

EFCCA MAGAZINE

European Federation of Crohn's and Ulcerative Colitis Associations

February 2022



**World IBD Day 2022:
IBD has no age**

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Something to Say!

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**On the cover
from the “IBD without filter” campaign
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www.ibd.org.sg/english

Trinidad and Tobago - NACCTT
www.crohnsandcolitistt.org

Ukraine - Fulfilling life
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From a virtual world to reality

Since 2020 despite the COVID-19 pandemic and the inability to meet in person and work as usual, EFCCA has invested resources and developed “virtual” projects to allow its members to continue to communicate and learn from each other.

We have organised the EFCCA Talks on topics deemed important by our members and the Happy Hours have become more non-formal moments to “see” each other and exchange ideas, inspiring practices and projects; a virtual room, a way to meet and continue to work together in the hope of seeing each other again soon in person.

One area we are focusing on is to identify and address the unmet needs of IBD patients. Living with a chronic disease means that the quality of life in general will assume importance and has a subjective dimension linked to the preferences of the individual. There is a growing demand on the part of patients to govern more actively the choices related to their health based on what guarantees them better management of their life.

The impact on a patient’s quality of life must therefore be a fundamental parameter for establishing the value of our care system. We will have to move from a disease-centered approach to a person-centered approach. From an approach centered on the needs of the organization to a health systems centered on the person’s needs.

For these reasons I am particularly pleased about our collaboration with KU Leuven University on a study on patient preferences targeting IBD patients. You will find more information about this exciting project under the patronage of Professor Séverine Vermeire in this issue.



“Living with a chronic disease means that the quality of life in general will assume importance and has a subjective dimension linked to the preferences of the individual.”

Another EFCCA flagship you will read about of course is the EFCCA Academy. We have launched new training modules on clinical trials and the more recent Youth Academy addressed to the younger IBD generation. With the training course addressed to our youth we aim to transmit the values and basis of EFCCA with the hope that the new generation will continue the journey that began with us so many years ago.

From the many activities mentioned in this issue and also from our member news you can see that the strength of our organisation is that we work with a wide diversity of actors, providing significant contributions in the pathways of correct information, support, and accompaniment to patients.

In the future, it will be strategic to relaunch and enhance the role of associations representing patients and citizens, especially those that operate transparently in the exclusive interest of the people they represent.

We have the trust that patients place in us. We must cultivate this trust, and we must commit ourselves to oppose those who abuse this trust.

We must work to defend our rights, enhance our role, and enhance our collaboration with doctors and institutions. Imagining the future also means committing to build it together because we are all nodes of a network that must guarantee assistance and solve problems.

There are so many ways to take care of the people we represent. One of these is to transform slogans into concrete action.

United We Stand,
Salvo Leone, EFCCA Chairman

EFCCA Happy Hour

At the end of last year (17 December) and just before closing the office for the annual holiday season we organized another online EFCCA Happy Hour in order to reconnect with our members and to brainstorm and exchange ideas for our upcoming activities.

We invited Elise Schoefs, a researcher from KU Leuven University (Belgium) as guest speaker to present a new planned study on patient preferences for Inflammatory Bowel Disease. The study wants to explore what the drivers are in IBD patients to select a specific therapy and to understand what is important to patients, what they expect from a therapy and how this process should best be steered. EFCCA will be collaborating on this promising project which is being carried out by a research team from KU Leuven University (Belgium) under the patronage of Professor Séverine Vermeire.

During Happy Hour we also explained our plans for World IBD Day 2022 under the theme "IBD has no age". You can read more about our World IBD Day plans on page 9. Several of our members presented

some of their activities and a lively discussion continued on how to work together and synergize our efforts in improving the quality of life of people with IBD.



EFCCA Academy: Empowering young IBD representatives

EFCCA launches the Youth Academy with the aim to increase the representativeness of the youth group, to create a cohesive group of leaders of tomorrow and to empower young representatives.

Last 29 November 2021 we launched the first module of a new training programme for young IBD patients via the EFCCA online learning platform. The training programme is addressed to young IBD patients (aged between 18 and 30) and the class includes 30 students from 20 IBD patient associations.

Our CEO, Luisa Avedano, and Deputy Director, Isabella Haaf, kicked off the programme with a module called “The history of EFCCA, its mission, values, and strategic priorities.”

Luisa took students on a journey that has lasted over 30 years and started with a bunch of IBD patients who turned a dream into a reality. *“The history of EFCCA, at least of the EFCCA we all know, also represents an important part of the history of the IBD patient community”* she explained. Students learnt about the establishment of the federation to the most recent developments including a presentation of the Statutes, mission, and vision that represent the skeleton of the working methodology as well as a presentation on how the EFCCA General Assembly works and which are the principles that rule our day-to-day operations. Isabella continued the journey by talking about the Executive Board such as its role, its activities and introducing the class to the current board members. She then explained the application process to become an EFCCA member and all the benefits that come with it and also what happens in the case of resignation or exclusions. To conclude, Isabella stressed the importance of building alliances and good working relations with other organisations and people that share EFCCA’s common agenda.

With this first module we want to bring the ins and outs of EFCCA closer to our young representatives.



FIRST TRAINING MODULE

The history of EFCCA, its mission, values and strategic priorities




WITH LECTURES BY LUISA AVEDANO - EFCCA CEO & ISABELLA HAAF - EFCCA DEPUTY DIRECTOR



Sharing our history and the pioneering spirit that has always been EFCCA’s hallmark we aim to transmit to our students the values and basis of EFCCA with the hope that they will continue the journey that began so many years ago.

In the next module we will listen about the journey that led to the creation of the youth group from two former EFCCA Youth Leaders.

Maria Stella De Rocchis,
European Project Officer

EFCCA Academy: towards the Certified Patient Award on Clinical Trials

Last November 2020 a group of motivated students joined the EFCCA Academy on Clinical Trials with the aim to have a better understanding of the complete clinical research process, and of the patient's role in supporting the design and implementation of clinical studies. We are pleased to present you with four projects accomplished by the students that participated in the training. A big thanks to students Delphine, Janek, Raffaele and Magdalena on behalf of EFCCA for their great commitment in sharing



their knowledge about clinical trials within their IBD communities. Great job!

We are looking forward to telling you more about other successful stories from the rest of the students.

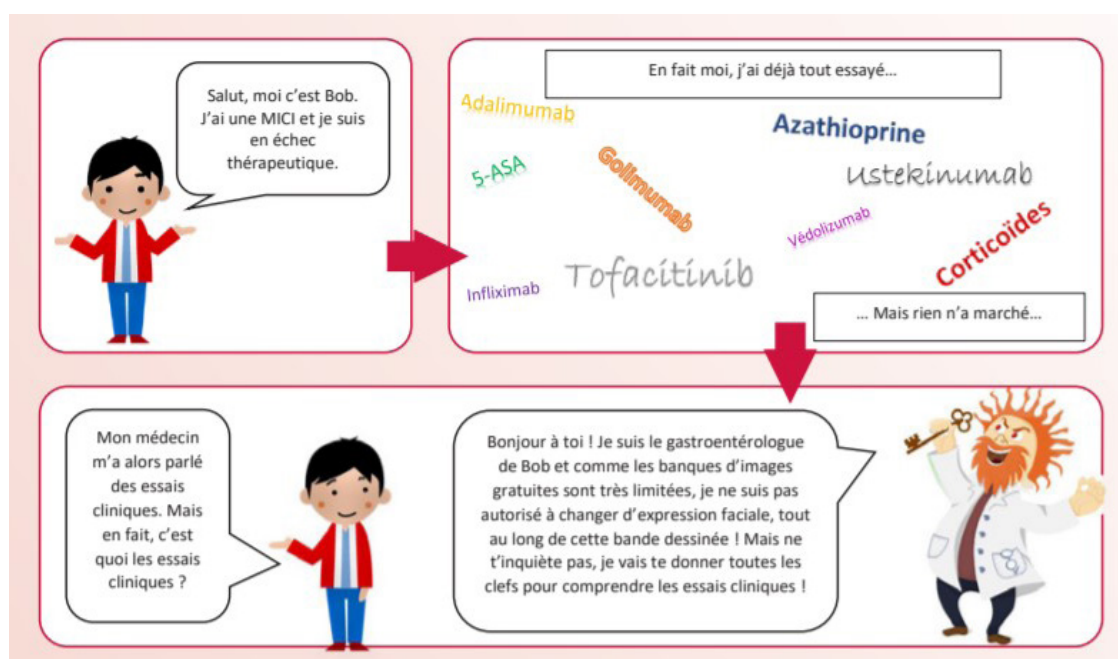
Stay tuned!

- Student: Delphine Khuu
- EFCCA Association: Belgium - Association Crohn-RCUH
- Type of activity: Comics published in the Belgian association's magazine

On the occasion of the September issue of the magazine "Crohnique of ASBL Crohn RCUH" Delphine Khuu, a volunteer of the Belgian association, has prepared a comic in which she has described in a very nice and funny way some of the main aspects

concerning clinical trials from the patients' point of view, like the first interview with the gastroenterologist, all the phases necessary for the implementation of a new therapeutic treatment, the advantages and disadvantages of participation, the doubts a patient may have and where to look for information.

The comic concluded with a reflection on the importance of scientific research, as well as the importance of the patient's active role and right to be informed.



- Student: Janek Kapper
- EFCCA Association: Estonia - EPSS Eesti Põletikulise Soolehaiguse Selts
- Type of activity: Clinical Trial Ambassador

As a result of the training received during the EFCCA Academy Janek Kapper, CEO of the Estonian IBD association, became "Clinical Trial Ambassador" with the aim of raising awareness of clinical trials among IBD patients in Estonia. Janek explains the reasons behind this: *"I became Clinical Trial Ambassador because Estonian patients need more information about ongoing clinical trials, find out what is involved in clinical trials and learn about the criteria to get involved in clinical trials from trusted sources."*

Janek helps Estonian patients with IBD in their research for reliable information, offering support at every stage of their research and identifying possible specialists and research centres to contact in order to be involved in clinical trials.

More info at:

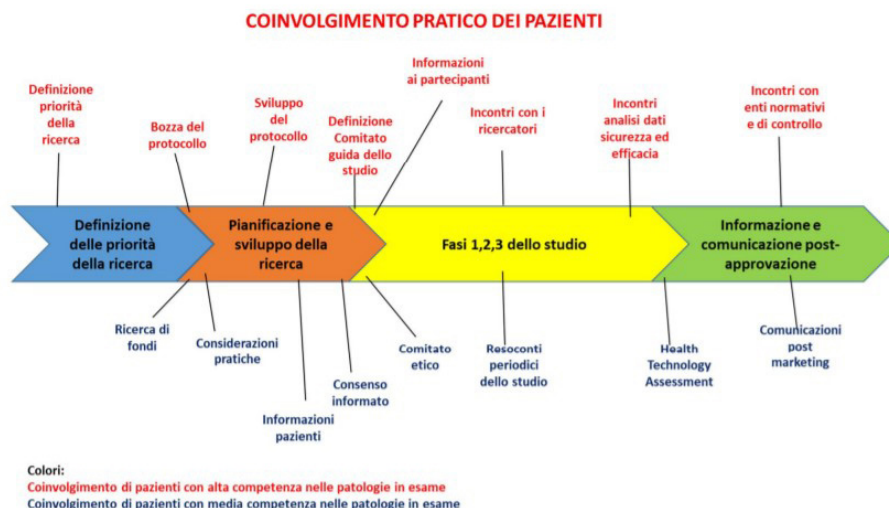
www.clinicaltrialambassadors.com

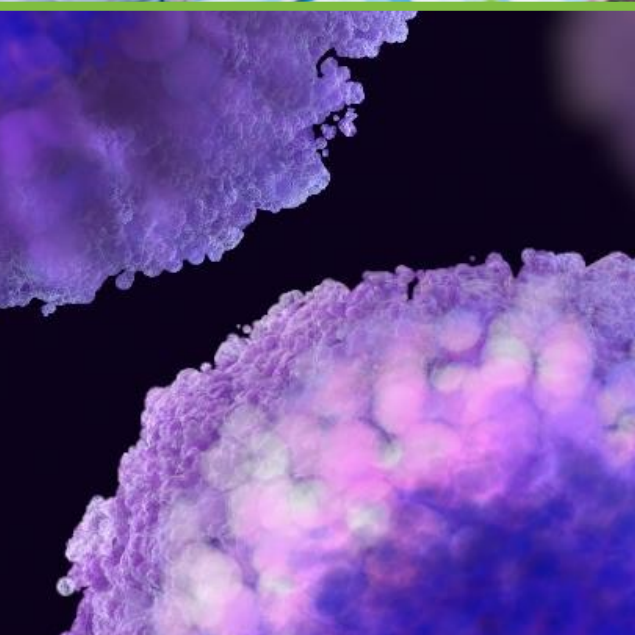
- Student: Raffaele Campanella
- EFCCA Association: Italy - AMICI ONLUS - Associazione per le malattie infiammatorie croniche dell' intestino
- Type of activity: webinar / document informative

Raffaele Campanella, volunteer and President of the Regional AMICI Italia Onlus branch of Friuli-Venezia Giulia worked on a very detailed booklet for the Italian IBD community which will be published soon on the Amici Onlus website. The aim of the booklet is to explain in basic words the complex functions of clinical trials. He explained: *"I hope that using text, schemes and drawings can be a useful way to help*

patients better understand the complex processes involved in Clinical Trials by stakeholders with several and sometimes non-coinciding interests. I would also like to give a good idea on how serious clinical trial organisation is involving scrupulous compliance with the procedures to help patients fight their disease. This is a small contribution to help people understand that this is the way that will allow science to turn IBD chronic diseases into curable ones."

Last November 2021 Raffaele also organized a webinar held by Dr. M. Marino, Principal Investigator of Clinical trials for IBD in Udine Hospital (Friuli-Venezia Giulia) for patients from Friuli-Venezia Giulia region.





Learning from the experts.

No one understands the patient journey quite like the patients themselves. That is why we are working closely with the patient community to deliver oral medicines to address patients' needs and help transform the treatment of inflammatory bowel disease.

Come and meet us at <https://www.arenapharm.com>

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PHARMACEUTICALS
Care More. Act Differently.

- Student: Magdalena Sajak-Szczerba
- EFCCA Association: Poland - J-elita - Polskie Towarzystwo Wspierania Osób z Nieswoistymi Zapaleniami Jelita
- Type of activity: Article published in the Polish association's magazine

We were pleased that our EFCCA Board member Magdalena Sajak-Szczerba participated in the EFCCA Academy on Clinical Trials and as results and with the support of MD/PhD Ariel Liebert, as well as one of the speaker of one of the training modules of the training, she prepared an informative article titled:

“Clinical trials - What every patient should know” for the release of the quarterly magazine “J-elita” of the Polish association.

The article describes very well all the reasons why a clinical trial is conducted, the different ones available, benefits and risk of participating in them, the process of developing a new drug and the introduction in the market. Special attention has been given to the vocabulary, the patients' rights and the Polish pharmaceutical law which regulates the clinical studies in Poland.



EDUKACJA

Badania kliniczne. Co każdy pacjent wiedzieć powinien

Po co prowadzone są badania kliniczne? Czym się różnią? Jakie są korzyści, a jakie ryzyka wynikające z uczestnictwa w badaniu klinicznym? Na te i inne pytania znajdziesz odpowiedź w tym artykule.

jest obowiązkowa nie tylko dla nowych leków, ale także dla istniejących już leków i kombinacji obecnych na rynku substancji czynnych, w przypadku oceny bezpieczeństwa i skuteczności w leczeniu innych schorzeń. Często badana

World IBD Day 2022

IBD has no age

This year's theme for our World IBD Day celebrations will focus on IBD and the elderly. Under the slogan “IBD has no age” we would like to raise awareness on the unmet needs of elderly IBD patients and launch a survey in order to gather much needed evidence around this issue.

In line with our EFCCA strategy plan our priority theme for 2022 is IBD & Life Cycles. The aim of this theme is to look at the impact of IBD during the different stages (life cycles) of a person's life (youngsters/seniors, IBD in the family and IBD and maternity). For World IBD Day we have decided to focus on IBD and seniors. This is a group that has been consistently

underrepresented even though the incidence and prevalence of IBD in older patients is rising. There are estimates that in the next decade, older patients with IBD will represent more than one-third of all patients with IBD. Yet, there is little scientific evidence to understand how IBD impacts on adverse health outcomes or quality of life in older people with IBD.

IBD has no age



#worldibdday2022 #ibdhasnoage

Some of the key issues in relation to this age group are:

- Common comorbidities, especially malignancy and increased disposition to infections, can render elderly patients more vulnerable to complications of immunosuppression.
- Surgical management of IBD in elderly populations can also be associated with high risk due to high comorbidity.
- It should be noted that most clinical data to inform these practices are based on observational data or indirect evidence because elderly patients with IBD comprise a very small proportion of participants enrolled in IBD clinical trials or long-term pharmacovigilance initiatives.

Our campaign IBD has no age will consist of various elements including:

- **Social media awareness raising campaign**
In the lead up to World IBD Day on 19 May we will publish material and patient testimonials putting the elderly with IBD in the spotlight.
- **Purple EFCCA Talk (Webinar)**
On World IBD Day we will host a webinar on the issue of IBD in the elderly and the need for more

comprehensive scientific evidence. We will invite representatives from the scientific community to discuss the challenges and unmet needs of elderly patients and to discuss possible collaboration on a joint survey on this topic.

- Later on, in the year we will launch a survey looking at the impact of IBD at various life cycles groups with a focus on the elderly. This will be a long term project with the aim to gather a wider range of information related in general on the impact of IBD on the quality of life and specifically on the age group of people 60 and above.
- We will compile material on the subject that is already available and that can feed into the preparation of the above-mentioned survey. As usual all our campaign material will be made available to our members and can be modified if needed to local needs and priorities.

Ultimately our main objective with this campaign is to improve the care of elderly people that are living with IBD and we strongly believe that managing an older individual diagnosed with IBD warrants a multidisciplinary approach.

Isabella Haaf,
EFCCA Deputy Director

Patient Preference

Since the beginning of 2021, EFCCA has been working on the issue of patient preference. This refers to a person's evaluation of aspects - physical, psychological, and social - of health outcomes and how this influences his or her health care choices. As expressed in recent research by KU Leuven, "Due to their disease, patients are experts by experience."

We started by collecting existing data on this topic and after a review of relevant health literature we discovered that there is very limited scientific research on patient preference targeting specifically the IBD patient community. Based on these findings, an important strategic objective for 2022 is to engage with the scientific community, support research, and elaborate possible solutions.

Within this framework, we are therefore delighted to have the opportunity to work with a team from KU Leuven to carry out a study on patient preferences targeting IBD patients. This project will take as its base a previous study carried out by the research team involving two focus group discussions with Belgian IBD patients.

EFCCA will collaborate with KU Leuven to prepare a patient-friendly questionnaire, to disseminate throughout the EFCCA membership base and to promote patient participation in the study.

This work will help us to determine how much importance patients attach to the characteristics discussed in the previous study and will also allow us to investigate the unmet needs of IBD patients that cannot be solved with existing therapies.

**Results from the base
study involving IBD
patients from Belgium**

What do patients with inflammatory bowel disease find important in their treatment?

Elise Schoefs(1), Séverine Vermeire(2,3), Marc Ferrante(2,3), João Sabino(2,3), Tessy Lambrechts(2), Arno De Potter, Luisa Avedano, Isabella Haaf, Maria Stella De Rocchis, Andrea Broggi, Rosanne Janssens*(1), Isabelle Huys*(1)

* These authors share last authorship

1 Department of Pharmaceutical and Pharmacological Sciences, KU Leuven, Leuven, Belgium

2 Department of Gastroenterology and Hepatology, University Hospitals Leuven, KU Leuven, Leuven, Belgium

3 Department of Chronic Diseases, Metabolism and Ageing, KU Leuven, Leuven, Belgium

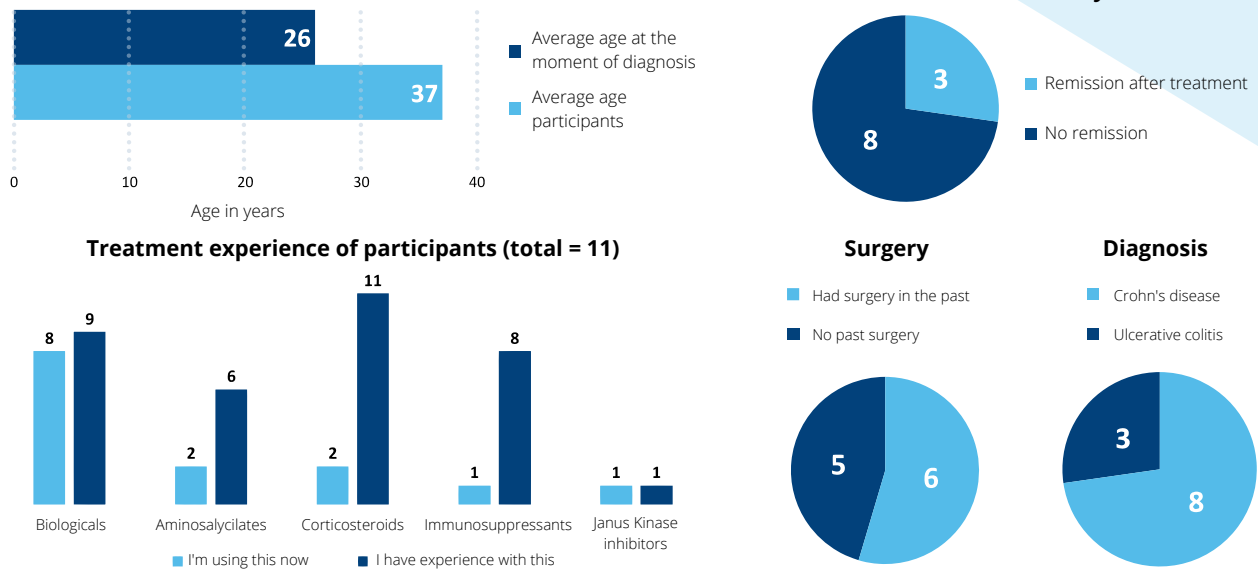
Why did we carry out this study?

Due to their disease, patients are experts by experience. Therefore they can provide insights on their treatment to inform drug development, approval and reimbursement. By conducting this study, we wanted to find out what patients with inflammatory bowel disease (IBD) find important in their treatment and why.

How was this study conducted?

Two group discussions with IBD patients were organised, where experiences were exchanged.

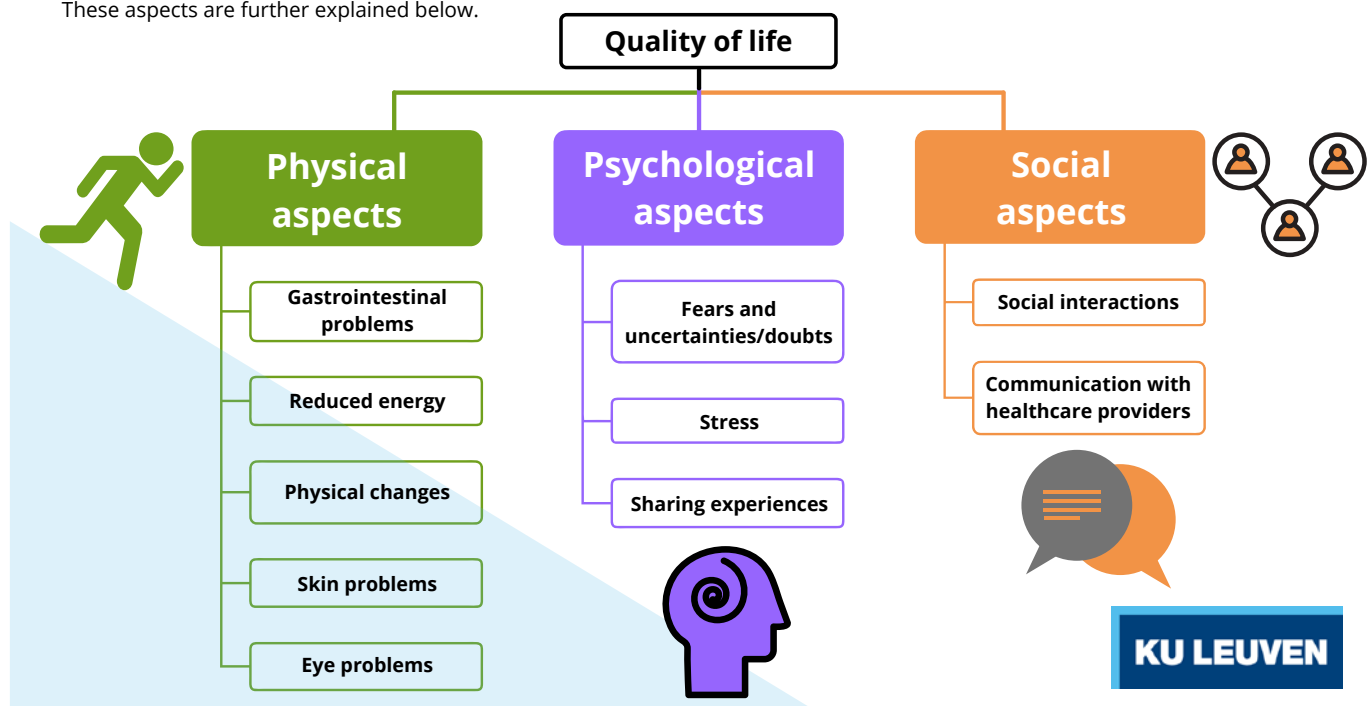
Who participated in this study?



What treatment features are important to IBD patients?

Patients want to be able to carry on with their lives as before the disease. The most important aspect for participants was therefore that medication could suppress their symptoms and their illness would remain stable; that the unpredictability of their symptoms would diminish and their daily lives would not be disturbed.

During the group discussions, the influence of **physical**, **psychological** and **social** aspects on patients' quality of life emerged. These aspects are further explained below.



Physical aspects



• Gastrointestinal problems

These problems contribute the most, due to the **physical discomfort, irregularity** and **unpredictability** of **sudden urges**. Therefore, gastrointestinal problems also have a major impact on both the psychological and social wellbeing of the participants.

• Reduced energy

Patients suddenly have to go to the toilet at night. This causes **sleep deprivation**, which has an impact on their work and social life. Medication can also cause chronic fatigue.

• Physical changes

The uncontrollable changes in **body weight and appearance** are bad for patients' self-esteem and often result from treatment with steroids.

• Skin problems

The importance of skin problems depend on the severity of this side effect. For example, acne is acceptable, but a serious rash is not.

• Eye problems

Patients are afraid of getting eye problems, as this can have a big impact on their lives.

Social aspects



• Social interactions

The lack of predictability of the disease prevents people from **making plans**. There is always a need for a toilet nearby. This makes it difficult to meet up with family and friends, or to go on holiday.

• Communication with healthcare providers

- Patients are generally **satisfied** with the communication between them and their healthcare providers, although it became clear that they often give **too little psychological support**. There is a feeling that the psychological impact of the disease is underestimated.
- Patients sooner want more **information** on the different treatment options, their impact, and short and long term side effects. They also want to be better informed on how to cope with the disease.



How will this information be used in the future?

The results will be used to draw up a questionnaire that we will send to IBD patients in different countries in Europe. In this way, we can mathematically determine how much importance patients attach to the characteristics discussed above. We will also investigate the unmet needs of IBD patients that cannot be solved with existing therapies.

Acknowledgements

We would like to thank all the patients who participated in this study.

For further questions, comments, or additional information, please contact:
Elise Schoefs: elise.schoefs@kuleuven.be
Arno De Potter: arnosteven.depotter@student.kuleuven.be

Psychological aspects



Patients often have **psychological problems** with their illness and/or their treatment. Several indicated that they needed psychological **support**.

• Fears and uncertainties/doubts

- There are concerns about the **efficacy** of medication. There is great uncertainty about whether a treatment will work or not, and **how long** it will work.
- The period between the start of a treatment and the occurrence of the desired effect varies greatly from patient to patient and between treatments. This uncertainty frustrates patients.
- Patients were concerned about the long term **side effects** of their treatment, and more specifically the increased risk of cancer.
- The need for **surgery** and the possible loss of an excessive amount of intestinal tissue is a concern, as it is not infinite and is necessary for proper food absorption.
- Patients are afraid of a **stoma**, fearing the **discomfort** and the **appearance**. One patient with a permanent stoma did share her positive experiences of living with a stoma.

• Stress

The negative impact of **stress** was discussed, and how it can cause abdominal cramps and sudden urges. Patients talked about the positive impact of sports and mental rest on reducing stress.

• Sharing experiences

Sharing experiences with fellow patients brings relief.

What to remember from the results?

- The most important aspect for patients in their treatment is that their symptoms are suppressed and they go into a long term remission.
- Patients want to avoid surgery and the need for a stoma.
- Patients want an improved quality of life. This means less frequent visits to the toilet and avoiding sudden urges. A reduced impact of their symptoms on work and social life is also essential.
- There is a need for more psychological support, also within the medical care pathway.



Pioneering for patients

We don't think it is good enough that countless people affected by fibrotic and inflammatory conditions are still living with debilitating symptoms. That is why we are determined to change this. We are relentlessly searching for medicines to tackle the progression of the disease itself. We are driven by thinking about the positive impact this could have, not only in changing the lives of those affected, but also on their families, friends and societies in general.

Discover more at [glpg.com](https://www.glp.com)

Galápagos
Pioneering for patients

Innovative Health Initiative (IHI)

In November 2021 the EU legislation creating the Innovative Health Initiative (IHI) a new European partnership for health under Horizon Europe, entered into force.

Among its objectives we can see: medical innovation, the role of science driving new avenues of research and development and the importance of cross-sectoral discoveries.



IHI is well placed to forge successful, cross-sectoral, collaborative projects with the pharmaceutical, medical technology, biotechnology, digital health, and vaccine industries on board as partners alongside the European Union and, most importantly, by working closely with patients, universities and the wider healthcare community. Therefore, IHI aims at supporting projects that will deliver meaningful results and have a real impact in areas of unmet need.

Some remaining IMI projects will still be implemented and while new opportunities are taking shape for patient organisations like EFCCA.

Being a second level organisation representing a disease area in evolution (from the clinical and research point of view) has meant that we have been approached by several groups of international partners (consortia) who have asked us to participate as full partners in research and trial projects relating to different aspects of IBD.

As described above, patient participation is a prerequisite for access to funding and, from our point of view, represents a formidable opportunity to enhance the knowledge and expertise of patients and patient associations and gain visibility within the international IBD community.

Therefore, in the last couple of months we have been involved in the design of four different international projects dealing with different topics of vital importance for IBD research: from the testing of innovative therapies to fibrosis in CD patients, from the study of biomarkers to empowering tools.

Each project has different deadlines and submission modalities, but we hope that they will be approved and that they will be an additional resource of knowledge and support for our community.

The Secretariat and the Board are working with dedication and passion and we hope to give you good news very soon.

Stay tuned!

Luisa Avedano, EFCCA CEO





LILLY FOR BETTER

The human race has always been curious, hopeful and resilient. Discovery is our purpose on this planet. It's our calling and the spirit that's defined Lilly since day one. After more than a century and nearly 100 medicines and countless innovations, we're still searching for the next great discovery that will make life better for people around the world.

Lilly

Educational webinar - biobetters

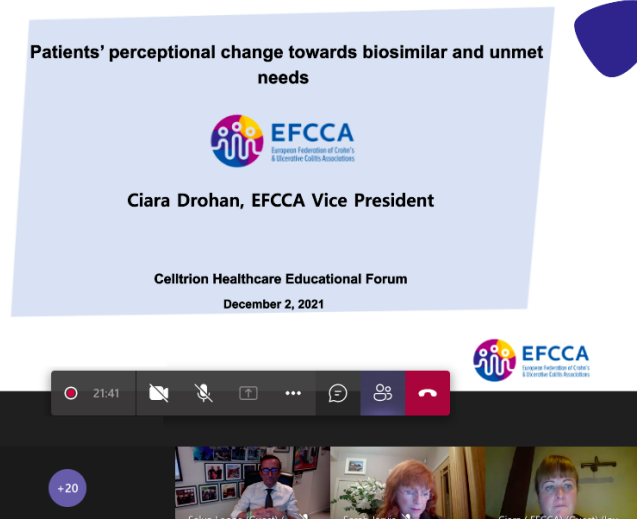
EFCCA participated in an educational forum “Biobetters: The future of biosimilars – post COVID-19” which took place online on 2 December 2022.

The objective of the forum was to understand the perspectives of patient representatives on key topics related to biological medicines, including treatment access and optimal care, and about changes in perception of biosimilars.

Our CEO Salvo Leone opened the forum and Vice President Ciara Drohan discussed the patients' perceptual change towards biosimilar and unmet needs over the past several years. Although biosimilars have been shown to be safe and effective - with more than a decade's worth of data to support their use - numerous hurdles to their adoption still remain.

This was followed by a presentation on the role of biosimilars and biobetters in which Prof. Laurent Peyrin- Biroulet gave an overview of the impacts and potential advantages of biosimilars and biobetters and how things will evolve with biobetters and their role in the future treatment landscape.

Finally, Dr. Philip Smith discussed how IBD during the COVID-19 pandemic has been a real challenge faced



by clinicians and patients and how biobetters could address unmet needs in existing biosimilars amid COVID-19, presenting a real world switching case. Many EFCCA member representatives participated at the event and contributed to a lively discussion following the presentations. The event was organised by the pharmaceutical company CELLTRION.

Informed consent in clinical trials: towards an electronic version? EFCCA participates in the debate

Patients who agree to participate in a clinical trial must give their written consent - free and voluntarily - after being duly informed. This concerns especially the following aspects:

- The purpose of the investigation
- The trial treatments and the probability of being assigned to one or another trial
- The procedures to follow and the existence of invasive tests

- The responsibilities of the participant
- Details of the experimental treatment
- Foreseeable risks
- Expected benefits; as well as
- Other available alternative treatments¹

Until now, this requirement, which is mandatory, has required the patient to travel to the center where the clinical trial is being carried out. Once there, the patient has a meeting with the researcher in order to read all the information on paper.

The researcher will resolve any doubts the patient may have before accepting to participate.

However, this procedure has been criticized for not fulfilling its purpose. In fact, for Sarah Wadmann, from the National Institute for Analysis and Research of Local and Regional Authorities in Denmark, “an increasing number of publications suggest that a considerable part of the research participants do not read or understand the information that is given to them, or they do not base their decisions about participating in the trial on the information provided”². Other authors also conclude that this procedure is outdated given the possibilities offered by new technologies, and even cite examples in which the electronic signature has been implemented to avoid unnecessary travel, as well as others in which graphics and videos have been used to explain the essential characteristics of the study and increase its understanding³. Although there is no consensus on how to scale it to the rest of the trials - despite the existence of certain initiatives that try to standardize it - this is producing uncertainty and delaying its use. Something that we believe, in times of pandemic, is playing against patients.

It is for this reason that KU Leuven invited EFCCA to participate last November in a series of focus groups that they are organizing to inform and find out the opinion of the different stakeholders on the creation of a European guidance framework related to the implementation of electronic informed consent in clinical research.

We decided to accept this invitation as we see it as an opportunity to express our perceptions of the different approaches being proposed by the EMA, the FDA and the pharmaceutical companies. Also, to discuss these important considerations:

- The legal doubts that arise from the exact interpretation of the current legislation. For example, when you state that the signature must be handwritten.
- The debate that prioritizes flexibility over patient protection should the researcher be present or not at the time of the remote signature?
- The importance of a European regulation that standardizes the process and is aligned with that of other regulators.
- The need for a standard that prevents the choice of one method over the others from altering both the participation and the competitiveness of the countries in recruitment.
- The inherent risk of digital platforms altering the experience of the process through the size of the font, the colors and even the intonation or the duration of the videos. And how these elements could bias the final opinion of the patient instead of informing him in a neutral way.

The study is not complete, but we will share the conclusions as soon as they are available. In the same way that we will continue working on this concept because of its relevance for Crohn's and ulcerative colitis patients.

Roberto Saldaña,
EFCCA Board



1. Good Clinical Practices Network. (n.d.). Informed Consent of Trial Subjects. www.ichgcp.net/publications/informed-consent-of-trial-subjects
2. Wadmann, S. (2016). Clinical trial informed consent information for participants can be improved. *Ugeskrift for Laeger*, 178(32).
3. Grady, C., Cummings, S. R., Rowbotham, M. C., McConnell, M. v., Ashley, E. A., & Kang, G. (2017). Informed Consent. *New England Journal of Medicine*, 376(9), 856–867. www.nejm.org/doi/10.1056/NEJMra1603773

New Zealand

Workshop for young adults with IBD

In July 2021, between Covid lockdowns, in New Zealand, we managed to hold our first ever seminar and workshop for young adults with IBD.

Some years ago, I attended two EFCCA Youth Group assemblies in Slovenia and Paris. Delegates shared how they run Youth Groups in their respective countries. On my return to New Zealand, I brought the idea of a workshop for young adults to the Board of CCNZ. The need for this was further cemented at Camp Purple Live, our camp for children and teens with IBD. We found that more and more of the young adult volunteer leaders were gaining just as much as the kids from sharing their experiences living with IBD. We also noted that the volunteers were asking the medical staff more questions about IBD than the campers.

Three years ago, we followed this up with a survey of New Zealand patients, asking them if they would be interested in attending an educational seminar for patients between 18 and 35 years of age. Over 90% of the young adults surveyed expressed an interest in attending a weekend event. In the survey we

got an idea what was needed, topics in which they were interested, and how we were going to pull it off well. Fast forward to the pandemic year 2020, and a venue was sourced in Wellington, our capital city, and preparations began. We gathered a small committee and we decided on a range of topics:

- IBD 101
- Fertility and pregnancy
- Navigating the healthcare system in New Zealand
- Diet and nutrition
- Travelling with IBD
- Mental health and IBD
- The IBD nurse's role
- Alternative medicines
- Employment Law and IBD

We also decided to have some panel discussions where patients could share their stories and experiences with the group.

- Stoma's
- Educating your partner about IBD

We secured funding towards the accommodation and venue costs, which dramatically reduced the registration fees. We were able to waive a few fees for those who were unable to afford to come. Thank you, Takeda, our sponsor for the event, for helping with this.

Friday 30th of July 2021 finally arrived, and although there was a looming lockdown in sight, we were able to proceed. We were welcomed by the Chair of CCNZ, Dr Richard Stein. Belinda Brown, our CEO, helped us get to know each other.



Saturday morning saw us jump into IBD 101 and finishing up the day at 3pm with IBD and mental health. Finishing up on such a deep topic, we broke away for some free time. It was awesome to see friendships starting. Some groups went to visit our capitals museum, Te Papa, others went exploring in Wellington City, and some just went to have a rest in their rooms to prepare for our dinner and guest speaker.

Just after dinner we had a guest speaker, the parent of an IBD patient, a local radio personality, active rugby referee and a local district councillor, Brent Gare. Brent spoke to the attendees about how they are the authors of their own story. Some groups then went out for a dance in the city and some met in small groups, talking and sharing stories in the hotel lobby.

Everyone turned up on time on Sunday morning, some brighter than others, and we were back with the second half of IBD 101. The day finished with a talk about employment law and IBD.

Feedback is always a great judge of how the event went. With over 90% of participants wanting to attend again, this was a very satisfying outcome of our first IBD seminar. Our committee will be meeting in the new year to decide on dates and a venue for 2022. Make sure you follow CCNZ's Facebook and Instagram accounts to keep up to date.



Instagram: @crohns_and_colitis_new_zealand

Facebook:

www.facebook.com/crohnscolitisnewzealand

Dana Smith,
CCNZ Trustee and Registered Nurse
Living with IBD - seminar & workshop

Germany

Hooray: Our Crohn's & Colitis Organisation DCCV will turn 40 this year!

The German Crohns & Colitis organisation "Deutsche Morbus Crohn/Colitis ulcerosa Vereinigung (DCCV) e.V. Will celebrate its fortieth birthday in autumn of 2022.

In 1982 a handful of people with IBD thought that it was important to advocate for the interests of patients with these diseases and to support each other and

other people with IBD in general. On a kitchen table in the south of Germany the DCCV was then finally born in September 1982.

Over the years DCCV has grown and is active in various areas and functions within the German health care system. In our activities we are always keeping the focus on the pillars that are essential for the work of any patient organisation: people with IBD support people with IBD.

Over the years the patient organisation has become more and more professional. Right now, we have more than 80 volunteers from all over Germany and 13 full-time employees in the main office in Berlin.

To celebrate our birthday, the DCCV will start a media campaign in spring to raise awareness about these diseases and show the concerns of people with IBD.

In October 2022 the highlight of this anniversary year will be a great birthday party. We keep you posted and let yourself be surprised!

Marika Vetter,
DCCV

The Netherlands

IBD presentation package for schoolchildren

This January 11-year-old Annabel gave a presentation to her classmates about her illness - ulcerative colitis. She did this with the help of the presentation package that Crohn & Colitis NL developed for schoolchildren aged 8-12 years.

Children regularly approach us asking for information and images they can use for their school presentation or paper. Often the children themselves have Crohn's disease or ulcerative colitis or their brother, sister, parent or grandparent. We warmly encourage children to tell their peers about life with a chronic illness and are therefore happy to help them.

The sooner other children know what IBD is and what its effects can be, the better. Also, it will allow them to gain more understanding of the impact chronic bowel disease has on a person's life.

Free package

To make it easier for children, we have put together a free package that they can request from us. It is made in such a way that it fits exactly through the letterbox. Children can also download everything from our website. As well as other useful images and illustrations.

The package consists of the following:

- A card with an explanation of the contents of the package.
- Crohniek Kids: a special magazine for kids up to 12 years old, with everything you need to know about Crohn's and ulcerative colitis and with experiences of 6 kids with IBD.
- Open your eyes cards (kids edition): a tin with three types of cards that kids can use to start the conversation with each other. Think of questions like: "Do you understand why I am sometimes too tired to meet up?" But also facts and myths about IBD, for example: Only during a flare up do you suffer from your disease. Myth.
- A set of cards to hand out to classmates: on these, classmates can write their questions or a nice message for the child giving the presentation.
- A poster with the workings of the bowels.

Good idea for other children

In our Crohniek magazine, which will appear in March, Annabel talks about her experiences with the package. We were there when she held her presentation and also took photos and made a vlog. These will be available on our website and via social media. We hope that many more children will request our package when they read or see how Annabel used it.

Curious to see all the materials? Go to:
www.crohn-colitis.nl/leven-met/kinderen-en-de-ziekte-van-crohn-of-colitis-ulcerosa/spreekbeurtpakket



Italy

Let's talk about Pouch - 40 years later

The latest Italian National Pouch Conference took place in Bologna last November 2021. Our IBD patient association AMICI Onlus organized the conference together with Ig-IBD (the IBD Medical Association), and Fais Onlus (the Italian Association for Incontinence and Pouch People).

The Conference celebrated its 40th anniversary of the proctocolectomy procedure with ileal pouch (IPAA). This innovative surgical technique has changed the lives of patients who were otherwise resigned to a definitive stoma.

One of the highlights of the event was the announcement by Senator Alessandra Gallone that the Italian Government has proposed 5 million Euros for IBD patients for 2022. This represents a big milestone for Italian IBD patients.

Other speakers present were Giovanni Molari, chancellor of the University of Bologna, and Matteo Lepore, Mayor of Bologna. Mr. Molari commented that *"the Bologna surgical medical school has made and continues to make important scientific contributions"* while Mr. Lepore added that *"Bologna has the ambition to be a city that takes care of its people as well as being a city of knowledge, therefore the close relationship with its University plays an important role in this"*.

Giuseppe Coppolino, president of AMICI Onlus remarked that *"science, research and surgery have made huge achievements in patients' life"* and that *"it was important to continue building trust between the patient community and the scientific world, such as this conference"*.

A revolutionary technique

Several specialists in the field presented updates in the developments of their research. Presenters at the Conference included names such as André D'Hoore, MD from the UZ Leuven Academic Hospital, Prof. Paolo Lionetti from Meyer University Hospital of Florence, Prof. Jerome Mattioli from the Gaslini Institute University of Genoa, Dr. Fernando Rizzello and Dr. Paolo Gionchetti from the University of Bologna.

The importance of specialized centers

Academic literature shows that in ultra-specialized contexts there is a lower incidence of complications and a higher percentage of success. It is therefore recommended that the IPAA procedure must be performed in specialized centers with specific expertise, defined as a minimum of 20 of these procedures performed at a center each year.

In Sant'Orsola Hospital about 1500 interventions of ileo-anus anastomosis were carried out over these forty years. These numbers made Sant'Orsola Hospital the top center in Italy for ileostomy operations, the second European center and one of the first five centers in the world.

A success story

An excellence that was not born by chance: this IBD center was founded in the '60s with the commitment of professors Gaetano Placitelli, Giuseppe Labò and Massimo Campieri, and also nowadays Prof. Gilberto Poggioli from the University of Bologna.

We all have great expectations for the future with new techniques such as the laparoscopic modality that allows almost scar-free surgery.

Cristiano Consorte,
AMICI Onlus, Italy



GUIDANCE TO BETTER LIFE

*We are a pioneer in the biopharmaceutical space in pursuit of a better life.
We help people around the world by expanding access to innovative and high-quality biologics.*

Celltrion Healthcare is committed to delivering innovative medications to promote patients' access to advanced therapies. Our products include the world's first antibody biosimilar, the world's first subcutaneous formulation of infliximab, the first high-concentration adalimumab biosimilar and a monoclonal antibody treatment for COVID-19. Celltrion Healthcare endeavours to offer high-quality cost-effective solutions through an extensive global network that spans more than 110 different countries. To learn more visit: www.celltrionhealthcare.com

Brazil

Traveling with IBD

We would like to share a story prepared for our members by Paulinha de Paula, a former Flight Attendant, Tourism Specialist and member of the Communication Committee of DII BRASIL.

Traveling with IBD - Crohn's disease or Ulcerative Colitis is possible indeed! But we must be aware of several important details that are valid for any destination, national or international and know what our support points are in each location.

Before traveling, the first step is to make an appointment with your doctor. Ask for:

- Complete Report of your disease including the medication used in your treatment;
- Prescriptions for all medications used in your treatment;
- If the trip is international, reports and prescriptions must be in English or Spanish, depending on your destination.

On trips within the national territory, you only need the Complete Report. We never know when we will have a crisis and, if this occurs, the emergency doctor will need all the necessary information to provide the correct assistance.

To travel with immunobiological medication (refrigerated conservation), the required documentation is the same as quoted above. You should also take a thermal bag and a freeze plate to keep it cooled. Check the duration of each plate and take the necessary amounts. Two very important things to consider:

- Health rules in all countries do not allow aircraft crews to refrigerate your medication on ice. Therefore, carry empty plastic bags and, if necessary, ask the flight attendants for ice.
- Dry ice is considered dangerous cargo on planes, and its transport is prohibited.



All your medication should go in your hand luggage! In some cases, you might have a lot of pills. If you take these in your checked luggage, it can be opened by the airport inspection and can be considered smuggling or trafficking.

Before you are off on your trip, save on your phone the numbers of the following organisations below. They are of patient associations in Europe and Latin America. United in networks, these alliances support patients in many countries and are extremely important to us Crohn's and Colitis patients. They are always our support network, a helping hand wherever we are.

BRAZIL: diibrasil.org.br
 EFCCA: efcca.org/en/members
 ARGENTINA: masvida.org.ar



WE'RE ON A QUEST TO HEAL

Discovering a new way forward in IBD treatment

Roche GastroImmunology is exploring unique molecules to redefine outcomes for patients who need it most. To us, altering the course of IBD is more than a goal – it's our mission.



GastroImmunology™

UK

Are You IN?

In 2021, Crohn's & Colitis UK launched the next stage of their Not Every Disability is Visible campaign - Are You IN? This campaign began in 2016, challenging public perceptions of disability and calling on venues to install Not Every Disability Is Visible accessible toilet signs, empowering people with invisible conditions such as Crohn's and Colitis to use accessible toilets in public without being challenged.

This time, the campaign was focused on increasing understanding and support of invisible conditions such as Crohn's and Colitis in the workplace.

An estimated 9.5 million people across the UK live with an invisible condition, that's around 1 in 7 people. This means many are managing a medical condition alongside their jobs, in workplaces which do not always take this into account. Are You IN? provides support and resources for workplaces so they can pledge their commitment to being more inclusive of people with invisible conditions.

For people living with an invisible disability, the hidden nature of their condition can make it difficult to disclose, as the effects it has on their life are not immediately apparent or easy to understand. This can lead to employees feeling like they cannot ask for adjustments to help them manage their condition.

For people living with Crohn's and Colitis, the stigma surrounding discussion of bowel habits can make it doubly hard to disclose their disability to an employer. It should not be down to 'luck' or 'a good manager' that people living with invisible disabilities and conditions in the workplace are acknowledged, understood and supported.



As the future of the office is reconsidered post-COVID, the Are You IN? campaign has come at the perfect time to support employers and their staff in building a more inclusive workplace for people living with Crohn's and Colitis, and many other invisible conditions.

As part of the Are You IN? programme, employers gain access to a free suite of assets to help workplaces roll-out the campaign, including training resources, an invisible disability badge of excellence and digital assets.

55 companies, from a range of sectors have already signed up, pledging to support their employees and increase understanding of invisible conditions in their workplaces. Plus, nearly 400 companies have expressed an interest in finding out more. Pledges include offering flexible and remote working, rolling out our invisible condition resources to all staff, and appointing an invisible condition representative.

Max lives with Crohn's and works in the medical manufacturing industry. Max's workplace has signed up to Are You IN? meaning they have been able to understand and support Max by making reasonable adjustments and allowing him to work from home.

"Working from home has been fantastic for me. I don't need to worry about using the bathroom, I can rest if I need to, I'm eating and sleeping better, and I'm less stressed without a long commute. I've also found that I'm more productive working from home, which has led to greater job satisfaction. All of these factors make it so much easier to manage my condition, and I'm lucky that my employer is committed to workplace flexibility going forwards."

It's not just employees who benefit from increased workplace inclusivity. Max's manager has seen the benefit of creating a workplace that supports people who are managing an invisible condition alongside work. *"Max's Crohn's experience has given him a number of critical skills that are impossible to teach: strength, resilience, optimism, perspective & calmness in stressful situations. By understanding, accepting and working together with Max, we have minimised the difficulties caused by Crohn's and unlocked the massive potential that comes with it. He brings a great sense of enthusiasm and perspective to our team."*

In 2022, Crohn's & Colitis UK are continuing to work with companies to get them signed up to Are You IN? to better support their employees with invisible conditions such as Crohn's and Colitis.

You can find out more here:

www.noteverydisabilityisvisible.org.uk



France

MICI Sans Filtre (IBD without filters)

At the end of 2021, Afa Crohn RCH France launched the “MICI Sans Filtre” communication campaign with the Janssen France laboratory. Based on the results of the “Regards Croisés” survey (carried out by the Afa and IPSOS in 2020), this campaign highlights 8 themes of life with Crohn’s disease or colitis: symptoms, diet, physical activity, psychological aspect, emotional life, work, isolation, but also relationships with loved ones, in short...all aspects of IBD that are obstacles to the daily life of patients!

To embody these themes, 8 patients and their relatives posed under the watchful eye of the famous photographer David Ken, known for his LOL Project.

Hervé, Cécile, Patricia, Hélène, Charlotte, Bastien, Frédéric and Dorothee share their “unfiltered” experiences of these invisible diseases that have a strong impact on their daily lives. But above all, they show, through their energy and optimism, that with the right support, people can live as normal as possible and even excel despite their disease.

This communication campaign is aimed at patients and their relatives: they are not alone and can count on AFA to help them live better on a daily basis through its many services. The campaign also raises awareness among the general public about these invisible disabilities and the need to break the taboo.

Pour 47%
des patients atteints de MICI, l'alimentation représente une contrainte importante

Et pourtant...
Bastien continue à se faire plaisir.

POUR LES PATIENTS ATTEINTS DE MALADIE DE CROHN OU DE RECTOCOLITE HÉMORRAGIQUE, IL EST PRÉCONISÉ DE MAINTENIR UNE ALIMENTATION ÉQUILIBRÉE ET DIVERSIFIÉE.

PARLEZ-EN AUTOUR DE VOUS, DES SOLUTIONS EXISTENT POUR MIEUX VIVRE AVEC UNE MICI.

Enquête IPSOS réalisée en regards croisés auprès de 3 435 Français (2 582 personnes atteintes de MICI et 853 proches d'une personne atteinte de MICI) de 16 à 75 ans, du 14 octobre au 23 novembre 2020, dans chacune des 12 régions métropolitaines et de 118 professionnels de santé (gastroentérologues), ayant dans leur patientèle des patients atteints d'une MICI, du 14 octobre 2020 au 3 janvier 2021.

afa janssen MICI Sans Filtre

61%
des patients atteints de MICI estiment que personne ne peut comprendre ce qu'ils vivent

Et pourtant...
Charlotte n'a pas renoncé au plaisir de voir ses amis.

LA MALADIE DE CROHN ET LA RECTOCOLITE HÉMORRAGIQUE ISOLENT LES PATIENTS.

PARLEZ-EN AUTOUR DE VOUS, DES SOLUTIONS EXISTENT POUR MIEUX VIVRE AVEC UNE MICI.

Enquête IPSOS réalisée en regards croisés auprès de 3 435 Français (2 582 personnes atteintes de MICI et 853 proches d'une personne atteinte de MICI) de 16 à 75 ans, du 14 octobre au 23 novembre 2020, dans chacune des 12 régions métropolitaines et de 118 professionnels de santé (gastroentérologues), ayant dans leur patientèle des patients atteints d'une MICI, du 14 octobre 2020 au 3 janvier 2021.

afa janssen MICI Sans Filtre



This campaign is available on social networks and has been well received by the press. Le Monde, an important daily newspaper in France, even published a full page about IBD with photos of the campaign.

Go to the campaign's website:
www.micisansfiltre.fr

Eve Saumier,
Afa Crohn RCH France

Cyprus

A dream came true... Just because you can't see it, doesn't mean that it is not there!

A dream in mind since November 2019, started to take shape on December 3, 2021, which is the International Day of Persons with Disabilities. At the initiative of the Cyprus Crohn's and Ulcerative Colitis Association (CYCCA) our President Mrs Natasa Theodosiou approached Mrs Thekla Georgiou PRM & Customer Care Officer proposing and explaining to her the project with the "Sunflower Lanyard" (Sunflower Lanyard is a green ribbon around the neck with sunflowers printed, as shown in the photo) which is being used in airports worldwide.



Since 3 December 2021 it is also available at the airports of Cyprus at Hermes Airports in Larnaca and Paphos! The “Sunflower Lanyard” service will provide assistance to people suffering from an INVISIBLE DISABILITY. It is an opportunity not to forget that not all disabilities are Visible. Our travels from now on, from Cyprus with the help of trained airport staff, may be made easier with the facilities that the sunflower ribbon can offer us.

What do you know about Crohn's disease and Ulcerative Colitis?

During 2021 we had 5 different, very successful on-line activities with our patients, in an effort to respond to their concerns regarding Covid-19 and IBD, dietology, psychology, etc. However, we always wanted to organize also a live conference so that the patients could come into direct contact with the doctors and ask all their questions face to face.

November was a good month for such activities, so we acquired permission and arranged a suitable venue for the meeting. Needless to say, all the measures regarding the pandemic were applied.



NOT EVERY DISABILITY IS VISIBLE, SOME ARE JUST NOT OBVIOUS

People choose to wear the Sunflower to discreetly indicate that they have an invisible disability and may need help, assistance or simply more time.

1. Ask if you can help
2. Be kind
3. Listen closely
4. Have patience
5. Do not judge
6. Show respect



I have accessibility needs

Εχω θέμα κινητικότητας

Please ask me what I need

Ρωτώ αν χρειάζεται βοήθεια από την υπηρεσία

PRM ή τι βοήθεια χρειάζεται από εμάς



I need more time

Χρειάζομαι περισσότερο χρόνο

Please be patient and keep calm. I may need more time to complete an action or to communicate with you

Είμαι υπομονετικός και παρομένω ήρεμος

ρωτώντας αν χρειάζεται βοήθεια στη διαδικασία



I need a place to sit and rest

Χρειάζομαι να καθίσω κάπου να ξεκουραστώ

I may need a place to sit down and rest

Προσφέρω κάθισμα στις πλησιέστερες θέσεις

προτεραιότητας



I may need urgent access to the closest toilet facility

Ζητώ να έχω άμεση πρόσβαση σε τουαλέτα

Please guide me to the closest toilet without questioning

Καθοδηγώ ή δίνω οδηγίες για την πλησιέστερη

τουαλέτα με διακριτικότητα και σεβασμό



Please give me space. I need your help to keep social distancing

Χρειάζομαι βοήθεια για να κρατήσω απόσταση

Please assist in having distance from other passengers or staff

Βοηθή να κρατήσω απόσταση από άλλους

επιβάτες και προσωπικό



Do not touch me. Physical touch can cause distress and pain

Μην με αγγίζετε. Η φυσική επαφή μου προκαλεί

άγχος και πόνο

I do not touch the customer

Δεν ακουμπώ τον επιβάτη



I have sight loss or limited vision and may find access to visual info or judging distance

Εχω περιορισμένη όραση και είναι δύσκολο να

διακρίνω γραμμάτια ή να υπολογίσω αποστάσεις

I guide the customer and assist with viewing

Καθοδηγώ ανάλογα με τι θέλει να δει ο επιβάτης και

τι βοήθεια χρειάζεται



I require large prints

Χρειάζομαι μεγάλα γράμματα

I guide the customer and assist with viewing

Καθοδηγώ ανάλογα με τι θέλει να δει ο επιβάτης και

τι βοήθεια χρειάζεται



I have a hearing impairment

Εχω ακουστική αναπηρία

I face the customer, speak clearly, and don't shout. If necessary, I write the message

Μιλώ καθαρά βλέποντας τον επιβάτη χωρίς να

φωνάζω. Αν χρειαστεί γράφω μήνυμα



I use sign language

Επικοινωνώ με νοηματική γλώσσα

I face the customer, speak clearly, and don't shout. If necessary, I write the message

Μιλώ καθαρά βλέποντας τον επιβάτη χωρίς να

φωνάζω. Αν χρειαστεί γράφω μήνυμα



I have food allergy

Εχω αλλεργία σε φαγητό

I inform the customer of the food ingredients

Λέω στον επιβάτη τα συστατικά του φαγητού που

παράγει ο επιβάτης. Φροντίζω να μην

χρησιμοποιηθούν στην προετοιμασία του φαγητού



I have a hidden disability

Εχω κρυφή αναπηρία

I approach and ask discreetly how I may assist

Προσεγγίζω και ρωτώ διακριτικά πώς μπορώ να

βοηθήσω



The speakers included two gastroenterologists and one clinical dietitian. The doctors spoke about the connection between IBD symptoms and the use of immunosuppressive and biological medicines, the vaccination of IBD patients and other relative medicines. We were very successful as we managed to attract the maximum number of attendees, (60, given the size of the hall and in compliance with the regulations), all of whom left very happy with what they saw and heard.

This event confirmed to us at CYCCA, the importance of live gatherings, especially after a two-year long absence of such meetings, and our reliance in the meantime, as everywhere, on virtual presentations.

Natasa Theodosiou,
CYCCA President



Poland

Revolution in biological treatments for Poland

After appeals from the Polish Association Supporting People with IBD “J-elita” together with other patient organisations and the medical community, the Polish Ministry of Health changed its adverse regulations on biological treatment from 1 January 2022.

In Poland, biological drugs for patients with inflammatory bowel disease are available in drug programs. They are given when standard therapy does not work, and it is necessary to intensify the treatment. Until now, drug programs have had their limitations. The duration of participation in the program for patients with ulcerative colitis was one year, and for patients with Crohn’s disease one or two years. After the expiry of this period, patients could not continue the reimbursed biological treatment. The regulations allowed them to be re-enrolled in the program and administer the drug only when there was a recurrence of the disease and severe worsening of its symptoms.

For patients, the discontinuation of effective therapy was often associated with personal drama. The fight for a change in the regulations lasted a long time, and “J-elita” Association had allies in the form of the most famous gastroenterologists in Poland.

They pointed out that discontinuation of biological treatment and re-enrolling patients in the drug program may lead to a decrease in the effectiveness of therapy, deterioration of patients’ health and the need for surgical procedures. A coalition of four patient organisations was also formed, which petitioned the authorities.

Our appeal was supported by the Patient Ombudsman. In the summer, the Minister of Health, key officials and journalists received an album with photos and stories of people with IBD (also from “J-elita” Association) describing their experiences with biological treatment and many articles on this issue involving people with IBD were published in the Polish media. Our actions were effective!

The changes to the drug programs were announced by the Ministry of Health in December. From January 1, 2022 there are no longer restrictions on the duration of biological therapy. How long a patient can take the medicine is decided by the doctor, not the regulations.

This is a real revolution for Polish IBD patients who no longer have to worry about what will happen to them after stopping a biological treatment.

“This is great news that we received as a gift for Christmas. However, this is not the end of our fight, because biological treatment is available only to the most seriously ill and, unfortunately, this also applies to children. In Poland, it is not the doctor who decides on enrolling in the program, but the points obtained in the scales for assessing the activity of the disease in the event of ineffectiveness of the standard treatment” comments the President of the Board of the “J-elita” Association.

“J-elita” Association

Romania

Attitude, Solidarity, Perseverance, Involvement, Innovation, Responsibility

On 15 December last year our association ASPIIR celebrated its 10 year's anniversary of projects and involvement for patients with Inflammatory Bowel Diseases (IBD) in Romania.

We organised this on-line event together with the Romanian Society of Gastroenterology and Hepatology (SRGH) and the Romanian Club for Crohn's Disease and Ulcerative Colitis (RCCC) which was attended by doctors, patients, government officials and representatives of other associations at European level.

With over 63 forums and webinars for patients organised between 2018-2021 impacting around 13,000 - 20,000 people, 2 projects funded by the European Commission, 7 centers dedicated to IBD patients and inaugurated in partnership with medical societies and hospitals and over 10 European projects ASPIIR is the only association in Romania

that aims to increase the quality of life of patients with inflammatory bowel disease and stomatitis through Attitude, Solidarity, Perseverance, Involvement, Innovation, Responsibility.



“10 years ago a small group of patients and doctors understood that patients with Inflammatory Bowel Disease needed a community dedicated to them and founded ASPIIR. An increase in the number of patients diagnosed with Crohn’s Disease and Ulcerative Colitis, too little information about IBD at that time in Romania, the appearance of complicated forms and the lack of a support for these patients were convincing reasons for more than 10 years to aspire to what ASPIIR is today” said Isabella Grosu, President of ASPIIR during the event.

“These have not always been easy years, and the last two years of the pandemic have been very difficult. It has shown us that we are not on either side of the table, but that we are doctors and patients together, that we need to work together to further the progress of patients and of doctors”, added Prof. Dr. Lucian Negreanu, president of the Romanian Club for Crohn’s Disease and Ulcerative Colitis.

Prof. Dr. Mircea Diculescu, head of the Gastroenterology Clinic, Fundeni Clinical Institute, Bucharest invited stakeholders *“to look to the future and see what we can do next with ASPIIR: the important thing is the commissioning of the National*

Register for IBD, the further development of IBD care centers not just in number, but also by moving to the next level as centers of excellence. The third important direction is the development of national programs, because IBD patients need a complex set of treatments and doctors who understand this.”

In her closing remarks Isabella Grosu stressed that ASPIIR aims to remain the voice of IBD patients and to continue the strong relationship with medical societies in order to improve the standards of care.

The online event “10 Years of Partnership and Involvement for Patients with Inflammatory Bowel Disease” was conducted with the support of Pfizer, Takeda, Janssen.

ASPIIR 10^{ani}

Parteneri: 

srgh

Cu sprijinul:

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**10 ani de parteneriat și
implicare pentru
pacienții cu Boli
Inflamatorii Intestinale**

LIVE

**15 decembrie 2021
ora 14.00**



Accelerating Clinical Trials in the EU (ACT EU): for better clinical trials that address patients' needs

In January this year, the European Commission (EC), the [Heads of Medicines Agencies](#) (HMA) and the European Medicines Agency (EMA) have launched an initiative to transform how clinical trials are initiated, designed and run, referred to as Accelerating Clinical Trials in the EU (ACT EU). The aim is to further develop the EU as a focal point for clinical research, further promote the development of high quality, safe and effective medicines, and to better integrate clinical research in the European health system.

Building on the application of the Clinical Trials Regulation and the launch of the Clinical Trials Information System (CTIS) on 31 January 2022, ACT EU will strengthen the European environment for clinical trials, whilst maintaining the high-level of protection of trial participants, data robustness and transparency that EU citizens expect.

The ACT EU strategy paper lists ten priority actions for 2022/2023, including enabling innovative trial methods, establishing a multi-stakeholder platform, and supporting the modernisation of [good clinical practice](#). Together, they will contribute to achieving the ambitious goals for innovation in clinical trials set out in the [European medicines agencies network strategy](#) (EMANS) to 2025 and the [European Commission's Pharmaceutical Strategy](#). ACT EU will be co-led by the European Commission, EMA and the HMA, who have also collaboratively developed the initiative.

The proposal to establish ACT EU was endorsed by HMA in November and by EMA's Management Board in December 2021. Further information will be made available on EMA and HMA webpages.

EU4Health work programme adopted to invest over €835 million in health

The European Commission has adopted the second EU4Health work programme. In 2022, the EU4Health will continue to invest in building stronger, more resilient health systems and pave the way for the European Health Union. With a budget of over €835 million, the new work programme will provide an unparalleled level of EU investment in health and ensure ambitious and decisive action in four focus areas: crisis preparedness, disease prevention, health systems and healthcare workforce, and digitalisation.

The EU4Health Programme supports building a European Health Union including the fight against COVID-19

pandemic, Europe's Beating Cancer Plan, and the Pharmaceutical Strategy for Europe, and the European Health Emergency Preparedness and Response Authority ('HERA'). The programme will provide funding to eligible entities from Member States, associated third countries, international organisations, NGOs and the private sector in the form of grants or procurement of specific services. NGOs will be able to apply through an open call for operating grants, as well as for action grants on various topics. The European Commission and the Health and Digital Executive Agency (HaDEA) will manage the programme.



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Joint Statement on Patient Safety Action Plan



On Patient Solidarity Day, the International Alliance of Patients' Organizations (IAPO), the International Pharmaceutical Federation (FIP), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), International Hospital Federation (IHF) and the International Council of Nurses (ICN), joined patients and families all over the world, in calling for governments and all health stakeholders to collaborate in the implementation of the WHO Flagship Global Patient Safety Action Plan 2021-2030 (GPSAP 2021-30) that was adopted at the 74th World Health Assembly in 2021. Every year, large numbers of patients are harmed or die because of unsafe health care, creating a high burden of death and disability worldwide, especially in low- and middle-income countries.

On average, an estimated one in 10 patients is subject to an adverse event while receiving hospital care in high-income countries. Available evidence suggests that 134 million adverse events due to unsafe care occur in

hospitals in low- and middle-income countries, contributing to around 2.6 million deaths every year. According to recent estimates, the social cost of patient harm can be valued at US\$ 1 trillion to 2 trillion a year. Patient safety is fundamental to the provision of health care in all settings. However, avoidable adverse events, errors and risks associated with health care remain major challenges for patient safety globally.

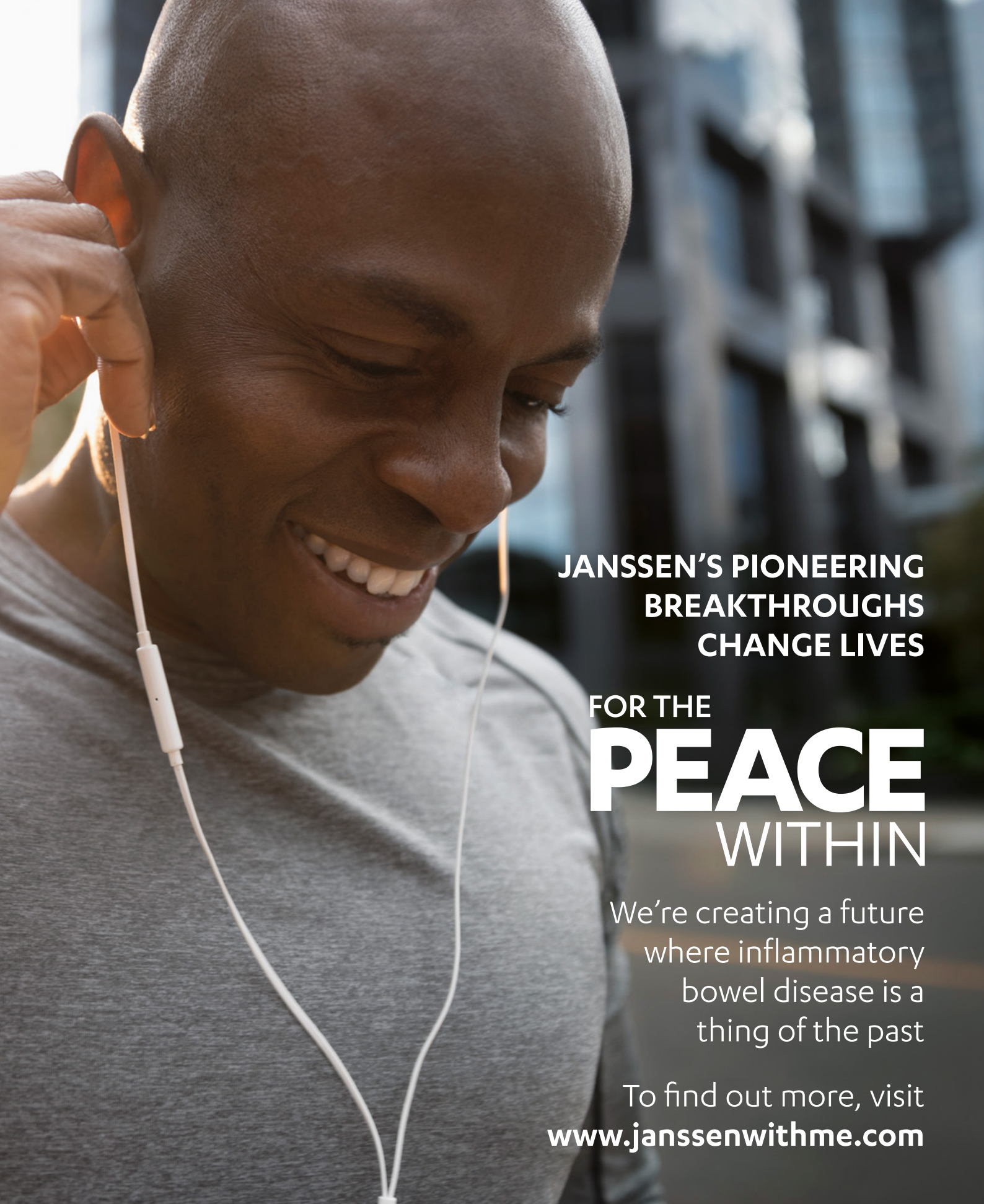
The global COVID-19 pandemic has highlighted the importance of building a culture of trust in healthcare systems, health professionals and medical products. Trust can be undermined by products and interventions that do not adhere to the highest standards of quality and ethical standards.

The joint statement therefore calls on all governments and health stakeholders to deploy patient safety as a health priority in health sector policies and programmes to achieve universal health coverage; and for all health stakeholders to uphold the guiding principles of GPSAP 2021-30, by working to:

- Implement Policies to eliminate avoidable harm in health;
- Foster high-reliability systems;
- Ensure safety of clinical processes;
- Maintain patient and family engagement;
- Secure continuous health worker education, skills and safety.

Representing key actors in health systems, the organization who signed the statement reaffirm their commitment to provide the highest quality health care and health products to patients and to work towards the GPSAP 2021-30 vision of "a world in which no one is harmed in health care, and every patient receives safe and respectful care, every time, everywhere".

Read more **about IAPO**: [Towards eliminating avoidable harm in health care](#)



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Something to say!

By Áine King

In December 2020, playwright Áine King won a commission from Birds of Paradise Theatre Company, to write a brand new radio play as part of the series, *Something to Say*. Áine's script "Bronagh and the Bum Goblin" follows the fraught journey of Bronagh, a mother with IBD, as she rushes to get to her son's school concert on time, taunted all the way by her inner projection of the disease - her Bum Goblin. In this article Áine (who also has IBD) explains her motivations behind writing a comic play about the condition.

There is nothing funny about Inflammatory Bowel Disease (IBD). Ulcerative Colitis and Chron's Disease are painful, frightening, humiliating, exhausting and often life-altering illnesses. They are also incurable and coming to terms with the Forever aspect of chronic illness is no fun at all.

The list of things Ulcerative Colitis has taken from me in fifteen years is long. The career I loved as a theatre director and teacher is on it, along with travelling, performing and most of my self-confidence. And time, so much of my precious irretrievable time has been diverted from my own life and my children into learning about my illness, learning to cope with it and learning how to hide it from other people. None of that's funny. So why on earth would I write a comedy radio play about it? That's a fair question.

Almost every person I have ever met with IBD has at least one funny story to tell about their struggle to live with it. And to hide it. Online support groups and Social Media pages are full of hilarious, heart-breaking "You won't believe where I pooped" stories, usually trailing a thread of "I can top that" comments. Job interviews... weddings... business presentations... family gatherings... lectures... long haul flights... dinner dates... music festivals. There can be few public situations where a person suffering with IBD has not felt the tell-tale rumble in their gut, checked and re-checked the distance to the door, seen the length of the queue for the loo and made a desperate, rapid, cheek-clenched, shuffling dash in search of "somewhere to go".



Perhaps one of the nastiest side-effects of IBD is what it does to our self-confidence and how it robs so many people of the freedom to enjoy simple things that most fit and healthy folks take for granted. When I wrote the play, I really wanted to emphasise how difficult 'simple' things can be. Bronagh is simply trying to catch a bus to get to her child's school concert, but because she has IBD, it's not simple at all.

Some of the craziest, funniest and most ridiculous stories and anecdotes I've heard always seem to be about people's desperate attempts to hide their condition, and to keep pretending nothing is wrong, even when things are very bad indeed. People are endlessly creative about solving their IBD problems, but some people would rather poo in their own laptop bag or out of a fourth-floor window than tell their colleagues about their illness?

The bottom line (see what I did there) is that we are really pants when it comes to talking about our bottoms, perhaps because so many 'rude' words get involved. It was this inability to talk frankly about bums, and the determination to hide the illness and appear normal at all costs that I wanted to put at the heart of the play.

It's a comedy. I wanted folks with IBD to laugh at it, especially when they recognise themselves in any of Bronagh's dilemmas. People without IBD can laugh too, of course, but hopefully they'll also get an idea of how difficult daily life can be for those of us with it.

The play opens with Bronagh running as fast as she can in search of a toilet. As she sprints through a bus station, knocking toddlers, pensioners and poodles out of her way we also hear the Bum Goblin providing a sarcastic commentary. As the play goes on we learn that Bronagh invented the Bum Goblin as an imaginary character to make it easier and less scary for her young son to understand the disease. As the years have passed the Bum Goblin has become a cruel, nagging voice in Bronagh's thoughts, relentlessly criticising and undermining her.

I think a lot of people will be able to identify with how Bronagh has invented an inner-voice that is always shaming and blaming her. Personifying the illness and giving it a voice in the play is a good way of illustrating how relentless and spiteful it can feel. Bronagh's "goblin" has become the voice of her own anxiety, guilt and frustration. Life would be so much better if our inner-voices were Life-Coaches boosting our confidence and praising our achievements, but few of us are wired that way. When I was first diagnosed I read everything I could find about IBD, including several warnings about feelings of guilt and low self-esteem. I thought 'I'm too smart for that', but of course I wasn't.



Áine King is a dramatist, director and designer. An Irish East-End-er, she studied at St Martin's School of Art, Brighton, Sussex and Royal Academy of Dramatic Arts, London. Áine was Associate Director for Otherplace Productions, Brighton from 2008 - 2013, and is now based in the Orkney Isles, Scotland.

Toilets have a major role in the play because when you have IBD - especially when you are coping with a flare-up - you plan and map your life from toilet to toilet. If you ever need to know where the loos are in any town, shopping mall or tourist attraction ask someone who's potty-training a toddler - or someone with IBD. We know where every toilet is, which ones are "patrons only", which ones need 20p or even 50p to get in and which ones to avoid unless desperate. We've seen the good, the bad and the downright ugly. At the start of the play Bronagh finds herself in the grotty bus station loos.

The goblin berates her for not making it to a local hotel with posh toilets. Writing this, I was remembering a day in New York which began with a loo-stop in a Park Avenue 'lobby bathroom' with warm lemon-scented towels and marble tiles, looked after by a very kind doorman, but ended in the loo at McDonalds on Broadway which was unbelievably awful, with every kind of human filth including used needles, but no light or lock.

Bronagh also has the problem of being a disabled person who 'doesn't look disabled' using the disabled toilet. I thought it was really important to include this in the play. I think a lot of people will have had similar experiences, with folks who don't understand that not all disabilities involve wheelchairs.

One of the joys of writing audio drama is that clever sound designers and tech folks add so much to it and help the audience to 'see' things in their imaginations. The sound design team did a great job creating Bronagh's environment and also her pain. Those of us with IBD know what gut-spasms feel like but deciding what a spasm sounds like was tricky. In the end I think I said, "Tie a knot in a wet rubber glove."

The SFX team created a huge range of horribly convincing pooing noises, and made the various loos sound cold and clammy, with lots of echoing drips and plops and splashes. My favourite scene, though, is the bus.

Like Bronagh, I hardly ever ride on buses. There are no toilets on buses, and there can be lots of people between you and the door. This scene is based on my memories of bus rides when I lived in Brighton. The bus would be packed with pushchairs and toddlers, dogs on leads, and elderly folks with sticks and folks with piles of shopping bags and art students with canvases and kids with skateboards and buskers with guitars. Getting to the doors in a hurry was impossible. I really wanted this moment in the play to be both funny and stressful, and I think the director, Lu Kemp and the sound design team did a great job in creating the soundscape of the bus and all the fragile items in the shopping bags that Bronagh tramples as she tries to get to the door.

Of course, the impact IBD can have on our lives is about more than toilets. It's far-reaching and complex, and impossible to convey in a short audio play.



I wanted the play to be not just about what IBD is, and what it does to us physically, but also what living with it does to us emotionally. I tried to convey how a life can be turned upside down as Bronagh finally breaks down and unpacks years of frustration, grief, anger and loss. Her job, her marriage, her friendships, her sense of herself have all been affected.

Plays have to tell stories, and stories need an ending. It was very important to me that Bronagh should move on in some way, but there's no 'happy ending' because there's no cure for IBD. Bronagh can't have a cure, but she has raised a mature, thoughtful teenage son and neither of them need the Goblin any more.

Writing comedy about something as serious as IBD is a bit risky. I'm not making light of other people's painful experiences with chronic illness. Rather, I wanted to raise awareness about IBD and celebrate the resilience of those coping with it. Humour is a lifebelt that we throw to each other – or to ourselves – so we don't go under in a crisis. There's something profoundly human about laughing at our own worst moments. It's healthy.

Áine King.

Something to Say is produced by Birds of Paradise, in association with Perth Theatre, with EHFM as broadcast partner. Listen to the *Something to Say* plays at www.boptheatre.co.uk/something-new-to-say

Researchers use stem cell technology to replicate diseased human guts and understand fibrosis in inflammatory bowel disease

Last December 2021 the Crohn's & Colitis Foundation (based in the USA) announced a breakthrough in the study of intestinal fibrosis in inflammatory bowel disease (IBD) patients, published in IBD Journal. Fibrosis is a common complication of IBD, defined as excessive accumulation of scar tissue in the intestinal wall.

Despite therapeutic advances in the treatment of IBD in the last two decades, the incidence of intestinal strictures in Crohn's disease has not significantly changed. Researchers at Cedars-Sinai, funded by The Jonathan D. Rose, MD, PhD, Crohn's & Colitis Foundation / Cedars-Sinai Pathology in Foundation's Fibrosis Initiative, applied a novel technology to generate stem cells from patient blood samples and create "mini-guts." This "gut in a dish" mimics the human gut and helps researchers study the precise role of genetics and bacteria in the fibrosis process. In addition to using this unprecedented methodology, researchers will be able to test potential therapies to prevent and/or treat fibrosis, and even potentially to personalize the therapies based on patient's own biology, a concept known as precision medicine.

"Our findings mark a major step forward in addressing the mechanism of fibrosis in IBD" said Robert Barrett, PhD, Assistant Professor of Medicine at Cedars-Sinai. "This research would not have been possible without the Crohn's & Colitis Foundation and the generous support of Dr. Rose. They inspired a completely new line of inquiry for my lab and gave us the perfect opportunity to apply our technology to address this vexing problem for IBD researchers, specialists, and patients. We look forward to using these mini-guts for many future investigations into the causes of and treatments for fibrosis."

Until now, fibrotic cells could only be obtained through patient surgery, which limited the possibilities for keeping a robust and continuous cell model system for therapeutics and biological research. Robert Barrett and Stephan R. Targan, director of the F. Widjaja Foundation Inflammatory Bowel and Immunobiology Research Institute at Cedars-Sinai reprogrammed Crohn's disease fibrotic patients' blood samples into stem cells, that were subsequently differentiated into mini-guts, in which the researchers induced a fibrotic response. This technology creates unparalleled opportunities for precision medicine in IBD. Using this mini-gut model, researchers can better understand what unique factors about each patient lead to fibrosis and test potential treatments.

This project was generously supported by Jonathan D. Rose, MD, PhD as part of the Jonathan D. Rose, MD, PhD, Crohn's & Colitis Foundation / Cedars-Sinai Pathology in Precision Medicine Research Collaborative. The Fibrosis Initiative is a multi-disciplinary collaborative study investigating the biological mechanisms of fibrosis in IBD. This is the first publication backed by the Initiative. To read the full study, please visit the IBD Journal [here](#).

About the Crohn's & Colitis Foundation

The Crohn's & Colitis Foundation is a non-profit, volunteer-fueled organization dedicated to finding the cures for [Crohn's disease](#) and [ulcerative colitis](#), and to improving the quality of life of children and adults affected by these diseases. It was founded in 1967 by Irwin M. and Suzanne Rosenthal, William D. and Shelby Modell, and Henry D. Janowitz, M.D.

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