many projects aimed at making significant positive change to both IBD and its patients.



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