

EFCCA MAGAZINE

The background image shows two women participating in a rappelling activity. They are wearing blue helmets with the 'PETZL' logo, purple t-shirts, and safety harnesses. The woman on the right is in a more dynamic pose, with one leg extended and arms raised, while the woman on the left is looking towards the camera. They are suspended from ropes against a blurred background of a cityscape and buildings.

EUROPEAN FEDERATION OF CROHN'S AND ULCERATIVE COLITIS ASSOCIATIONS

OCTOBER 2023

**Cover image:
Crohn's & Colitis Ireland
Fundraising event**

page 32

**Interview with Ingrid Klingmann Chairman of EFGCP:
Addressing Urgent Patient Needs for Cross-
Border Clinical Trials Access in Europe**

page 34

New features in DIVA

page 9

EFCCA Members

Austria - OMCCV
www.oemccv.at

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

Bulgaria - BCUCA
www.babkuk.org

Croatia - HUCUK
www.hucuk.hr

Cyprus - CYCCA
www.cycca.org

Czech Republic - Pacienti IBD
www.crohn.cz

Denmark - CCF
www.ccf.dk

Estonia - EPSS
www.ibd.ee

Finland - IBD ja muut
www.ibd.fi

France - AFA
www.afa.asso.fr

Germany - DCCV.e.V.
www.dccv.de

Greece - HELLESCC
www.crohnhellas.gr

Hungary - MCCBE
www.mccbe.hu

Iceland - CCU
www.ccu.is

Ireland
Crohn's and Colitis Ireland
www.iscc.ie

Israel - CCFI
www.ccfi.co.il

Italy - AMICI
www.amiciitalia.org

Latvia - LKKSBB
www.lkksb.lv

Lithuania - CCLA
www.draugija.info

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

Malta - MACC
www.macc.org.mt

Montenegro - CUKUK
www.cukuk.me

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

Netherlands
Crohn & Colitis NL
www.crohn-colitis.nl

Norway - Magetarm
www.magetarm.no

Poland - J-elita
www.j-elita.org.pl

Portugal - APDI
www.apdi.org.pt

Romania - ASPIIR
www.aspiir.ro

Serbia - UKUKS
www.ukuks.org

Slovakia - SCC
www.crohncub.sk

Slovenia - SAIBD
www.kvcb.si

Spain - ACCU
www.accuesp.com

Sweden - MOT
www.magotarm.se

Switzerland - SMCCV
www.smccv.ch
www.asmcc.ch

Turkey - IBHDYD
www.ibhportali.com

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

Associate Members:

Argentina - Mas Vida
www.masvida.org.ar

Brazil - DII Brasil
www.facebook.com/diibrasil

Lebanon - I Battle Disease
www.ibattledisease.org

Kazakhstan - FPVZK
www.vzk.kz

Mexico - CUCI
www.crohncuci.org.mx

Russia - Trust
www.vzk-life.ru

Singapore
Crohn's and Colitis Singapore
www.ibd.org.sg/english

Trinidad and Tobago -
NACCTT
www.crohnsandcolitistt.org

Ukraine - Fulfilling life
www.gofullife.com.ua

Content

EFCCA News	4
.....	
Project News	13
.....	
Member News	18
.....	
News from Partners	34
.....	
Living with IBD	38
.....	
Medical Review Corner	41
.....	
Clinical Trials	45
.....	

Every effort has been made to ensure that the information in this publication is presented accurately. The contents are provided for general information and should not be relied upon for any specific purpose. Descriptions of, or references to, products or publications do not imply endorsement of that product or publication. Patients should consult their doctors if they have any medical concerns. Neither the Officers of the Executive Committee nor the editor can be held responsible for errors or for any other consequences arising from the use of information contained herein. As part of its commitment to transparency EFCCA will fully comply with the EFPIA code, and other applicable national codes of practice as appropriate, which govern ethical and transparent relationships with commercial and pharmaceutical companies. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, without the prior permission of the EFCCA Secretary.

Foreword



Dear Members, dear Stakeholders,

As I go through the pages before us in this latest edition of the EFCCA Magazine, I really appreciate the collective efforts that have brought us to this point of the EFCCA journey.

This magazine showcases the impressive work accomplished not only by EFCCA, but also by our members and stakeholders. It clearly shows the dedication and commitment of each individual who has contributed their time, expertise, and effort to furthering our common cause - to fight Crohn's and Ulcerative Colitis and to improve the lives of people living with these two chronic conditions.

You will find a wealth of information that puts into evidence our efforts in advocacy, research, networking and awareness raising, from the latest advancements in IBD treatment and management to personal stories of triumph over adversity.

Together, WE STAND UNITED in our mission, and it is with great anticipation that I look forward to witnessing the continued progress that we will achieve together.

Salvo Leone,
EFCCA Chairperson

Editorial



Dear Readers,

It's with great pleasure that we present to you the latest issue of the EFCCA Magazine. This edition brings with it an exciting development - an expanded format that allows for deeper insights and a new section dedicated to our stakeholders. Here, you will find information concerning the latest advancements in research and ongoing clinical trials related to IBD.

In addition, the magazine also provides you with an update of our activities, ranging from the introduction of new features in DIVA to comprehensive coverage of our recent General Assembly and new strategy plan.

In particular, I would like to invite you to read the inspiring interview with Ingrid Klingmann, Chairman of the European Forum for Good Clinical Practice (EFGCP) and co-founder of the EU-X-CT Initiative. In the interview we highlight an important initiative aimed at breaking down barriers to cross-border clinical trials in Europe and to potentially better support patients seeking broader treatment options.

I hope you will find this issue to be a source for inspiration and for a better understanding of the IBD patient community. I would like to thank all those who have contributed to its creation.

Isabella Haaf,
Editor-in-Chief

Gathering for Change: EFCCA's 2023 General Assembly

From 9-11 June 2023 EFCCA gathered its members in the Slovakian capital, Bratislava, for its Annual General Assembly (GA). The Assembly proved to be an excellent opportunity for participants to connect, share experiences, and set the stage for a future characterised by a strong commitment for international collaboration.

The Value of Meeting Face to Face

In today's interconnected world, where virtual platforms and digital communication dominate our lives, the value of meeting face to face should never be underestimated. And the GA in Bratislava, as a face to face follow up to our online institutional GA meeting that took place just two weeks previously (27 May), exemplified this truth. Participants from diverse backgrounds and cultures gathered in a shared space, overcoming geographic boundaries to exchange knowledge, experiences, and ideas.

Being in the same room allowed us to engage in fruitful discussions, listen to personal stories and learn about the challenges faced by our members, some very similar, others more related to the national or regional context.

These conversations do not only take place during the meeting itself, they also take place in more informal settings during the coffee breaks, lunches, dinners and social events. It becomes evident that the bonds formed through face-to-face encounters foster a stronger sense of belonging among attendees. They give a tangible meaning to the work we do and reinforce our mission to drive positive change for individuals living with Crohn's Disease and Ulcerative Colitis.



The Importance of Collaboration

The General Assembly served as a reminder that collaboration lies at the heart of achieving our collective goals. It is through cooperation that we can pool our strengths, share resources, and work towards innovative solutions that benefit the entire Inflammatory Bowel Disease (IBD) community.

What struck me most was the genuine willingness of participants to collaborate, irrespective of their geographical location or organisational size. Whether representing a large association with substantial resources or a smaller group driven by volunteers, everyone recognised the importance of working together towards our common goals.

During the General Assembly we also had the privilege of hosting Professor Caitriona O’Driscoll as a guest speaker presenting the GENEGUT (Horizon Europe) project, in which EFCCA is a consortium partner. Her presentation provided a unique opportunity for delegates to gain a deeper understanding of the GENEGUT project’s objectives, methodologies, and potential impact on the IBD community.

The presence of Professor O’Driscoll emphasised our commitment to specific projects aimed at advancing research and healthcare for people with IBD. Through the GENEGUT project as well as four other Horizon Europe projects EFCCA is currently working on, we will make sure of a more patient-centric approach, promoting the exchange of knowledge and interdisciplinary discussions and incorporating patient perspectives in the research agenda.

The EFCCA Strategy Plan

The General Assembly in Bratislava also marked an important milestone in EFCCA’s journey towards greater international cooperation. As we unveiled our Strategy Plan, it became apparent that our commitment to collaboration extends far beyond Europe. Recognizing the interconnected nature of our global community, the plan sets the stage for increased engagement with members from other continents, encouraging a diverse range of voices and perspectives to shape our collective approach.

By creating strategic alliances, fostering dialogue, and promoting international cooperation, we aim to amplify our impact, strengthen advocacy efforts, and bring about a knowledge exchange on a global scale.

All in all, the Assembly in Bratislava served as a reminder of the value of meeting face to face and the transformative power of collaboration. By standing united, we can indeed make an impact, improving the quality of life for individuals living with Crohn’s Disease and Ulcerative Colitis around the world.

Isabella Haaf,
EFCCA Head of Communication



EFCCA New Strategy Plan 2023-2027

Last June, in Bratislava, the 2023-2027 new Strategy Plan was presented to the EFCCA delegates and finally endorsed by the General Assembly.

It has been a progressive journey made of consultations and exchanges started the year before in Barcelona that involved our members and was periodically discussed by the EFCCA Executive Board. The Strategy plan must be considered the socio-political framework through which EFCCA annual work plans, actions, initiatives and projects will be shaped.

The Plan aims to be an open lab where ideas can become projects and we are confident all our members will find their place and be able to concretely contribute to paving the way to a more empowered, stronger, and impactful global community of IBD people.

I think it is important to start from the subheading of the document: “Global collaboration based on shared knowledge” to begin our journey into it and to better understand its innovative approach and the value it is aiming to bring to our IBD community.

I consider this sentence the real essence of our Strategy Plan, the innovative and in a way revolutionary red thread through which we will be able to make EFCCA’s opinion value within our wider community.

In fact, boosting the IBD patient community through a global collaboration based on shared knowledge requires a strategic and organised approach. DIVA is the methodology we are developing exactly for this purpose as we believe DIVA can outline the benefits of shared knowledge and the positive impact it can have on patients’ lives. By creating a data bank (our EFCCA lake) we aim to put at disposal to our members (and other stakeholders in a near future) a hub where



patient organisations, healthcare professionals, researchers and advocates from around the world can come together and be able to elaborate evidence-based opinions able to impact policy decisions.

This means to identify and engage key stakeholders, their know-how and collective expertise. I’m thinking of patient organisations that are not EFCCA members yet, but also our members that could share their data and work together in identifying priorities, i.e. those unmet needs that are often focused on the clinical/medical ones and very rarely take into consideration patient preferences and wellbeing. The great opportunity there is to be able to create a repository of credible resources and references that our members can access and utilise also at a national/local level.

The pillars of the EFCCA house show us the implementation of the plan and can help to build our activities.

Awareness raising campaigns will be able to highlight and disseminate accurate information about IBD, its impact, and the global patient community priorities.

Empowerment actions will be structured around our Academy training modules in order to boost patient education; we are already working on different formative proposals, and we are eager to get your suggestions for further educational opportunities focused on enhancing patients' proactive role in managing the disease and speaking out about their needs.

Research and Development is a new pillar of our Strategy Plan, and we are confident that thanks to DIVA and its data collection we can better collaborate with healthcare institutions and researchers to gather data on patient experiences, treatment outcomes, and quality of life. In fact, this data can be used to identify trends, challenges, and areas for improvement.

By participating – as we are already doing – in transnational projects such as those of the Horizon programme, we aim to promote patient-centric research that directly involves patients in the design and implementation process to ensure that studies address real-world concerns and priorities.

Finally, **networking** is seen as the basis of our work, and we want to structure it into three different layers:

1. Stakeholder Engagement: to reinforce our relationships with healthcare professionals, researchers, policymakers, pharmaceutical companies, and other relevant players;
2. Cross-Community Collaboration: to collaborate with other patient communities in particular those representing other immune mediated diseases areas, sister organisations and associations working on related health issues. We strongly believe that sharing resources and knowledge can lead to a stronger collective impact;
3. Proactive interaction with international institutions such as the European Commission, the European Medicine Agency, and the WHO;

The roof of the EFCCA house is advocacy, a key aspect of our activities that needs to be reinforced and requires a lot of investment in the next few years. We aim to work on evidence-based advocacy and take advantage of the data collected through DIVA and other relevant sources with the purpose to promote innovative policies at a national and transnational level that address specific challenges faced by the IBD patient community globally.

To conclude, I see the implementation of our Strategy Plan as a continuous learning and adaptation process; EFCCA will stay open to feedback from its community, monitor the effectiveness of our efforts, and adapt its initiatives (by the means of our annual work plan) as needed.

Embracing a culture of continuous improvement is what we need as we want to become more impactful. We have all the requisites to represent not only the real needs to the IBD people but to pave the way for a stronger and vocal IBD community in all continents.

Luisa Avedano,
EFCCA Chief Executive Officer

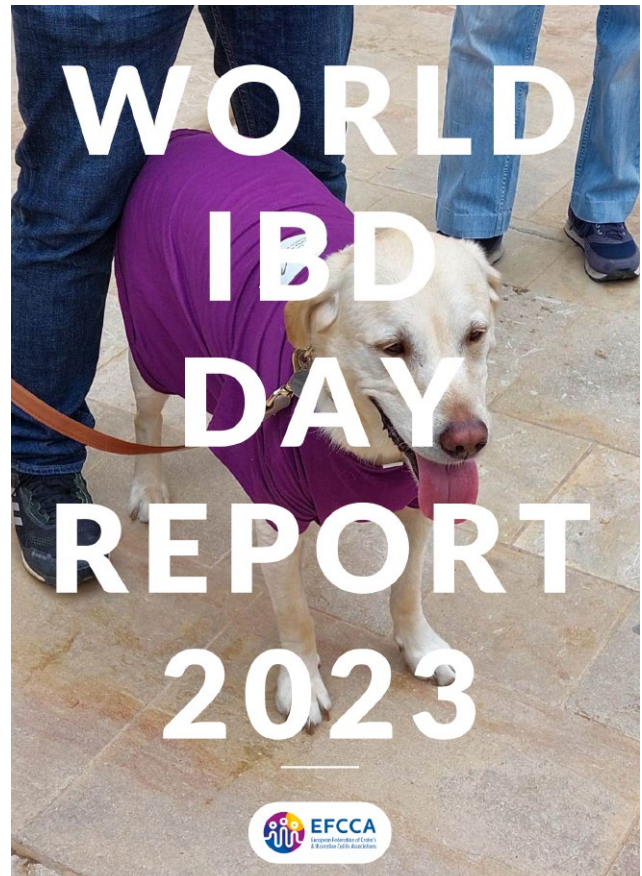
World IBD Day 2023 Highlights: Global Unity for IBD Awareness

World IBD Day 2023 was an important occasion for raising awareness about Inflammatory Bowel Disease (IBD). The event showcased a diverse range of initiatives, all aimed at promoting global awareness through impactful activities. EFCCA's worldibd.org website and social media initiatives played a vital role in aggregating and presenting these activities. Serving as a central hub, the website facilitated global information dissemination, with over 40 national associations actively contributing by sharing their events within the dedicated 2023 section.

While 19 May, the official World IBD Day, stood out as a significant date, numerous associations sustained their involvement throughout the week and extended participation across the month. Activities ranged from city walks to creative flash mobs and enlightening exhibitions. These collective efforts helped uniting members in their determination to raise awareness about Crohn's Disease and Ulcerative Colitis.

Globally, landmarks illuminated in purple spotlighted the challenges of IBD, while local events engaged citizens in Brazil, India, Italy, South Korea, and beyond. Notable events included the "Walk of Warriors" in Malta and a flashmob by the "Microbiota, Intestine and Inflammation" research team in Paris. Associations in the Netherlands, New Zealand, and Norway encouraged story-sharing, with the Czech Republic hosting a photo exhibition. Social media and public gatherings were instrumental in boosting awareness, with numerous associations adopting EFCCA's "IBD Has No Age" motto, making the cause relevant to all age groups.

For the first time our members from Latvia, Lithuania, and Estonia organised a Baltic States regional meeting in Vilnius on 20 May. The event featured lectures, interviews, and public performances, underscoring



the collaborative spirit of World IBD Day. Our board member Magdalena Sajak-Szczerba represented EFCCA during this event. Healthcare professionals in countries like Belgium and France showcased unwavering support, highlighting their essential role in enhancing the quality of life for IBD patients.

Pharmaceutical companies and stakeholders also played a vital role, endorsing our "IBD Has No Age" theme, and participating in awareness campaigns. Horizon Europe research projects significantly contributed to advancing World IBD Day, alongside our survey targeting individuals aged 60 and above with IBD.

All in all, the success of World IBD Day 2023 owes much to the dedication of EFCCA members and the many volunteers who participated in diverse campaigns. These actions, from local to global, have fostered empathy and support for those living with IBD, shining a light on the challenges faced and uniting communities in a common cause. Thank you all!

We invite you to learn more about all the events in our annual World IBD Day Report, available on our [website](#).

Francesc Esparza-Pagès
EFCCA Communication Assistant



New features in DIVA

We are pleased to share new features of DIVA (Data Insight for added therapeutic value), our platform specifically designed to support IBD patient advocates in their daily activities.

EFCCA has continued its work throughout the summer to achieve significant advances in our DIVA data analysis platform. The main features are:

1. Internal Library

We have created an internal library to nourish DIVA with knowledge. We have added public publications and materials for patients produced by EFCCA and national associations. We have also incorporated open scientific articles that offer the patients' perspective.

2. Advanced Virtual Assistant

We have created a virtual assistant to facilitate the exploration and interpretation of data, thanks to its ability to extract information from this new library.

Currently, the assistant can help us understand the patients' opinions regarding:

- Epidemiology
- Patient profile
- Symptoms and disease impact
- Needs and priorities of patients
- Similarities and differences in health systems
- Trends in pharmaceutical R&D
- Characteristics of clinical trials (past and present)

3. Support Manual

We have created a detailed support manual to ensure the virtual assistant functions at its maximum capacity. This document has been used to train the assistant.

4. Access to CTIS trials

Before this update, DIVA only had access to trials from the old European clinical trial registry. Now, with the inclusion of clinical trials from the CTIS, we have a broader and more detailed view of ongoing research in Europe.

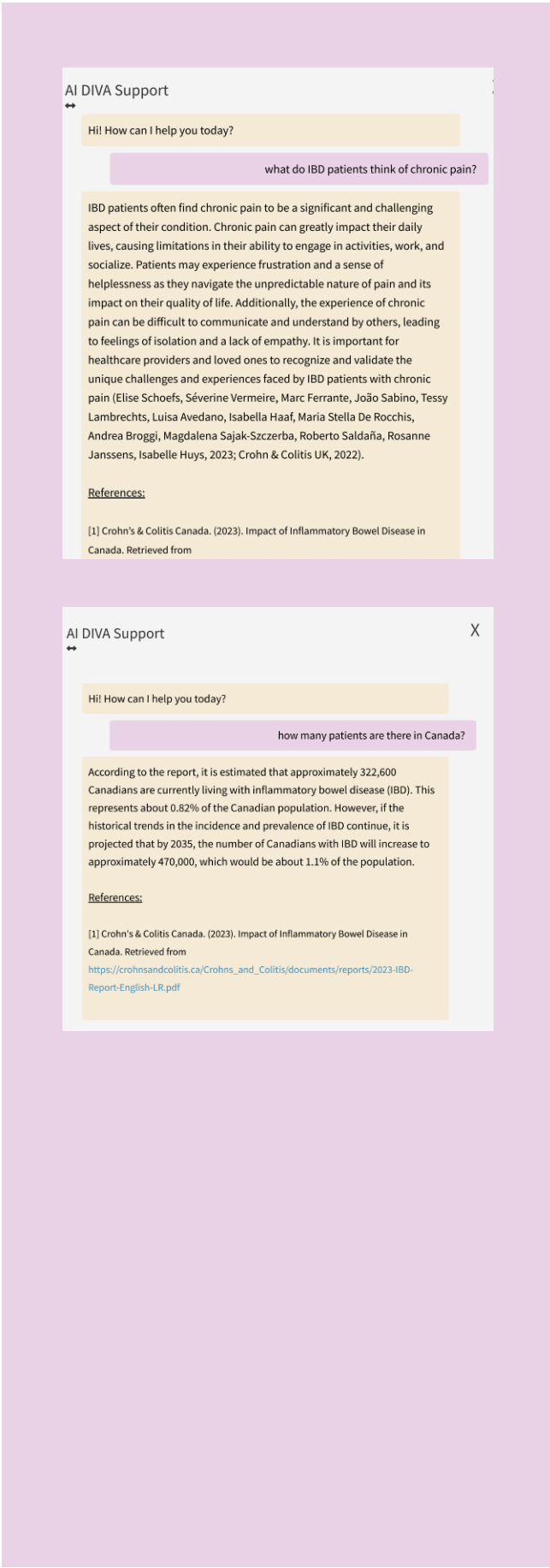
5. Stability Improvements

In addition to significant inclusions, minor corrections have been made to the platform, ensuring that DIVA is more stable and reliable for its users.

The future of DIVA is promising, and these updates are just the beginning. If you want to explore the virtual assistant and everything DIVA offers, visit diva.efcca.org. Once you log in, press the “support” button in the bottom left corner.

These advancements reaffirm EFCCA’s commitment to continue innovating and providing valuable and updated tools for its community. In a constantly changing world, it is essential to have platforms that evolve at the same pace.

Roberto Saldaña,
EFCCA Innovation and Patient Engagement Officer



Leaders of tomorrow - EFCCA Youth Academy

At the end of 2021 we have launched our first Youth Academy with the aim to enhance youth representation, foster a cohesive group of future leaders, and empower young representatives.

Targeted at IBD patients aged 18 to 30, this training program saw 14 students successfully complete their course and embark on final assignments choosing from the following options:

- Implementing a youth engagement project
- Assisting the national association in implementing an awareness campaign
- Contributing to EFCCA's upcoming Youth event

Starting with this issue of the EFCCA magazine, we will provide summary information on their assignments, while full details of the assignments will be available on our website.

Bridging Experiences Between Camp Purple and EFCCA Youth Summer Camp

Jasneel Deo from CCNZ - Crohn's and Colitis New Zealand shares his experience as a volunteer for Camp Purple, a camp set up for children aged 9-17 living with either a Crohn's or Colitis diagnosis to experience a week's long camping trip.

It is held in three main cities of New Zealand: Auckland, Wellington, and Christchurch. Held yearly since early 2010, it has grown from a small group of dedicated individuals to now operating in 13 different regions in New Zealand aiming to provide fellowship, education, and participation in fundraising.

Jasneel volunteered in 2021 and was motivated to join by a sense of belonging, he confessed. *"Ever since I got IBD I never truly felt that no one got me, and I felt alone. I didn't have anyone to talk to or anyone for support and I really wanted to meet other people and*



hear their story with IBD." Drawing from his experience in organising the Purple Camp in NZ, he felt it would be beneficial to present his own ideas on how to contribute to the next EFCCA Youth Summer Camp.

Empowering Youth: The Emerging HELLESCC Youth Group


Vasiliki-Rafaela Vakouftsi from HELLESCC shares with us some news regarding the newly established youth group, created with the goal of supporting young members and giving them the opportunity to actively engage, express their ideas, and play a key role in shaping Greek IBD patients' future. Since the group is newly formed, they are actively seeking enthusiastic young individuals to join.

We look forward to hearing about the exciting challenges and projects they will undertake soon and congratulations to Vasiliki for the great initiative!

If you want to find out more about the Youth Academy and discover the details about both projects, please visit our website at: efcca.org/news/efcca-youth-academy

Maria Stella De Rocchis,
EFCCA European Project Officer

The Impact of Crohn’s Perianal Fistula on Quality of Life We are pleased to share that the results of the Patient Survey on the Impact of Crohn’s Perianal Fistula on Quality of Life have been published on 23 July 2023 in the Journal of the Crohn’s and Colitis Foundation. Please find below an infographic highlighting the main findings. Read the study at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10390083/>




Patients speak: the impact of Crohn’s perianal fistula on quality of life

Crohn’s perianal fistula (CPF) is a common yet debilitating complication of Crohn’s disease (CD) and affects between 23%-38% of patients living with CD.^{1,2} An estimated 70-80% of CPF are complex.³


CPF can cause fecal incontinence, rectal pain, swelling, and fever, which can have a significant negative impact on an individual’s quality of life and overall well-being.^{3,4} Despite this, awareness and understanding of the true patient experience and impact on quality of life remain low. Treatment of CPF is challenging and complex, and patients are often resistant to conventional therapies, including immunomodulators, antibiotics and biologics.^{5,6}

The European Federation of Crohn’s & Ulcerative Colitis Associations (EFCCA) commissioned an international, patient-reported survey to assess the additional burden and impact of CPF in patients with CD.⁷ 820 patients from >10 countries participated in the survey. 532 (64.9%) of patients reported the presence of fistula, with 272 (51.1%) reporting complex fistulas. The full results were published in the July 2023 issue of *Crohn’s & Colitis* 360.⁷


Fatigue was the most common symptom for patients with both **CD only** and **CPF**, followed by **joint pain**.



44% of patients with **CPF** experienced pain in or around the anal area and 32.1% experienced perianal leakage, compared to 13.2% and 4.2% of patients with **CD only**.



32%




4%

FAST FACT: Complex perianal fistulas involve the upper part of the sphincters, have multiple external openings, may form an abscess and involve the rectum or vagina.^{8,9}


More women than men with **CPF** reported fatigue, joint pain, diarrhea and stomach cramps.

Patients with **CPF** reported a higher impact on overall quality of life and well-being, saying they feel more “dirty” and “uncomfortable” than those with **CD only**.

Feeling dirty




Feeling uncomfortable




Patients with **CPF** reported a greater impact on relationships with family and friends, saying they:

Feel guilty about the impact of CPF on family and friends



Find it difficult to talk with them about their condition



Feel judged



Compared to those with **CD alone**, more patients with **CPF** reported that they:


Were unable to take part in sports and exercise (37.4% vs 25.7%)

Had to carry a personal hygiene kit when leaving their home (47.7% vs 25.7%)

Only left home if they knew clean toilets were accessible (32% vs 25%)

Had to change their profession/career path (14.3% vs 8%)

26.4% of patients with **CPF** said they avoid intimacy with their partner, compared to 14.8% of those with **CD alone**...
...and they also feel more inadequate as a spouse or partner.



DID YOU KNOW? More women than men with CPF reported a greater impact on their social and professional lives, and relationships with their partner.

These results highlight the additional burden of CPF compared to CD alone on a patients’ overall quality of life, relationships, and social and work life.

However, diagnosing and managing CPF is complex and requires a multidisciplinary approach.

These results may help healthcare professionals address the symptomatic and psychological burden experienced by patients with CPF.


DID YOU KNOW? There are several classifications of perianal fistulas. Clinically useful classifications of perianal fistulas in Crohn’s Disease would enable the physicians to determine the optimal management strategy. At present, there has been no consensus regarding which classification system should be used.

For more information on survey methodology and to read the full results, please see <https://pubmed.ncbi.nlm.nih.gov/375929012/>.

References

- Marzo M, Felice C, Pugliese D, et al. Management of perianal fistulas in Crohn’s disease: an up-to-date review. *World J Gastroenterol*. 2015;21(5):1394-1403.
- Schwartz DA, LoftusEV, Jr, Tremaine WJ, et al. The natural history of fistulizing Crohn’s disease in Olmsted County, Minnesota. *Gastroenterology*. 2002;122(4):875-880.
- Panes J, Reinisch W, Rupniewska E, et al. Burden and outcomes for complex perianal fistulas in Crohn’s disease: systematic review. *World J Gastroenterol*. 2018;24(42):4821-4834.
- Reyca F, Stalinger PPM, Pórtak M, et al. Patient and general population values for luminal and perianal fistulizing Crohn’s disease health states. *Eur J Health Econ*. 2019;20(Suppl 1):91-100.
- Sandborn WJ, Fazio VW, Feagan BG, Hanauer SB; American Gastroenterological Association Clinical Practice Committee. AGA technical review on perianal Crohn’s disease. *Gastroenterology*. 2003;125(5):1508-1530.
- Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG clinical guideline: management of Crohn’s disease in adults. *Am J Gastroenterol*. 2020;115(4):481-517.
- Spinelli A, Yanai H, Girardi P, et al. The impact of Crohn’s perianal fistula on quality of life: results of an international patient survey. *Crohn’s Colitis* 360. 2023;5(3):otad036. doi: 10.1093/ecco/otad036.
- Lee JL, Yoon YS, Yu CS. Treatment strategy for perianal fistulas in Crohn disease patients: the surgeon’s point of view. *Ann Coloproctol*. 2021;37(1):5-15.

European Federation of Crohn’s and Ulcerative Colitis Associations (EFCCA)
Rue des Chartreux 33-35, B-1000 Brussels
Tel/Fax: +32 2 540 8434
E-mail: info@efcca.org
www.EFCCA.org

The information provided is not a substitute for professional and/or medical advice. Please consult a healthcare professional for further advice. The European Federation of Crohn’s & Ulcerative Colitis Associations (EFCCA) international patient survey was co-developed with medical and patient representatives, and sponsored by Takeda. Copyright 2023 Takeda Pharmaceutical Company Limited. All rights reserved. TAKEDA and  are registered trademarks of Takeda Pharmaceutical Company Limited, used under license.

C-ANPROM/EUC/GI/0013 / September 2023

12

A new project aimed to help prevent and treat fibrosis/fibrostenosis in IBD

EFCCA, together with 7 other public and industry partners, took part in the launch of the European-funded project, “FIBROTARGET: Validation of novel immunotherapeutic targets against fibrosis in inflammatory bowel diseases” in Leuven, Belgium, on 1 April 2023.

The 5-year initiative aims to improve the prevention, diagnosis, and treatment of intestinal fibrosis and fibrostenosis-challenging conditions associated with inflammatory bowel disease (IBD), with no treatments available yet.

To achieve this aim, project partners will:

- Discover and validate biomarkers for early detection of fibrosis and to reduce the likelihood of irreversible tissue damage.
- Develop and test cutting-edge techniques to enhance the diagnosis and prognosis of intestinal fibrosis.
- Implement a first-in-human, proof-of-concept trial of immunotherapeutic drugs for IBD and other possible fibrosis-related diseases.

The rise of this project stems from the ongoing challenges related to IBD in Europe, where some 3.4 million people are affected by the condition.

A disease on the rise with no current cure available

Intestinal fibrosis - or the accumulation of scar tissue in the gut wall due to chronic inflammation - and its more severe and obstructive form, fibrostenosis, significantly reduce patients' quality of life. Work and school productivity decrease, and social interactions take place less and less. These conditions also increase the odds of hospitalisations and surgical interventions, as well as health expenditures. Annual

direct IBD healthcare costs across Europe have been estimated to reach between 4.6 to 5.6 billion euros. Alarmingly, IBD incidence is on the rise.

These figures warrant an intervention like FIBROTARGET

With FIBROTARGET, patients, researchers and clinicians can potentially look forward to novel immunotherapeutic drugs that aim to address intestinal fibrosis and fibrostenosis. Until now, therapies for IBD have only targeted inflammation. Even current treatments do not resolve the issue of how to predict who will develop fibrosis and strictures.

So, contributions made from this European project will be certain to leave a promising legacy in health systems and outcomes, especially for those living with IBD.

A multi-faceted approach to help prevent and treat fibrosis/fibrostenosis

For the first time ever, this consortium will validate therapeutic targets to prevent and treat fibrosis in samples obtained from patients with IBD.

Studies of these novel immunotherapies will eventually help project partners shape the first-in-human, proof-of-concept randomised trial of such drugs. To conceive this trial, the consortium will also develop and validate diagnostic and prognostic tools for fibrosis. Throughout this entire process, EFCCA will play an active role to ensure patients' voices and insights are heard.

As KU Leuven Coordinator Professor Séverine Vermeire and Principal Investigator Gianluca Matteoli affirm, *“Results obtained from FIBROTARGET could have strong implications for both the scientific and patient communities. If we can identify early triggers of extracellular remodelling and fibrosis, we can pave the way for new therapies to emerge and revert fibrosis. Understanding the role of certain biomarkers can help us select patients at possible risk. At the same time, risk and imaging tools can improve for better monitoring of how these anti-fibrotic drugs are working.”*

Multiplying benefits across the scientific, health and patient communities

The implications of this project are wide scale and positive for different societal members.

By validating target-specific and anti-fibrotic compounds, FIBROTARGET aims to pave the way for personalised immunotherapies for fibrosis. Similarly, as the project plans to technologically develop models to detect and validate possible early warning signs of fibrosis, researchers would have the sturdy groundwork to explore and release anti-fibrotic drugs. As these treatments intend to help care for fibrosis-related



conditions and IBD, the European Union and other countries worldwide can potentially see a decrease in direct and indirect costs per IBD. Lastly, and most importantly, thanks to FIBROTARGET, patients living with IBD would be able to experience less work/school absenteeism, more energy and productivity, and a better quality of life.

For the FIBROTARGET project, the goal goes beyond just changing the landscape of fibrosis/fibrostenosis. This consortium is set to revolutionise care so those living with IBD can enjoy the quality life we all deserve.

Contact Annarita Sibilio, FIBROTARGET Project Manager, for more information:
asibilio@teamitresearch.com

Follow FIBROTARGET on [Twitter](#) and [LinkedIn](#) for more information about the project.



Launch of Patient Preference Survey

On 24 July EFCCA launched the Patient Preference Survey. Help us to find out which aspects, factors, and characteristics are important for patients when choosing a treatment for IBD.

There is very little scientific evidence on patient preference targeted at the IBD patient community. This is why in 2020 EFCCA started investigating this theme to know more about.

“Which quality of life effects are important to you?”, “Which side-effects do you want to avoid?”, “Which characteristics should future drugs have according to you?”

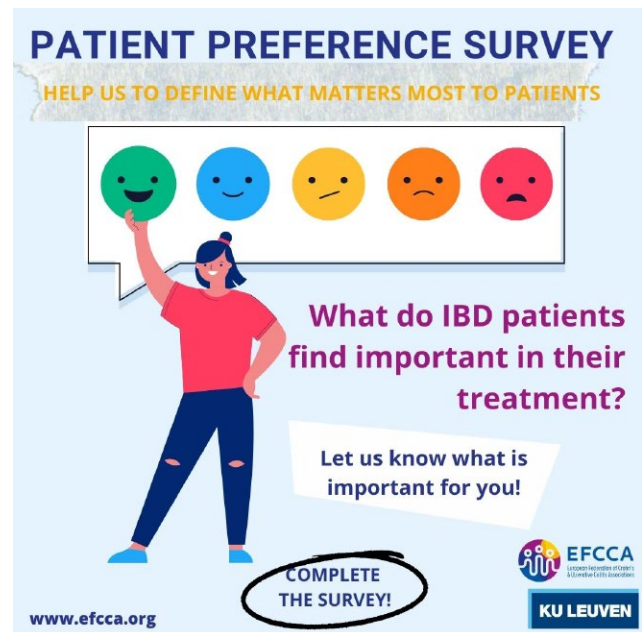
These are a few of the questions we aim to answer in the Patient Preference Survey we finally recently launched in collaboration with the University of Leuven (KU Leuven – Belgium).

What is the purpose of the survey?

As there are several treatment options available for IBD with their own characteristics, the development of new drugs must be tailored to what patients themselves consider important. Therefore, this study aims to assess the importance that IBD patients assign to the characteristics related to their treatment and disease.

Why is it important to participate?

Asking patients about their preferences can help the pharmaceutical industry, regulators, and those who pay for healthcare understand what matters to patients in their treatment. This can lead to decisions that focus on patients' needs and create better treatments for the whole community of IBD people.



Help us spread the survey and find out what matters most to patients.

Read more about the study here:

<https://bit.ly/presentation-quantitative-study>

Go directly to the survey:

<https://ibdpatientpreferencesurvey.sawtoothsoftware.com>

Survey on People Aged 60 and Above

Coinciding with World IBD Day 2023, EFCCA launched its survey targeting individuals aged 60 or older with IBD. This initiative builds upon the achievements of the “IBD has no age” campaign from 2022, aiming to shed light on the experiences of people aged 60 and over dealing with Crohn’s Disease and Ulcerative Colitis.

The increasing prevalence of IBD among people aged 60 and over is met with insufficient research representation and limited data, hindering a comprehensive understanding of its implications on the well-being and quality of life for that age group.

In response, EFCCA has launched a survey on 19 May for those aged 60 and above, aiming to investigate aspects such as comorbidities, polypharmacy, and Quality of Life related issues. Through the gathering of such data, EFCCA aims to gain a better understanding in order to shape future initiatives and more effectively meet the needs of people with IBD aged 60 and over.

During World IBD Day, patient associations proactively engaged, leveraging social media and diverse platforms to amplify the survey’s reach. Additionally, collaborations with pharmaceutical firms and research teams, including those affiliated with the Horizon Europe project, enhanced the survey’s impact by involving a diverse pool of respondents.



The survey, so far, has been translated into 20 languages from within the EFCCA network. This accomplishment is owed to committed volunteers who dedicated their time and energy, ensuring equal accessibility to the survey.

Remarkably, by 20 August, over 2000 participants had completed the survey. Notably commendable is the contribution of the Dutch EFCCA members, Crohn&Colitis NL, who recognising the digital challenges for that age group printed and distributed the survey via traditional mail to their members promoting inclusivity and expanding survey participation.

Finally, we extend our gratitude to all EFCCA members who have supported our survey and participated in its translation and dissemination. We encourage you to continue assisting us in advancing this vital initiative, which holds immense value for the broader patient community.

You are welcome to distribute our survey if you have not done it yet! Please find it at the following link:
<https://efcca.org/news/survey-people-ibd-aged-60-and-over>



EFCCA Project Digest

In August, EFCCA launched the Horizon Europe Projects Newsletter named EFCCA PROJECT DIGEST on our website. This newsletter marks a significant step in our commitment to keeping you informed about the latest developments in these important research projects.

In our inaugural issue, we highlighted a range of exciting events and initiatives around the projects: webinars from Methyloomic and Idea-Fast, and the recently unveiled first newsletter by GlycanTrigger, along with an upcoming podcast series set to explore the project's work.

Furthermore, our CEO provided exclusive insights into EFCCA's essential role within Horizon Europe Projects, illuminating the significance of these projects and the valuable benefits they offer to the IBD community. Lastly, we had the privilege of introducing the testimonial of Oona Liikanen, a Crohn's disease patient and unwavering IBD advocate who shares her inspirational journey as part of the Genegut's Patient Stories blog series.



The Project Digest will be published approximately every 2-3 months, providing our members with a regular dose of knowledge and inspiration. We are confident it will be an indispensable tool for gaining deeper insights into our ongoing research projects, which hold outstanding relevance for the IBD community.

Download the very first issue!

<https://efcca.org/sites/default/files/EFCCA%20Project%20Digest-Issue1.pdf>



Greece

Raising IBD awareness

May and June were two very productive months for HELLESCC. On 15 May, on the occasion of World IBD Day and in collaboration with EOMIFNE - Hellenic Group for the study of IBD - we organised an informative event entitled “Learning to live with IBD” with a particularly productive discussion that lasted more than two hours. Participants in the panel of the event consisted of gastroenterologists and surgeons, members of EOMIFNE and the president of HELLESCC.

In addition, on 19 May, for World IBD Day, we lit up in purple the “Umbrellas” sculpture in Thessaloniki, while volunteers distributed printed material and informed passersby about IBD.

Also, on the occasion of World IBD Day, this year we were very active with a presence through articles or interviews in the media with the aim of raising awareness about IBD.

As every year, this year too we participated in the 21st Panhellenic IBD Conference organised by EOMIFNE that took place from 25 to 28 May in Volos. During the conference, we participated in a speech and a presentation at a round table on the topic “What is the future of IBD in Greece”, presenting the perspective of patients.

On 8 June, a webinar was organised by iatronet.gr under the auspices of HELLESCC entitled “IBD - new data and treatments” that feature renowned scientists as well as patients as speakers. The webinar was attended by a large number of people with active participation and questions to the speakers.

Finally, on 23 June, we participated in the 5th Paediatric Surgery Seminar entitled “IBD: The transition from child to adult” which took place at Attikon University Hospital. The talk on behalf of HELLESCC was about the transition process from the perspective of the patients.



We do not rest and are committed to continue our action at all levels through actions and synergies that will aim to better inform patients with IBD and a better future for patients with IBD.

Vasiliki Rafaela Vakouftsi
HELLESCC

Belgium

World IBD Day celebrations

19 May was World IBD Day. CCV-vzw (the Flemish IBD patient association) has not been idle and so we want to list for you all the actions and projects around World IBD Day:

Flanders turns purple

During the worldwide campaign, famous landmarks were lit purple to raise awareness about the daily challenges of living with IBD. Many countries, cities and people around the world joined our fight against IBD.

We would like to thank the municipalities of Kortrijk, Nazareth, Deinze, Genk, Tongeren, Torhout and the Kinopolis Antwerp for illuminating their buildings. The municipality of Schelle created attention for IBD on their social media channels. We also appreciate this very much.

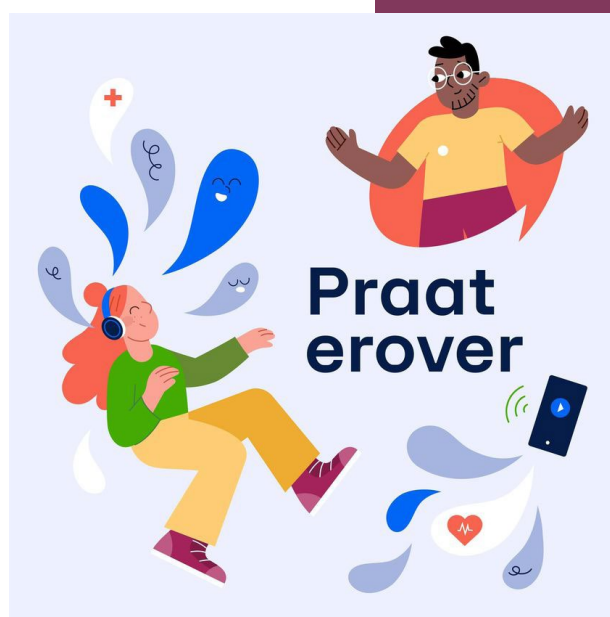
By the way, “Manneken Pis” in Brussels was also dressed in his IBD-awareness clothes.

Let's move

Between 19 May and 19 June, we tried to break the silence around inflammatory bowel disease by moving, for and together with all IBD patients, their families and circle of friends. In two Strava clubs we collected kilometres together hoping to break last year's record (13,113 km).

IBD care teams

A warm and caring team that you can turn to as an IBD patient is extremely important. Together with BIRDgroup, we asked the different IBD teams of Belgium to take a photo of them and share it on social media for World IBD Day to create awareness.



One year free membership for children under 14 years of age

Starting World IBD Day, children under 14 years of age now receive, as a support of CCV-vzw, one year of free membership.

New podcast “Bewegen & IBD” (“Exercise and IBD”)

We have four new episodes of “The Gut Feeling” for you! Aster Nzeyimana has candid conversations with gastroenterologist Filip Baert and IBD nurse Evva de Jonckere of AZ Delta.

Stuffed animals and dolls for young IBD patients

In cooperation with The Magic Angels vzw and individual hobby crocheters, on World IBD Day, we launched a new project for children with IBD! More than 100 stuffed animals and dolls are ready to be distributed in the paediatric IBD centres. They are already available at UZ Gent! Soon also in UZA - University Hospital Antwerp and UZ Brussels.

New Podcast “Praat erover!!”(“Talk About it!!”)

Four patients talk about IBD, their daily lives with various challenges and share their hopes for the future in this new podcast.

CCV-vzw on tour

On the occasion of World IBD Day, CCV-vzw toured the hospitals of Flanders. Our volunteers set off packed and ready with new materials, gadgets, and a listening ear.

Celebrate your IBD-nurse

IBD nurses are an important link for patients between the hospital and the gastroenterologist. We advocate for the official recognition of an IBD nurse so that they can be employed in any IBD centre. For World IBD Day, we had a postcard campaign to celebrate IBD nurses.

Lena Callens Kühle
Crohn & Colitis Ulcerosa Vereniging vzw



 **Boehringer
Ingelheim**

Value through
innovation

*Transforming lives for generations
– Our purpose.*

Our curiosity, creativity and passion for science lead us to take the paths scientifically less travelled and the courage to face challenging journeys as we relentlessly pursue the next generation of breakthrough therapies that will transform lives now, and in generations to come.

www.boehringer-ingelheim.com

Image: Boehringer Ingelheim

Netherlands

Top reached with Expedition IBD

“Menne, how would you feel about climbing a mountain with a group of people with IBD?” That was the question that gastroenterologist Vincent de Jonge, himself an avid mountain climber, asked Menne Scherpenzeel, director of Crohn & Colitis NL, in early 2022. Over a year later, in the last week of June, 14 people with IBD left for Austria, together with Menne, Vincent and two mountain guides. After months of intensive preparations, the aim of their trip was to climb the Grossglockner, Austria’s highest mountain (3798 metres).

Meeting goals

“I was immediately excited when Vincent asked me his question last year,” says Menne. Although he has no climbing experience himself, he wanted to take up the challenge. *“I also wanted to show that people can achieve goals they didn’t think possible, despite their chronic disease. And it was a great opportunity to raise money for three lifestyle events. To introduce even more people with IBD to the benefits of a healthy lifestyle.”* But before that could happen, participants and sponsors had to be found for Expedition IBD.

Representing the IBD population

The call in Crohn & Colitis NL’s magazine attracted more than 80 applications. *“This exceeded all our expectations. We ended up selecting a group of 14 people. People who like sports, but also people who have very little fitness because of their disease. People of all ages, and also people with a stoma. In short, really representing the entire IBD population.”* Each participant discussed participation in the expedition with their own gastroenterologist and were medically screened. Participants then started their training schedule in October. There were also two joint training days.



Boundaries pushed

Not everyone was able to prepare according to the training schedule. Some participants suffered flare-ups, or injuries. Yet everyone remained positive, as they had a common goal. The group bond grew closer and closer. At the end of June, the time finally came. *“It was tough, but everyone had a great time. Many boundaries were pushed back. People walked foot for foot over a ridge only 40 cm wide, walked on a rope over a glacier, supported each other when others were not feeling up to it, and really did it together”,* Menne looks back.

Meeting goals

“I was immediately excited when Vincent asked me his question last year,” says Menne. Although he has no climbing experience himself, he wanted to take up the challenge. *“I also wanted to show that people can achieve goals they didn’t think possible, despite their chronic disease. And it was a great opportunity to raise money for three lifestyle events. To introduce even more people with IBD to the benefits of a healthy lifestyle.”* But before that could happen, participants and sponsors had to be found for Expedition IBD.

Representing the IBD population

The call in Crohn & Colitis NL’s magazine attracted more than 80 applications. “This exceeded all our expectations. We ended up selecting a group of 14 people. People who like sports, but also people who have very little fitness because of their disease. People of all ages, and also people with a stoma. In short, really representing the entire IBD population.” Each participant discussed participation in the expedition with their own gastroenterologist and were medically screened. Participants then started their training schedule in October. There were also two joint training days.

Boundaries pushed

Not everyone was able to prepare according to the training schedule. Some participants suffered flare-ups, or injuries. Yet everyone remained positive, as they had a common goal. The group bond grew closer and closer. At the end of June, the time finally came. *“It was tough, but everyone had a great time. Many boundaries were pushed back. People walked foot for foot over a ridge only 40 cm wide, walked on a rope over a glacier, supported each other when others were not feeling up to it, and really did it together”*, Menne looks back.



Own summit

The goal of Expedition IBD was to reach the top of the mountain together. Not everyone made it to the summit in the end, but everyone reached their personal summit. The participants had an unforgettable experience together. And they also raised € 12,345 for three lifestyle events.

Curious about the experiences of some of the participants? Watch the film and join them at the summit of the Grossglockner, via our Vimeo-channel: vimeo.com/863487782. The film is in Dutch. We are planning to add a version with English subtitles shortly.

Barbara Davidson,
Crohn & Colitis NL

Czech Republic

A Successful Patient Conference on Gastrointestinal Health in Karlovy Vary

In the enchanting setting of Karlovy Vary, a renowned spa town, the second Patients' Conference on Gastrointestinal Health took place on Thursday, 24 August 2023. With more than 50 attendees, the event proved to be a success, continuing its legacy of providing valuable insights and information to individuals seeking to understand and manage issues related to inflammatory bowel diseases (IBD) and benefits of spa treatment.

The conference was inaugurated and moderated by Ing. Martina Flekalová from the Czech patient organisation Pacienti IBD. The gathering commenced with an introduction by MUDr. Blanka Zbořilová, who delved into the intricacies of inflammatory bowel

disease. MUDr. Stanislava Maulenová directed attention towards the therapeutic potential of spa treatments for IBD. Subsequently, MUDr. Natalia Lakshina showcased the possibilities of rehabilitation and relaxation exercises tailored to patients.





One of the questions explored during the event was, “How do various foods impact individuals with IBD?” This question was answered by Ing. Veronika Hanzlíková. On a slightly different note, JUDr. Michal Sýkora shed light on the significance of travel insurance for patients dealing with IBD, addressing a topic of practical importance for many attendees. Wrapping up the conference, Bc. Lenka Slabá, a representative from the hosting organisation Pacienti IBD, shared insights about the organisation’s activities planned for the ongoing year.

Adding an element of holistic well-being, the attendees also engaged in a morning yoga session on the following Friday, setting the tone for the day. In the evening, a bowling session brought everyone together for a night of camaraderie and fun.

The interest and participation witnessed during the conference were truly heartening, reflecting the growing importance of such events in the patients community. As the echoes of this year’s Karlovy Vary conference resonate, there is an optimistic anticipation that this tradition will endure, fostering knowledge exchange and empowerment for individuals living with IBD.

Lucie Lašíková
Pacienti IBD

EMBRACE LIFE

Celltrion Healthcare will continue its innovation to promote better and happier lives for humanity.



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

United Kingdom

Little Things Can Mean A Lot: Understanding Crohn's and Colitis

Crohn's & Colitis UK's new campaign helps family and friends feel empowered to support their loved ones with Inflammatory Bowel Disease.

We all know that a diagnosis of Crohn's or Colitis can be life-changing, not just for the patient, but also for those closest to them. More than 500,000 people in the UK are living with Crohn's and Colitis, and there are millions more who are trying to learn more about Inflammatory Bowel Disease so that they can support them in their everyday lives. They often contact Crohn's & Colitis UK to find out what more they could be doing to help.

As one of our supporters put it: "Sometimes I feel helpless knowing there is nothing I can do to take my partner's Crohn's symptoms away. I try to make her as comfortable as I can and distract her from the pain. I always offer to run her a hot bath, make sure she is hydrated and has all her medications available. It is my job to be the support she needs."

Stories like this prompted us to launch our "Little Things Can Mean A Lot" campaign, aimed at more than 12 million people in the UK who are closely-connected to those with Crohn's and Colitis. The purpose is to drive awareness of the charity and remind those who are in that supportive role that, although there are no "quick fixes" or cures for IBD, there are small things you can do which, if they work, can make a big difference. Crucially, it reassures them that they are not alone, and we have many resources to help them as well as their loved ones who are living with a diagnosis of Crohn's or Colitis.

We have promoted the campaign with a mix of radio, Spotify, and podcast adverts, as well as posters in motorway service stations across the country. We have also featured real-life stories in the press and on social media.

CROHN'S & COLITIS UK

LITTLE THINGS CAN MEAN A LOT

You can't stop the flare-up that keeps them awake for hours. But you can bring them a hot water bottle and a bunch of flowers.

You can't shorten the drive home when they don't feel their best. But you can build in some pit stops, loo-breaks and rest.

You can't boost their energy or know what's on their mind. But you can listen with care and give them space to unwind.

The truth is, you can't take their pain away. But in these little ways, you can show up for them today.

Find more little things you can do to help someone with Crohn's or Colitis.

Visit crohnsandcolitis.org.uk/littlethings

Scan

Registered charity in England and Wales Number: 1117149, Scotland Number: SC038652

All our campaign activity directs people to a section on the charity's website, where they can find practical tips and information compiled by Crohn's & Colitis UK's expert Knowledge and Information team.

Finally, we are asking our supporters to share their "little things" on social media. The feedback we have received is wonderful and encouraging, showing that this campaign, although in its infancy, is already having a big impact.

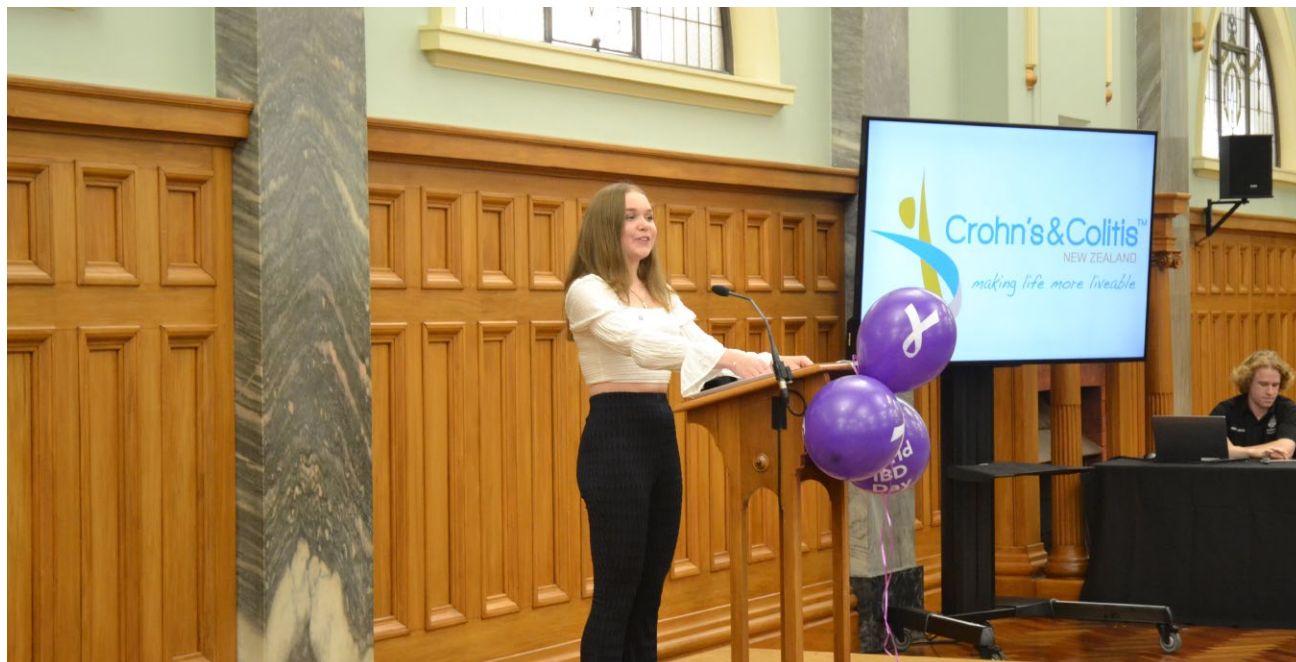
Geraldine Cooper,
Senior Media Lead, Crohn's & Colitis UK

New Zealand

Embracing the Blessings of Living with IBD: Highlights from World IBD Day

This year's World IBD Day event in New Zealand took place at the Grand Hall in New Zealand's Parliament. Rather than highlighting the hardships of living with IBD, our World IBD Day committee decided instead

to view these diseases from a different perspective. We asked our members to share their personal stories about the "unexpected blessings" of living with these chronic illnesses.



Nicole Thornton, CCNZ Ambassador addresses the crowd



Belinda Brown, CCNZ CEO; Hon Dr Ayesha Verrall, NZ Minister of Health; Dr Richard Stein, CCNZ Chair

This year's World IBD Day event in New Zealand took place at the Grand Hall in New Zealand's Parliament. Rather than highlighting the hardships of living with IBD, our World IBD Day committee decided instead to view these diseases from a different perspective. We asked our members to share their personal stories about the "unexpected blessings" of living with these chronic illnesses.

Attendees were welcomed to explore the Grand Hall adorned with quotes penned by IBD patients, their friends, and family members from all corners of New Zealand. These narratives shared personal insights into their unique blessings or silver linings that arose from living with conditions like Crohn's and Ulcerative Colitis.

Annually observing World IBD Day carries immense significance. The event usually provides a platform to address the challenges presented by IBD. Our event on 19 May gave patients the opportunity to present a lesser-acknowledged aspect of IBD—the blessings and achievements that come in the midst of sickness and pain.

The Honourable Dr. Ayesha Verrall, the New Zealand Minister of Health, graciously hosted the event, delivering the opening speech. Her words were followed by a series of speeches delivered by various IBD representatives, each sharing the blessings they have encountered throughout their journeys with this chronic condition.

Following the speeches, food platters and beverages circulated through the room. Soon the hall reverberated with animated conversation, occasional laughter, and exchanges of personal stories that highlighted the numerous blessings that accompany life with IBD.

To all members of the IBD community, let us continue to cherish 19 May as our annual day to celebrate our infinite resilience, courage, and the unique blessings that unite us in our journey.

Here are some representative excerpts:

"IBD has shown me that I can always create light in darkness. – Nicole Thornton"

"I have learnt to take life one day at a time as you'll never know what tomorrow could bring."

"IBD has taught me to be resilient, to show discipline, and to appreciate the small joys in my everyday life."

"A strong, clear, wonderful memory I have is dancing together at 4am in the hospital room and talking late at night."

"Having Ulcerative Colitis has made me a more compassionate, attentive and patient-centred doctor. My ongoing IBD journey keeps me humble."

Nicole Thornton,
CCNZ Ambassador

Founder of Crohn's and Colitis New Zealand Trust Steps Back After 13 Years

Crohn's and Colitis New Zealand Charitable Trust came into existence in February 2010, thanks to the vision and determination of Brian Poole, QSM. Assisted by a small Board and his wife, Janet, Brian embarked on a journey to make a difference in the lives of so many individuals with IBD.

To some of you who have been part of the IBD community for some time, Brian's name is probably familiar as he represented CCNZ at EFCCA General Assemblies over the years.

Now, after 13 years, Brian Poole, founder and past chairman of CCNZ, has made the decision to take some well-deserved time for himself.

We extend our heartfelt gratitude to Brian for his support of patients, their families, medical professionals, and all those affected by IBD. Through his efforts, he has

forged a sense of community and made "life more liveable" for so many people.

While Brian is stepping back from his roles on the CCNZ Board, we are pleased to announce that he will continue to contribute his expertise as a member of our National IBD Card Working Group.

We would like to thank Brian for his remarkable contributions and dedication. His impact on the IBD community is immeasurable, and we are so grateful for everything he has accomplished. Brian's legacy will continue to shine through the ongoing support and advocacy work of our current Board.

Belinda Brown,
CEO of CCNZ

Brian Poole, Founder and past Chair of CCNZ



France

New Leaders and New Headquarters for AFA Crohn RCH France

2023 is a year of many changes for Afa, the French Crohn's and Ulcerative Colitis Association.

Chantal Dufresne stepped down after 12 years as President at the 2023 General Meeting in March. Corinne Devos has been a volunteer at Afa for 15 years and is the new President with Vice-President, François Blanchardon, a long-term volunteer as well. Corinne has served in many missions from administrative tasks as a starter to active listening to a major role in "ETP" Therapeutic Patient Education, having also served as Regional Delegate of the Paris region. She has also collaborated in many institutional missions as a member of the Board.

She has gotten to know who and what make AFA's DNA. She served as Vice-President for several years until 2018 when she became particularly committed to Afa's Therapeutic Patient Education Program, where specially trained Patient-experts help patients and their close family and friends to learn and use their capabilities in self-esteem to become independent and able to better manage their illness.



François Blanchardon & Corinne Devos

Now a new team is at work and Corinne can count on François Blanchardon, Vice-President, Marie-Hélène Ravel, Secretary, and Bastien Corsat, Treasurer and Afa's delegate to EFCCA along with the 13 other members of the Afa Board.

Besides the new Board of Administrators, Afa also has a new CEO, replacing Alain Olympie who retired after 18 years instilling growth and development and efficient management in Afa.



Anne Buisson, new Afa CEO

Many EFCCA and ECCO members know Afa's new Managing Director, Anne Buisson, who took office at the beginning of 2023. Anne is the most knowledgeable of the history of Afa as one of its earliest employees. Starting out as a very young assistant, she has mastered the art of working with all the IBD medical staff in France and in Europe who have been responsible for the advancement of IBD medicines and treatments for the last two decades and more. She has raised awareness to enable doctors to recognize the patient as the centre of decision making. She is a dynamic advocate in discussions with the French Ministry of Health and the Social Security decision makers.

We congratulate our new Afa Leaders, and we wish them many more years in the Fight Against IBD.

And finally, as to mark these transitions, new Afa headquarters were inaugurated in July moving to Paris 11th, 15 rue de la Forge Royale, in Paris Centre, in the Bastille district, near the Gare de Lyon. These new quarters on a street side ground floor are more

accessible and inviting for patients and their family and friends. The new offices will also accommodate meetings with the teams of volunteers in the Paris Region.

If you happen to be in Paris, don't hesitate to come over and visit!

Madeleine Duboé
Afa Crohn RCH France

Brazil

IBD Brazil advances in the fight for public IBD policies

Meeting in the Federal Senate with the team of Senator Flávio Arns marks an important step for the approval of draft bill 5.307/2019, aimed at the institution of “Purple May”.

In a significant milestone for the promotion of Brazilian public health, DII Brasil (IBD Brazil) an organisation that has been dedicated to the cause of Inflammatory Bowel Diseases (IBD), announces new advances in relation to draft Bill 5.307/2019. On Wednesday, September 13, 2023, the president of IBD Brazil, Patrícia Mendes, and the director of government relations, Ilso Ronchi Junior, met in the Federal Senate with the team of Senator Flávio Arns, an important ally in the fight for improvements in health policies.

The draft Bill, originally presented by Federal Deputy Domingos Sávio, aims to institute the “Purple May”, a month dedicated to raising awareness about IBD, such as Crohn’s Disease and Ulcerative Colitis. The initiative seeks not only the most effective dissemination of these conditions, but also a faster diagnosis and easier access to laboratory and imaging tests by the Public Health System (SUS).



After being approved by the Health Commission and the Constitution and Justice Commission in the House of Representatives, the project reached the Federal Senate in August of this year (2023), where it still must be processed to be approved by the corresponding Commissions.

Senator Flávio Arns, known for his work in defence of minorities and people with rare diseases, was highly receptive to the cause. The IBD Brazil team requested him to follow the processing of the project in the Senate and also asked for the 1st national public hearing to discuss the relevance of the issue. “The positive reception by the senator and his team renews our hopes,” says Patrícia Mendes, president of IBD Brazil.

She detailed the importance of the new partnership. “We have come a hard way so far, facing several bureaucratic and social obstacles. However, we are

firm in the goal of moving forward and seeing this law finally approved, bringing dignity and quality of life to those who live with IBD in Brazil. Therefore, we always count on the support of partners”

With this news, IBD Brazil renews its optimism and hopes that, in a next edition of EFCCA Magazine, we can already bring new information about the implementation of this much-needed law for the country.

Ivanete Damasceno
Translation: Thiago Carvalho



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.

GM-36250

Lilly

Ireland

Crohn's & Colitis Ireland's 2023 Highlights

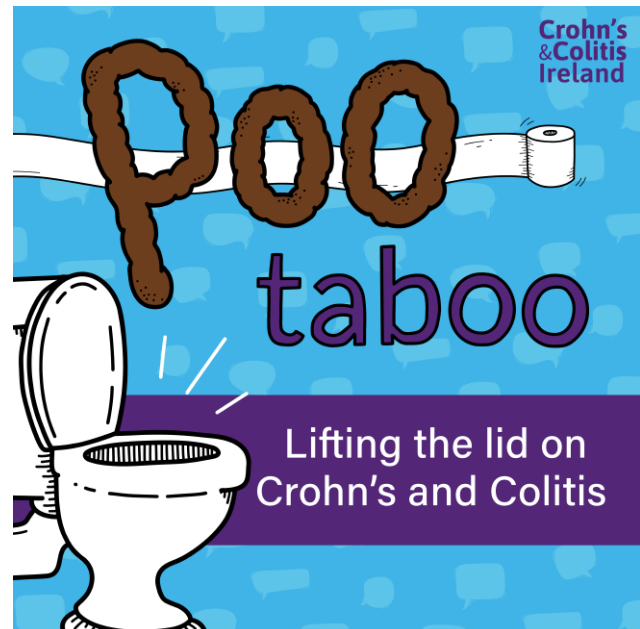
This year has been an exceptionally busy year for Crohn's & Colitis Ireland.

Crohn's & Colitis Ireland launched a new campaign as part of World IBD Day called the "Poo Taboo" which aims to encourage people to recognise Crohn's Disease and Ulcerative Colitis symptoms, and not be embarrassed to get checked out. The campaign featured a symptom checker where in just 30 seconds the respondent would know what to do, including whether to contact their GP and what symptoms to highlight during the appointment. Within the first 3 months of the symptom checker the response rate had exceeded the initial target with 12,999 responses. 96% of respondents, 12,444, were told to speak with their GP in the next few days as they were experiencing IBD symptoms.

From the campaign IBD was mentioned in over 90 various media outlets in May 2023, including national radio, tv, and print, digital, podcasts and local radio and print.

On Thursday 25 May, Crohn's & Colitis Ireland presented to Members of Parliament and Senators in Dáil Éireann on what it is like to live with IBD in Ireland and the support we need to live well.

Speaking on the panel was Prof. Colm O'Morain HSE/ RCPI Clinical Lead in Gastroenterology & Hepatology. Emeritus Professor of Medicine, Trinity College Dublin. Gastroenterologist, Tallaght University Hospital, Mary Hamzawi, Clinical Nurse Specialist, St. Vincent's Hospital & Crumlin Hospital, Victoria Spillane, CCI Board member and IBD patient and Amy Kelly, Head of Communications and IBD patient, CCI.



Separately this year, CCI has also launched a new bi-monthly online support meeting called CCI Connect for people diagnosed with IBD, held patient days, team building and fundraising events such as a 150ft abseil from the iconic landmark Croke Park.

We are currently putting exciting plans together for 2024 as we prepare to celebrate our 40th anniversary!

Amy Kelly
Crohn's & Colitis Ireland



We innovate in gastroenterology
so patients can live in the moment



Addressing Urgent Patient Needs for Cross-Border Clinical Trials Access in Europe

In this interview we are talking to Ingrid Klingmann, Chairman of the European Forum for Good Clinical Practice (EFGCP) and co-founder of the EU-X-CT Initiative to learn more about access to cross border clinical trials.

What led to the creation of the EU-X-CT Initiative?

The European Forum for Good Clinical Practice (EFGCP) is a not-for-profit organisation that was created in the early nineties with the idea of working on practical solutions for all types of problems in clinical trials and through our collaboration between Pharma companies and ethics committees we aimed to find better ways of reviewing clinical trials and jointly improving the protection of patients.

In recent years we have been discussing with the European Federation of Pharmaceutical Industries and Associations (EFPIA) the problem of cross-border access to clinical trials, especially in rare and life-threatening diseases, and how various organisations claimed that it didn't work.

EFPIA supported our consortium consisting of EFGCP, KU Leuven, Patvocates, and EORTC with an unrestricted grant to systematically investigate this issue in surveys and interviews with patient



representatives, regulators, sponsors, investigators, patient organisations, and several experts relevant to clinical trials and patient access.

As a result of these findings we reached an agreement with EFPIA to establish a roadmap initiative to cross-border access to clinical trials, aiming to engage as many stakeholders as possible in finding solutions on a European and national level. Currently, this Roadmap Initiative has over 50 members from all involved stakeholder groups from 19 countries.

What are the current challenges for a patient who wants to participate in a clinical trial in another EU country?

We have a European directive that guarantees EU patients access to healthcare in another country. However, this directive, concerning cross-border access to healthcare, does not address the specific conditions of clinical trials -and there are quite a few of these conditions-.

The findings were clear: there is an **urgent need for patients who have no other treatment alternatives** to access trials in other countries. However, the obstacles are substantial because there is no infrastructure in Europe that supports such access.

For instance, while the sponsor covers the specific trial expenses, they do not cover the necessary hospital stay if it is part of the standard of care and routine treatment, along with routine diagnostics; only the study-specific costs are accounted for. Moreover, there is no guarantee of compensation for travel expenses, and in severe cases, a caregiver often needs to accompany the patient.

Additionally, if the treatment duration is longer, this requires patients to reside in a location, such as an apartment, for several weeks or even months. This may present challenges for schooling opportunities for paediatric patients. Patients also find it difficult to identify ongoing trials and their locations. And the costs for travelling to the site, just to learn that they are not suitable for the trial, are not covered by the sponsor or any healthcare system.

Surprisingly, when it does happen, i.e. accessing a clinical trial in another EU country, it tends to happen in Western European countries, with for example individuals from France participating in trials in Germany or Denmark, often having to cover all expenses themselves. This means it is accessible only to the wealthy and those who can afford it. The reality is that desperate, less wealthy patients resort to selling their houses, pooling their family's resources, just to have the opportunity to take part in a clinical trial.

What kind of practical solutions are you exploring?

We want to identify the current available options in different countries, compile experiences, and highlight best practices. With this in mind, we are creating a freely accessible database website with information about the legal landscape and financial options in each country. This includes information about practices of healthcare payers and insurance companies, reimbursement policies and other financial aspects in each of the European countries.

We will also gather information and experiences from investigators. This includes investigators who have successfully enrolled patients from other countries and

“The reality is that desperate, less wealthy patients resort to selling their houses, pooling their family’s resources, just to have the opportunity to take part in a clinical trial.”

those who have attempted but failed. We will investigate the situation for academic and commercial sponsors, and finally, but not least, of patients. We aim to launch a comprehensive survey addressed to patients and patient organisations to share their experiences and unmet needs as concerns cross board access to clinical trials.

How about the regulatory framework?

On the regulatory front, we have limited options: we attempted to collaborate with the European Commission, but they were unwilling to amend the access to healthcare directive to accommodate the specific needs and aspects of clinical trials.

Of course, we are not giving up on legislative efforts and we have approached DG Research and Innovation and we are also identifying EU-funded projects, such as for example PRIME-ROSE that focus on precision medicine, enabling them to identify patients with specific genetic traits who could benefit from a drug being investigated in clinical trial sites in countries A, B, and C, while the patients are in country X. These patients have no other treatment alternatives, so collecting information and providing assistance to them is crucial.

What are the next steps?

Given the evolution of clinical research, there is an increasing need to facilitate such research across borders. Many initiatives aimed at enhancing Europe's clinical research landscape face challenges due to this current lack of infrastructure and we are joining forces with various initiatives and activities to coordinate our efforts.

Our database website with currently available options for access to cross border clinical trials will be launched by the end of this year and on 18 January 2024 we are organising a public workshop in Brussels to present what we have discovered so far. The aim of the workshop will be to gather insights from various stakeholders across Europe to learn about their recommendations for the way forward and their experiences.

Additionally, we want to understand what is needed to achieve sustainability of the EU-X-CT Initiative because, after these initial two years, the database website will need continuous updates, expansion, and further investigation. It requires a specific infrastructure to ensure that this tool remains useful over time.

We are currently exploring whether this could be linked to activities of the European Commission,

which might have resources to sustain this effort, or if any organisation could fund a project to ensure its continuation for at least the next five years.

However, our ultimate long-term goal is to bring about legal changes that benefit patients. Therefore, we will persist in our efforts at the EU level.

Any further comments?

One thing that motivates us is the realisation that if we don't undertake this work now, no one will do it in the next ten years. There is no political or legal solution in sight; it simply will not happen. While everyone may voice their complaints, achieving real change requires a critical mass.

This critical mass has been achieved across various stakeholder groups within our consortium and has generated the momentum needed to truly improve the situation. We have many enthusiastic individuals who invest an enormous amount of effort to drive this initiative forward. Maintaining this level of enthusiasm will be crucial. I urge people to join and support us in this effort.

Act4Biosimilars: The Action Plan and Americas Deep Dive Report are now live!

Act4Biosimilars is a global initiative that aims to increase patient access to biologics by facilitating greater Approvability, Accessibility, Acceptability and Affordability (the 4As) of biosimilars.

The initiative is led by a multidisciplinary Steering Committee and has a [Mission](#) to increase global adoption of biosimilar medicines by at least 30

percentage points in 30+ countries by 2030. Earlier this year, Salvo Leone, EFCCA Chairman joined a virtual meeting with key stakeholders from across the healthcare space to preview the Act4Biosimilars Action Plan, a global roadmap to empower and equip stakeholders with the strategies, tools and activities needed to enact change and contribute to achieving the Mission.

On 15 June 2023, the initiative launched the [Action Plan](#) alongside the first in a series of Deep Dive Reports focussed on the Americas, which brings into focus the challenges hindering biosimilar adoption across the region. The Action Plan features 12 key initiatives that offer the biggest opportunities to accelerate biosimilar adoption across the 4As, and provides actionable steps designed to help local stakeholders improve patient access to biologic medicines.

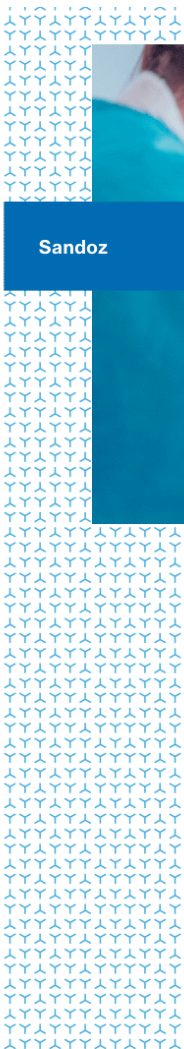
The [Deep Dive Report](#) contains country-specific insights spotlighting key challenges, such as interchangeability regulatory guidelines in the United States and the prevalence of single-winner tenders in Mexico and Brazil.

Progress is being tracked via the Act4Biosimilars [Impact Index](#) which assesses 30 initiative-tracked countries and the favourability of the local environment towards biosimilars under each of the 4As. The

index will be updated every two years to ensure local stakeholders are kept up to date on the most critical issues preventing biosimilar adoption and how change is supporting better adoption country by country.

As an immediate next step, the Steering Committee is working with local stakeholders across the Americas to implement the Action Plan and identify and address the key challenges holding back wider biosimilar adoption. This will be followed by a series of regional rollouts with Europe in Q4 2023, the Middle East & Africa in Q1 2024, and Asia Pacific in Q2 2024.

If you're passionate about expanding patient access to life-changing biologic treatments, visit [Act4Biosimilars.com](#) and follow LinkedIn and Twitter to learn how you can get involved as a partner or even a Steering Committee member, and download the Action Plan if you're ready to make a change!



Pioneering Access for Patients

Modern medicine has changed the world — but it has not yet solved the problem of global access to healthcare.

That is why all Sandoz associates share one common Purpose: To Pioneer Access for Patients. Our overarching goal is to find novel ways to help more people around the world access high-quality medicines.

It all starts with the core of our business: providing affordable, high-quality off-patent medicines in over 100 countries, in order to improve access and help to ensure the sustainability of global healthcare. Sandoz medicines already reach more than 500 million patients every year.

But that is not enough — we know we can do more, and we are determined to do so. Because every patient who cannot access the medicine they need is a patient too many.

To learn more visit www.sandoz.com

Blog Shitzusjes – Summer stress

By Daphne van de Shitzusjes

Daphne and Esmée are sisters who both have ulcerative colitis. They both live with their partners in the east of the Netherlands. Daphne is Seppe's mother and has been forced to stop working due to her illness, so she is now looking for new meaning and hobbies in addition to caring for her family. Her disease is difficult to control. Esmée is studying to become a Dutch teacher and is doing an internship at a secondary school. She has been carrying her disease for a number of years and it is reasonably under control, but never completely absent.

Together the sisters founded the [Instagram Shitzusjes](#) where they share stories and experiences about their illness, which has similarities, but also certainly has differences. They come from a family where IBD is common, but where there is also a lot of humor and conviviality. They therefore like to view their illness with humor and optimism.

The end of the school year is in sight, the holidays are already knocking on the door and... I Still Have. A Lot To Do. I am going to fly for the first time since my diagnosis and that brings excitement. Just ask the gastroenterologist for an explanation, visit the pharmacy for my medication overview, call the airline to see if everything is okay. But all those things that need to be done now form a to-do list that scares me. I notice it in my body, I am more agitated, my breathing is restless and shallow and I have that ominous feeling all day long that I am forgetting something important.

It's a form of stress I can avoid all year round; during the yoga weekend I decided that I would no longer get carried away.

To top it all off, my body says stop. The room spins when I wake up at night. Still in the morning. Dizzily, I walk to the bathroom and plop down on the toilet. This won't happen today. I reschedule my appointments for that day. Something that I can normally tolerate, but this time I'm disappointed that my body is not cooperating. Because I still HAVE to do everything.



When I visit my psychologist a few days later, she opens a drawer full of good tips: focus on time instead of on the task. Do something for 20 minutes and then rest for 10 minutes. Leaf through a magazine, stare out the window. At home I start with good courage. During my first 10 minutes of rest I suddenly realize: I want too much. I often say it to friends who have a busy life:

“During my first 10 minutes of rest I suddenly realize: I want too much”

“The feeling of being busy is a lack of courage to make choices”. Maybe I should listen to myself. I start my days again with yoga, cancel unnecessary appointments and take an afternoon nap where possible. Going on holiday should also remain fun.



In the meantime, I sometimes stare outside and look forward to the plane, because when I'm on that plane, these weeks will be over. Then I made it. Two wonderful weeks of sun, sea, beach and nothing. Fortunately, I am not a teacher, like my sister Esmée. Because then you have even more things to arrange and even write this blog.

Daphne van de Shitzusjes
Instagram: @shitzusjes

Salvatore Aranzulla: My secret? Motivation, passion, and discipline

Despite a diagnosis of Ulcerative Colitis, the famous entrepreneur and blogger who founded Italy's most consulted technology portal at the age of 12 has never stopped, one goal after another. The last one? Becoming a dad.

Salvatore Aranzulla is a super well-known name in Italy. In his blog, you can find all the solutions to your technology doubts, and that's why Italians use his blog very often, at least once in their life.

“If before we were two, now we are three”. With these simple words, Salvatore Aranzulla announced on Instagram his paternity.

“I couldn't stand up anymore”

Salvatore moved from Sicily to Milan to study Economics and Management. *“I started feeling sick just a month after my arrival in Milan: more than 15*

diarrhoea episodes with blood. I thought it was due to a poor diet, since I consumed a lot of take-away food. December arrived but the situation did not improve: I was struggling to stand up because of my weight”.

Back in Sicily for Christmas, he fainted the day of his arrival. At the hospital doctors tried a colonoscopy, but unsuccessfully: the risk of perforation was too high. Salvatore had to be hospitalised until February.

The importance of physical activity

Back in Milan, doctors found a solution and now he is followed by doctor Flavio Caprioli. Motivation and work passion have always pushed him to never stop. *“I have a pedometer and every day I force myself to walk, and I also took gym seriously. This is crucial for body and mind”*. In his apartment in Milan, he has an equipped room where he keeps fit every day. All this, without forgetting the importance of nutrition.

Pain teaches you a lot...

He didn't stop to travel, his passion. A city that he likes a lot is Tokyo with a perfect organisation, like his life. Salvatore defined his pain as a compass for moving in the present. *"Only when you have been ill can you truly appreciate the joy of feeling good"*.

And this is the joy that appears on his face after the announcement about his paternity. The profession has a decisive weight for him, but we are sure that his greatest success is there with him, and he is lovingly holding it in his arms.

"Physical suffering has never impacted my work. Of course, sometimes there is tiredness, but I manage it"



Together we are living innovation

We don't think it is good enough that countless people affected by immune-mediated 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.

Driving forward advances in treatments for IBD patients

This article is commissioned by Celltrion. The content presented here is intended for informational purposes and is based on the study titled “Subcutaneous Infliximab Monotherapy Versus Combination Therapy with Immunosuppressants in Inflammatory Bowel Disease: A Post Hoc Analysis of a Randomised Clinical Trial”. To learn more about the study, you can explore full details [here](#).

This year is a historic milestone in biologic therapies, as it marks a decade since the European Medicines Agency (EMA) approved the world’s first monoclonal antibody biosimilar infliximab.[1]

With over two decades of use in clinical practice[2], infliximab has been a cornerstone in managing IBD, encompassing both Crohn’s disease (CD) and Ulcerative Colitis (UC).[1] However, as with any medical advancement, there’s an ongoing pursuit to continue improving treatment and maximising patient quality of life.

Subcutaneous monotherapy: exploring a new possibility

The advent of subcutaneous (SC) infliximab ushered in possibilities in IBD care. Administered via an injection rather than intravenous (IV) infusion, it offers patients a convenient and accessible treatment option. Historically, intravenous infliximab was typically combined with immunosuppressants such as azathioprine, 6-mercaptopurine, or methotrexate (combination therapy) to optimise its effectiveness.[3]

While this approach is particularly beneficial for moderate to severe IBD patients who have not received immunosuppressants and biologic/ TNFi (tumor necrosis factor inhibitor) treatment before, concern about the potential increased risk of adverse events from long-term use such as infection relative to combination therapy with immunosuppressants as was previously reported in studies considering the IV infliximab formulation, has prompted further research.[4]

Whether the advantages of combining an immunosuppressant with IV infliximab also apply to SC (subcutaneous) infliximab treatment, has not been addressed so far. Thus, exploring the potential of subcutaneous infliximab as the sole treatment, known as monotherapy, could have significant benefit for IBD patients.[3]

Subcutaneous infliximab monotherapy may potentially address these worries and open up new possibilities for patients. However, this transition necessitates a deep understanding of its effectiveness and implications. To continue to grow the clinical evidence base, a recent study[3] was undertaken to compare the benefits observed with combination therapy in intravenous infliximab to its subcutaneous counterpart.

Study methodology

Pivotal trial (CT-P13 SC 1.6):

In the pivotal trial, patients with active Crohn’s disease or Ulcerative Colitis who had not received treatment before initially received intravenous infliximab at the start and in week 2. In the sixth week, patients were randomly assigned to one of two groups: one receiving subcutaneous infliximab every 2 weeks, and the other continuing with intravenous infliximab every 8 weeks until the switch to subcutaneous administration at week 30.

Post hoc analysis:

Among these patients, the post hoc analysis focused on 66 patients randomly assigned to subcutaneous infliximab, 37 of whom received subcutaneous infliximab monotherapy (without a concomitant immunosuppressant) and 29 received subcutaneous infliximab combotherapy (in combination with an immunosuppressant).

Patient impact

The findings of the study offer an encouraging picture for IBD patients and healthcare providers alike. Clinical outcomes were comparable with subcutaneous infliximab monotherapy and combotherapy with immunosuppressants in patients who had not received treatment before, providing initial evidence for its viability as a treatment option.

These results could be regarded as initial evidence that subcutaneous infliximab combotherapy is not superior to subcutaneous infliximab monotherapy, paving the way for patients with Crohn’s disease or Ulcerative Colitis to have access to a potentially safer and equally effective monotherapy option. This development not only offers convenience but also underscores the importance of personalised treatment plans that cater to individual patient needs.

Charting a new course

The evolution of IBD treatments has been characterised by continuous innovation, and the introduction of subcutaneous infliximab marks a pivotal moment in this trajectory. As we celebrate a decade of advancements since the approval of the monoclonal antibody biosimilar infliximab in Europe, we also herald in a new possibility where monotherapy options are within reach for patients with active Crohn’s disease or Ulcerative Colitis. This study not only bridges a knowledge gap but may potentially open doors to a future where personalised and effective treatments define the standard of care for every IBD patient.

References

1. European Medicines Agency Summary of Product Characteristics (SmPC), Remsima. Available at: https://www.ema.europa.eu/en/documents/product-information/remsima-epar-product-information_en.pdf
2. Billiet T et al., Prognostic factors for long-term infliximab treatment in Crohn’s disease patients: a 20-year single centre experience. *Aliment Pharmacol Ther*, 44: 673-683. <https://doi.org/10.1111/apt.13754>
3. D’Haens G et al., Subcutaneous Infliximab Monotherapy Versus Combination Therapy with Immunosuppressants in Inflammatory Bowel Disease: A Post Hoc Analysis of a Randomised Clinical Trial. *Clin Drug Investig* 43, 277–288 (2023). <https://doi.org/10.1007/s40261-023-01252-z>
4. Louis E et al., Withdrawal of infliximab or concomitant immunosuppressant therapy in patients with Crohn’s disease on combination therapy (SPARE): a multicentre, open-label, randomised controlled trial. *Lancet Gastroenterol Hepatol*. 2023;8(3):215-227. doi:10.1016/S2468-1253(22)00385-5

Patient reported survey results reveal substantial differences in disease management and health care experiences of people living with UC based on social, mental health and demographic factors

This article is a lay summary of a recently published research paper, called *“Health Care Disparities, Social Determinants of Health, and Emotional Impacts in Patients with Ulcerative Colitis: Results from a Global Ulcerative Colitis Narrative Patient Survey”*.

The research paper was published on 10 June 2023 in the Inflammatory Bowel Diseases medical journal, and is a “post-hoc analysis” of an earlier research article.

The earlier research article was called, “Ulcerative Colitis Narrative Global Survey Findings: The Impact of Living With Ulcerative Colitis-Patients” and Physicians’ View’ and was published in 2021. The aim of the survey was to identify the impact of UC in patients

and compare perceptions of UC burden and the management of their disease. The original research paper surveyed 2,100 people who reported living with UC and 1,254 physicians across 10 countries, between August 2017 and February 2018.

What was the purpose of this post-hoc analysis?

This post-hoc analysis looked at the original research paper and conducted a new analysis to see how income, employment status, educational level, age, sex and mental health might unfairly impact the disease management, health experience and quality of life of people living with UC.

The post-hoc analysis looked at a subgroup of the patients in the original research (n=1,000) from 5 of the original 10 countries, including the United States, Canada, Japan, France, and Finland.

What did this post-hoc analysis find?

That there are substantial differences in disease management and health care experiences of people living with UC based on factors such as income level, employment status, educational level, age, sex, depression, and anxiety.¹

“A ‘post-hoc analysis’ is a deeper dive of the data after the original research has been conducted, to gain further insights from a different perspective. In this case, the analysis looked at health care disparities in Ulcerative Colitis (UC).”

Factors that may contribute to different health outcomes in patients with UC:

When looking at **income level**, low-income patients were **70%** less likely than high-income patients to have taken part in a peer mentoring program and **49%** less likely to have been referred to a UC education program to help manage their disease.¹ This suggests that low-income patients may be particularly vulnerable to lack of information and additional support.¹

Similarly, patients with low **educational** levels* were **41%** less likely than those with high educational levels to have reached out to patient associations/ organizations.¹

**In this analysis, low educational levels refer to high school degree or less (United States and Japan); high school diploma or less (France); graduated from secondary school or less (Canada) and matriculation examinations or less (Finland).*

Patients who were not **employed** were **42%** less likely to report being in “good/excellent” health than patients employed full time and those not employed were generally less likely to be satisfied with their medication.¹

Age also contributed to how patients managed their disease. Compared with patients aged 50 years or above, patients aged under 50 years were **81%** less likely to say they were not currently taking prescription medication for their UC and were **53%** less likely to say that reducing the need for prescription medication was important to managing their UC, compared with patients aged 50 years and older.¹

Male patients were **34%** less likely to be currently seeing their gastroenterologist (GI) than females.¹ Yet males were more likely to report that they had been hospitalised or had two or more UC flares in the past 12 months, than females.¹

Finally, when looking at **mental health**, patients who self-reported symptoms of depression were **59%** less likely to say that they were in “good/excellent” health, compared to those without.^{1*}

What can we learn from these results?

This post-hoc analysis of patients with UC identified substantial disparities in patient-reported assessments of disease management and health care experience, based on factors such as income level, employment status, educational level, age, sex, and mental health. This may help healthcare professionals to better understand the perspective of their patients and

address differences that could affect health outcomes, patient care, and quality of life.

Limitations of this analysis

Limitations of this analysis include a reliance on accurate recall by patients and their understanding of the questions surveyed, and that recruitment for the survey was based on self-reported diagnosis of UC, with no clinical disease activity assessment. Furthermore, while these results have been reported as global outcomes, the findings may not be applicable to all countries due to regional differences in healthcare systems, variable access to care, and cultural differences, among others.

**Presence of psychological comorbidity, such as depression, was self-reported via a survey question that asked patients if they had been told by a doctor that they had the condition.*

For more detailed information on this analysis and to read the full research paper, click on the QR code here:



This article was developed as part of Pfizer’s sponsorship of the European Federation of Crohn’s and Ulcerative Colitis Associations, and in collaboration with Isabella Grosu (Romanian Association of Patients with Stoma & IBD) and Tina Aswani-Omprakash (South Asian IBD Alliance).

Pfizer sponsored the “Global Ulcerative Colitis Narrative Patient Survey” and commissioned The Harris Poll to conduct the research and the statistical analysis.



References

1. Odufalu, F-D, et al. Health Care Disparities, Social Determinants of Health, and Emotional Impacts in Patients with Ulcerative Colitis: Results from a Global Ulcerative Colitis Narrative Patient Survey. *Inflammatory Bowel Diseases*, izad102, <https://doi.org/10.1093/ibd/izad102>. June 2023.

EFCCA routinely shares information from external partners aimed at promoting clinical trial awareness. The activities and content below are not affiliated with EFCCA. However, EFCCA invites you to browse through the below sponsored clinical trials that might be of interest to the IBD patient community.

Crohn's - who's in charge?

If your Crohn's disease is out of control, join a clinical study aiming to put you back in charge!

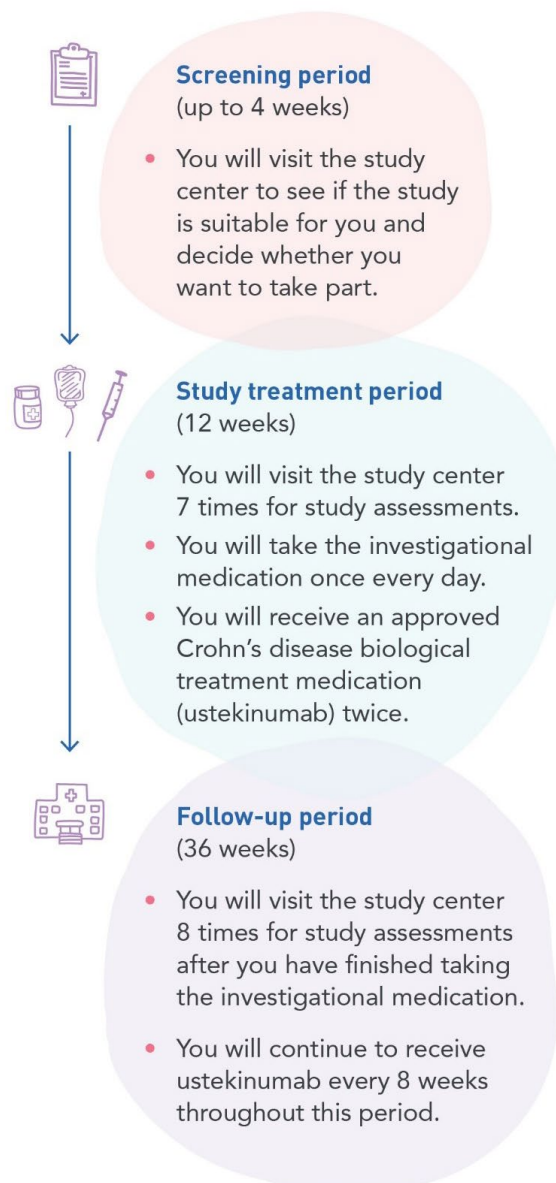
About InCharge

The InChargeStudy is a clinical research study that will include up to 76 people with Crohn's disease (CD). The study will look at how safe an investigational medication is and whether it works when taken with a CD medication (ustekinumab) that is already approved for use. The study is sponsored by Boehringer Ingelheim. You can find participating investigative sites at this website: www.clinicaltrials.gov using search term 1425-0003.

Why is this study important?

CD is a condition that causes inflammation in the digestive tract. There are multiple treatments available for people with CD. However, for many people with CD, these treatments do not work, only partly work, or stop working over time. Therefore, it is important to research new treatment options that work differently from the treatments that are currently available.

The investigational medication is a medication taken by mouth, which is a kinase inhibitor which is intended to blunt the inflammatory response to microbiome in the gut. It is hoped that blocking this protein will reduce inflammation in the intestines and lessen the symptoms of CD.



Who can take part?

You may be able to take part if you:

- are 18–75 years of age
- have moderate to severe CD
- have taken an anti-tumour necrosis factor antibody medication for CD that did not work well enough, stopped working, or had to be stopped because of side effects or for other reasons.



Disclaimer:

This trial-related material is approved by ethics committees and is officially published for the following countries: Czech Republic, Denmark, Germany, Italy and Poland.

The trial itself is approved and recruiting in the following countries: Belgium, Czech Republic, Denmark, Germany, Hungary, Italy, Netherlands, Poland, Spain and USA.

New Hope for Fibrostenotic Crohn's Disease Patients: The STENOVA AGMB-129-C102 Study

Introduction

If you or someone you know has been living with fibrostenotic or stricturing Crohn's disease, you're likely aware of the challenges it poses: the pain after eating, frequent diet modifications and the concern of maintaining body weight, intestinal blockages, cramping, and ultimately the need to undergo surgery. Moreover, the absence of any treatment option makes life even more difficult. However, there's promising news on the horizon - the STENOVA study by Agomab Therapeutics is testing a possible first new treatment for the fibrostenotic Crohn's disease community.

Objective

Fibrostenotic Crohn's disease is characterised by the formation of scar tissue (fibrosis) in the intestines, leading to narrowing and blockages. AGMB-129 is an oral capsule designed to treat this scar tissue locally in the gut with the aim to alleviate symptoms, improve patients' quality of life, and potentially reduce the need for surgery over time. This first study in patients will assess the safety of AGMB-129, study what the body does to drug (pharmacokinetics) and evaluate what the drug does to your body and associated disease (pharmacodynamics). Moreover, initial effectiveness of the drug will be assessed by monitoring symptoms improvement over the treatment duration.

Methodology

In this carefully designed clinical trial, participants will be randomly assigned to receive either AMGB-129 or a placebo (an inactive substance). 2 out of 3 participants will receive AGMB-129 and 1 out of 3 will receive a placebo. This double-blind approach ensures that neither the patients nor the researchers know who is receiving the actual treatment until the study has been completed, reducing bias on its evaluation. Patients are allowed to continue their current IBD treatment throughout the trial. The safety and activity of AGMB-129 will be compared against placebo over the 12-week treatment period.

Benefits to the IBD Community

The STENOVA AGMB-129-C102 study holds significant potential benefits for the IBD community, especially those suffering from fibrostenotic Crohn's disease. If the investigational treatment proves successful, it could lead to:

- **Improved Quality of Life:** Patients may experience reduced symptoms, less pain, and fewer intestinal blockages, allowing for a better overall quality of life.
- **Reduced Surgery:** If the treatment can prevent or delay the progression of fibrosis, it may eventually decrease the need for surgical intervention, which is the last resort for patients.
- **New Treatment Options:** This study represents a step forward in the development of targeted therapies for fibrostenotic Crohn's disease, offering hope for individuals who have exhausted existing treatment options.



Recruitment Criteria

To participate in the study, candidate patients must have a confirmed diagnosis of fibrostenotic Crohn's disease and meet specific eligibility criteria. The recruitment process will be conducted at multiple medical centres in the EU, US, and Canada.

Conclusion

The STENOVA AGMB-129-C102 study from Agomab Therapeutics is a ray of hope for individuals living with fibrostenotic Crohn's disease. Through rigorous research and clinical trials, this program aims to bring a potentially life-changing treatment to the IBD community. While there are no guarantees in clinical research, the STENOVA study may provide important clinical benefits in patients with this difficult to treat disease. If you or someone you know is eligible, consider participating in this study to contribute to the advancement of Crohn's disease treatment options.



EFCCA

European Federation of Crohn's
& Ulcerative Colitis Associations

EFCCA Contact Details

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

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

Chairman:
Salvo Leone
Salvo.leone@efcca.org

Honorary Secretary and
Vice President: Ciara Drohan
ciara.drohan@efcca.org

Treasurer:
Marko Perovic
marko.perovic@efcca.org

CEO: Luisa Avedano
Tel: +32 483 371 194
luisa.avedano@efcca.org

Head of Communication:
Isabella Haaf
Tel: +34 606 849 937
bella.haaf@efcca.org