

The background of the cover features large, flowing, organic shapes in yellow, dark blue, medium blue, and magenta. A white-bordered blue rectangle is centered in the upper half, containing the title text.

EFCCA

Annual Report

(March 2021 - March 2022)

EFCCA's Vision

Our vision is to find a cure for IBD.

As no cure has yet been found, the members strongly believe that our vision remains to find the cure for IBD.

EFCCA's Mission

Our mission is to improve the overall well-being of people affected by Crohn's Disease and Colitis, collectively referred to as Inflammatory Bowel Disease (IBD).

The word "well-being" is replacing the word "life" used in the previous mission, as it better reflects EFCCA's work. Both Crohn's disease and Colitis are placed in the mission sentence. "Ulcerative" is left out to make sure the mission also covers other forms of colitis, e.g. undefined colitis. Instead of "people with IBD" the members decided to refer to "people affected by IBD" as this covers also e.g. patients' families, friends.

EFCCA's Values

United We Stand

1. People: We believe that people are the focus of our efforts. We believe people make EFCCA and people are our greatest resource.

2. Unity: We are a community aiming at improving well-being of people with IBD and we believe that together we work better towards our mission and to support, learn and share with each other.

3. Integrity: We have strong principles of ethics, honesty, transparency and expect high ethical standards also from our partners. We will always follow through on our commitments and demonstrate the highest standards of personal and organisational behaviour.

4. Commitment: We are dedicated to make a valuable contribution to the well-being of people affected by IBD by fostering engagement, involvement, activism and to ultimately find a cure for IBD.

Our 4 strategic areas in which current activities are structured are:

1. **Networking**
2. **Awareness Raising**
3. **Advocacy**
4. **Empowerment**

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Foreword

2021 has been another busy and unusual year for EFCCA. With the on-going COVID-19 crisis we had to adapt many of our usual activities and at the same time provide new services aimed at presenting clear and timely information relating to COVID-19 and its aspects associated with IBD.

As a response we have been involved in several studies such as "Implementation and short-term adverse events of anti-SARS-CoV-2 vaccines in Inflammatory Bowel Disease patients: an international web-based survey" and "The effects of COVID-19 vaccine in patients with inflammatory bowel diseases" and have collaborated with the SECURE-IBD team to identify COVID-19 outcomes in IBD patients and evaluate the safety of IBD medications globally.

Despite these challenges we have managed to put attention to other strategic areas of our work plan. For World IBD Day 2021 we started a dialogue on the psychological impact of IBD on the well-being of people with IBD through our campaign #breakthesilence. By highlighting of what it is really like to live with IBD we aimed to give a better understanding to the public, health care providers and other stakeholders and to ultimately find solutions that will have a meaningful impact on a person's quality of life.

Another successful activity has been our EFCCA Academy. The Academy has been created with the aim to provide specialized training on issues important to the IBD patient community. In 2021 we saw two training programmes (on Clinical Trials and Youth representation) that delivered excellent insights and resources for our members.

In this report you will find further evidence of the tremendous work and achievements that EFCCA has made in the areas of empowering, awareness raising, advocacy and networking.



Salvo Leone EFCCA Chairman

And even though many of our activities have moved to the virtual realm, EFCCA has remained an important player in ensuring the voice of IBD patients is heard and promoting a patient centered approach amongst its stakeholders.

One reason for this success, of course, are our members. When we work closely together, when we talk to each other, brainstorm, gather ideas for projects, that's when we see our strength.

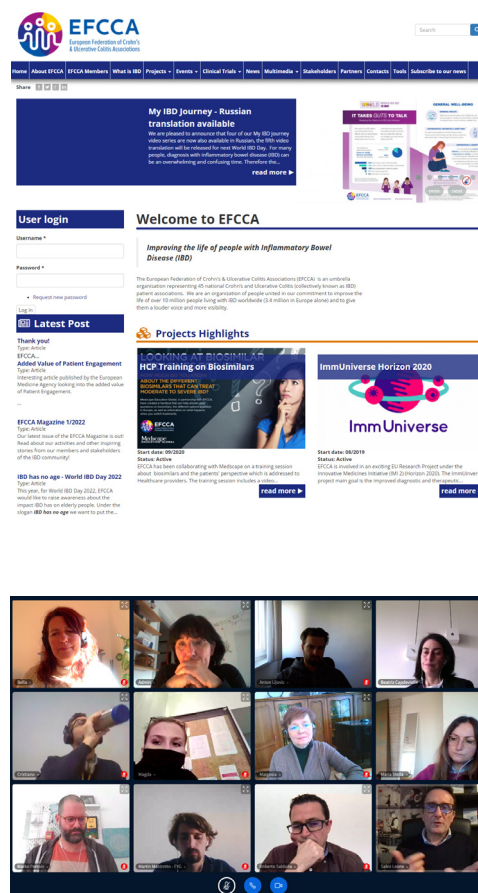
We all share a commitment to serve people living with IBD and to do our best to improve their quality of life. That's what brings us together and makes us who we are.

United We Stand,

Salvo Leone
EFCCA Chairman

The year in figures

- 62** events attended by EFCCA
- 50** delegates attended our second online General Assembly
- 44** IBD students trained through the EFCCA Youth Academy and the EFCCA Academy on Clinical Trials involving 32 IBD patient associations
- 6** online events organised by EFCCA involving over 200 participants
- 4** Patient Advisory Boards (pharma sponsored) including EFCCA representatives
- 4** EFCCA Executive Board meetings held in 2021/22
- 4** new patient associations joined EFCCA bringing our total membership to 45 associations
- 4** publications in scientific journals and
- 4** publications of the EFCCA Magazine



Digital Impact



61.412
facebook reach



6.817 70% women
30% men
facebook followers



39.916 visit
EFCCA website

Networking

Representing a relatively small disease group, it is vital that EFCCA develops and strengthens synergies and partnerships that are beneficial for all. We encourage and facilitate collaboration, exchange of information, knowledge and practices, and the promotion of international activities. We strive to collaborate with different stakeholders to establish and strengthen relationships to build a stronger IBD community.

Congresses

In 2021-22 EFCCA participated in three major medical congresses relevant to IBD.

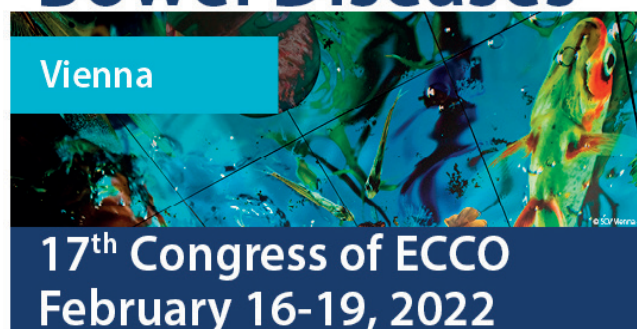
The 17th Congress of the European Crohn's and Colitis Organisation (ECCO), February 16-19, 2022 (online)

Originally planned as the first physical meeting since the COVID-19 pandemic started, the organisers decided last minute to hold the meeting online instead. The 4-day event was attended by nearly 6000 attendees with 17 virtual booths informing about major breakthroughs, highlights, and trends in the field of IBD ranging from *"Long-Term Outcomes for Patients with Very Early Onset Inflammatory Bowel Disease"* to *"Contributing Factors for Chronic Abdominal Pain in Inflammatory Bowel Disease"*.

The 16th Congress of the European Crohn's and Colitis Organisation (ECCO) from July 2-3 & 8-10 July 2021 (online)

Among the highlights of the Scientific Programme of the Congress were topics like direct comparison and combination of drugs as well as the role of artificial intelligence in IBD, to choose the safest therapeutic option in an era of multiple medications and to tailor therapeutic strategies to patients' profile such as age. Top IBD specialists provided new insights on the real burden of IBD, the optimal management of disease complications, the best way to monitor patients and the ultimate therapeutic goals. EFCCA presented the results of the Fistula project (page 14).

Inflammatory Bowel Diseases



The United European Gastroenterology Week (UEG WEEK), from 3–5 October 2021 (online)

UEG WEEK hosted a range of exciting presentations on a wide variety of topics, ranging from the predictive value of intestinal ultrasound for inflammatory bowel disease (IBD) outcomes, on the use of frailty screening for risk stratification for hospitalisation in elderly patients with IBD to the wide differences observed across various European countries in IBD care and education.

Patient Organisations

EFCCA Happy Hour

Given the travel restrictions in place due to the COVID-19 pandemic, in 2021 EFCCA organised **4 EFCCA Happy Hours** online meetings.

The Happy Hours were born from the desire to reinvigorate contacts with all our members. They were intended to provide an informal opportunity to connect with our members, to exchange ideas, brainstorm and discuss common projects. These meetings took place on the following dates and were attended by most of our members ensuring lively discussions and opportunities for networking:

- EFCCA Happy Hour, 17 December 2021 (guest speaker Elise Schoef from KU Leuven University to present Patient Preference study (see page 15).
- EFCCA Happy Hour, May 5, 2021
- EFCCA Happy Hour, April 30, 2021
- EFCCA Happy Hour April 23, 2021



Crohn Colitis Ulcerosa Vereniging VWZ (Belgium)

On 14 February 2022, EFCCA teamed up with its member from Belgium, **the Crohn Colitis Ulcerosa Vereniging (VWZ)** to contribute to the association's training programme for Belgian IBD patients.

Our secretariat was happy to share information about "EFCCA and the International Landscape of IBD" and to network with representatives of our local member.

Patient Expert Training - Belgium



AFA Crohn RCH France

Our Chairman and CEO had the great honour to attend the award ceremony of the title of Chevalier de la Légion d'Honneur to Chantal Dufresne, President of our French member AFA, which took place in Paris on 18 October 2021.

This important recognition was awarded to her by the President of the Republic on 14 July and also reflects the joint efforts of AFA, its team and their many supporters in the fight against IBD.

The ceremony was a great occasion to finally meet in person our French friends as well as many local players who act to support medical research and IBD patients.

Vivir con Crohn y CUCI (Mexico)

On 26 June 2021 EFCCA Board member, Roberto Saldaña, presented a webinar on clinical trials in cooperation with our Mexican member which was attended by around 30 IBD people living with IBD.

The areas covered included health systems and standard of care, innovation cycle, introduction to

clinical trials, ethics in clinical trials and informed consent and usual doubts that patient associations recommend to clarify before accepting participation in a Clinical Trial.

European Patient Forum

EFCCA is a member of the European Patient Forum and participates in relevant meetings and congresses of EPF. Our CEO joined the online **EPF General Assembly** last April 17, 2021. Besides the presentations and approval of the institutional activities, the Board elections took place and Marco Greco (former EFCCA chairman) was re-confirmed as the new EPF President.

EFCCA also attended the **European Patients' Forum Congress 2021** on the digital transformation of healthcare which took place from 26-29 October 2021. It reflected on EPF engagement in EU policies focusing on digital health, and the experience of the COVID-19 pandemic. From the patients' perspective,

it is important to point out that although the COVID-19 pandemic had accelerated the uptake of digital health, its impact is yet to be realised in healthcare systems. Taking action is key to tackling the "digital gap".

During the panel discussion on "Artificial Intelligence (AI) in Healthcare" our member from Estonia represented by Janek Kapper (EPSS) discussed the challenges and opportunities of AI in health. He highlighted the important role that doctors must play in providing and explaining the results or predictions from AI. Further, patients want to be informed as to whether their doctors are using AI or predictive algorithms to analyse their data so they can ensure that their inputs or answers are of high quality.

2021 **EPF**
Congress

#EPFCongress2021

digital transformation of **healthcare**

Day Two Opening Address

Tjasa Zajc

Congress Co-Host



Ivett Jakab

Congress Co-Host

Other stakeholders

European Health Forum Gastein

EFCCA participated at the virtual EHFG 2021 (European Health Forum Gastein) which took place online from 27 September to 1 October 2021 under the theme “Rise like a phoenix - Health at the heart of a resilient future for Europe”. It has been the second fully digital edition due to the COVID-19 pandemic.

Speakers and participants from Europe came together to explore new visions for a European Health Union, which put patients’ engagement at its heart, highlighting the need for a collaboration between the public and private sectors to improve patient access to novel medicines across Europe.



**EUROPEAN
HEALTH FORUM
GASTEIN**

SECURE IBD

As an immediate response to the COVID-19 pandemic a team of renowned physicians put in place the Surveillance Epidemiology of Coronavirus Under Research Exclusion (SECURE-IBD) project which was an international, pediatric and adult registry to monitor and report on outcomes of COVID-19 occurring in IBD patients. EFCCA joined forces in disseminating information about this project and encouraging healthcare providers to report cases of confirmed COVID-19 in their IBD patients.

The overarching goal was to identify COVID-19 outcomes in IBD patients and evaluate the safety of IBD medications globally in a collaborative, ethical, transparent, and timely manner.

At the end of December 2021, the SECURE-IBD team has announced the close-down of reporting to the SECURE-IBD database. SECURE-IBD served a valuable purpose at a time when our IBD community needed fast answers to pressing questions.

As since mid-last year we moved into a new phase of the pandemic with different variants, evolving vaccines and vaccination strategies, re-infections, and COVID-



specific treatments, the most pressing questions have shifted away from “What are the medication and other risk factors for developing a more severe course of COVID-19 in patients with IBD?” to new questions about vaccines, immunity, testing, and treatments.

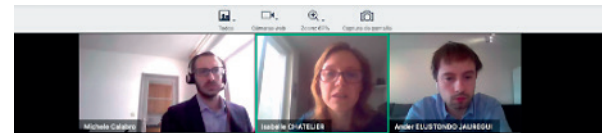
As SECURE-IBD was designed to address the initial question rather than these current questions, the SECURE-IBD team believes that new studies are needed and that continued reporting to SECURE-IBD will not be as valuable as earlier in the pandemic.

For more information go to: <https://covidibd.org>

DG Sante and the European Patient Forum

EFCCA Board member Roberto Saldaña participated in a meeting organised by DG SANTE and the European Patient Forum. Discussions were around the European Health Data Space (EHDS) concept: an initiative to stimulate the use and re-use of health data to facilitate research, better policies making and improve healthcare.

The main idea is that the UE want to foster by 2025 a single market for digital health services through the, among other means, cross-border exchange of patients' data. In fact, there is already a pilot in progress.



European Health Data Space (EHDS)



However, there are some barriers to solve before it can be fully implemented. Some of them are data ownership, privacy policies, labelling, reimbursement of digital services, etc.

Luisa Avedano
CEO, European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA)

Biosimilars and Sustainability
Thursday, 1 July 2021 | 4:00 - 5:15 CET

Biosimilar and sustainability

We have collaborated with IQVIA (Human Data Science Company) and Biogen by participating in a webinar they organised on biosimilars. The webinar was based on the IQVIA report "Spotlight on Biosimilars Optimising the Sustainability of Healthcare Systems" and provided us a good opportunity to give a patient perspective on the issue.

Global CPF Patient Organization Summit

On 26 and 27 May 2021, EFCCA, together with representatives from 11 patient organisations from North America, Europe, and Israel has participated in the online Global CPF Patient Organization Summit organized by Takeda, focusing on inflammatory bowel disease (IBD) and addressing the needs of people with Crohn's Perianal Fistulas (CPF).

Our Project Coordinator presented the EFCCA CPF patient survey, the results of which have been also presented at the European Crohn's and Colitis Organization (ECCO) congress in July 2021, then the meeting focused on best-practice case studies and brainstorming for action. In smaller groups, the delegates explored the unmet needs of their local CPF communities and developed tactical activities to address those needs.

EFPIA PATIENT THINK TANK

All quarterly meetings have been organised online (10 February, 11 May, 15 September, 2 December) and 2021 work plan was based on the following themes: access to medications, pediatric regulation, definition of unmet needs, drug shortage. The meetings usually involve several representatives from pharmaceutical industries and patient advocate or patient representatives.

Patient Advisory Board meetings

EFCCA representatives have been involved in four Patient Advisory Boards organised by various pharmaceutical companies. We believe our collaboration with industries will benefit the IBD patient community and these meetings allow us to

provide the patient perspective as a group (and not as an individual) for a range of activities such as clinical research and exchanging information on the patient pathway.

IBD Patient Council

Organized by Roche and structured around different topics. Several EFCCA members participated in the online meetings. It ended in December 2021 with a final report where the main findings have been published. The core theme was clinical trials and patients have been involved not only in brainstorming

but also in real feedback about the outcomes of some clinical trials that were presented by renowned gastroenterologists such as Pr. Severine Vermeire from KU Leuven. A final IBD Clinical Trial Play book will be the next outcomes and it will be based on the two last year's brainstorming among patients.

Global Patient Summit

Participation and involvement in the organisation of the "Global Patient Summit" (promoted by Boehringer Ingelheim) and follow up. The Global Patient Summit took place beginning of 2021 where employees of the pharmaceutical company and various patient

organisations met at eye level to work out solutions and where the focus was on the needs of the patients. During the follow-up meetings discussions centered around finding practical solutions for collaborating on the identified unmet needs.

Patient Engagement Council

Promoted by Galapagos involving key stakeholders, not necessarily patients, but also advocacy experts, in a wide discussion around unmet needs, patient rights, representation and empowerment. The first concrete outcome (Spring 2021) has been the Patient

Partnership Charter based on the commonly agreed principles:

1. To establish a shared purpose;
2. To build a partnership of equals;
3. In a transparent way.

International Patient Council

Promoted by Arena. Two main topics have been approached in 2021: clinical studies and drug development: how to explain and present these topics in a patient friendly way. Articles on the topics the

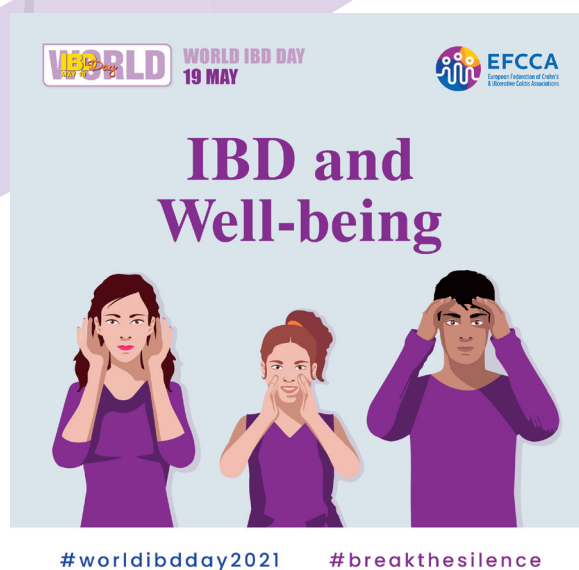
scripts of two videos have been discussed as well as the Plain Language Summary. The first theme to be discussed in 2022 is how to develop material for adolescents.

Awareness raising

This is a strategic area for EFCCA since there is still little public understanding of the pain and chronic suffering with which IBD patients courageously cope with every day of their lives. Through various initiatives, education and tackling taboos and stigmas around IBD, we want to have IBD accepted and recognized, taking into consideration the needs of all those who are affected.

World IBD Day

World IBD Day remains one of our key activities in term of awareness raising and since its creation in 2010 it has grown in visibility and number of participating countries/ organisations. EFCCA continues to maintain the World IBD Day website which hosts information of all the activities that are being carried out around the globe. For more information please visit: www.worldibdday.org



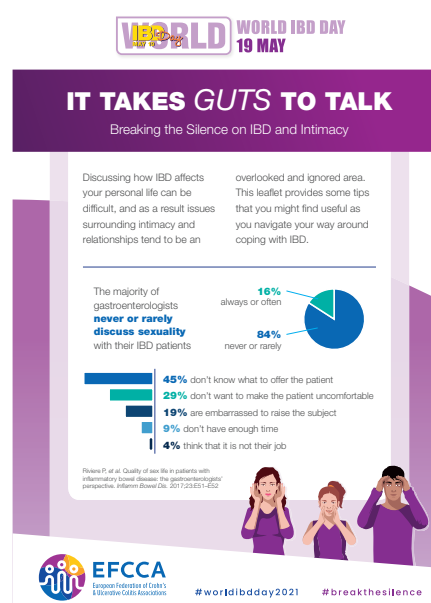
IBD and wellbeing

For the last few years EFCCA, in line with its Strategy Plan, has developed yearly themes for World IBD Day following discussions within the board on yearly priority areas. For 2021 the theme for World IBD Day was on IBD and wellbeing. By wellbeing we are referring to *“a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”*.

It is important to understand that IBD can take a toll on many aspects of day-to-day life including general well-being and mental health. Living with a chronic disease might lead to depression, anxiety and a negative self-image affecting not only the person with IBD but also his/her family and friends.

We carried out a social media campaign leading up to 19 May to raise awareness about the hidden facts of what it is like to live with IBD.

Under the hashtag #breakthesilence we invited the IBD patient community to talk about things they feel are not usually talked about.



We initiated discussions around taboo subjects such as for example IBD and Intimacy and prepared and published a comprehensive leaflet with relevant background information and practical advice that gives a good overview of the issues involved. We were pleased that several of our EFCCA members have used this leaflet to provide better services to their members and to stimulate discussions in their own country on this taboo subject.

With our awareness raising campaign entitled #breakthesilence we:

- Started a dialogue and raised awareness on the psychological impact of the disease both on social media channels and through several of our members this theme was also taken up in national media news channels.
- Provided the public, health care providers and other stakeholders with a better understanding of the main issues as concerns IBD and Well-being.
- Provided subject related resources and developed an information leaflet on one of the identified taboo subjects “IBD and Intimacy” which fed into some of our members local activities.

We are still in the process of discussing with Health Care Providers and other stakeholders on the outcomes of the campaign and to work together to find solutions that will have a meaningful impact on a person's quality of life.

For more information please visit: www.efcca.org/en/projects/break-silence-world-ibd-day-2021

(IBD) Families First

We organised an EFCCA Patient Talk to present an exciting new study that investigates first degree relatives of IBD patients on their preferences and fears for prediction & prevention interventions.

The EFCCA Patient Talk which took place on-line on 30 June 2021 was moderated by our Vice-President Ciara Drohan and included speakers Catarina Fidalgo (MD), Bárbara Morão (MD) and Joana Torres (PhD) from the Hospital Beatriz Angelo (Portugal) who are the leading team of the study.

First degree relatives of IBD patients are the population at higher risk of developing Inflammatory Bowel Disease (IBD). Such risk can be further assessed by using prediction models (blood, stool, endoscopic, imaging tests). As global IBD prevalence is rising we need to improve treatment and search for a cure while improving PREDICTION and PREVENTION of new cases.

The identification of biomarkers for IBD suggests that it may be possible to identify people at high risk for developing disease.



Thus, PREDICTION opens the possibility of treating the disease in its pre-clinical phase, preventing its occurrence. As concerns PREVENTION this is an ambitious idea, but it is being sought in other areas such as for example in Type I diabetes.

Before designing the study and interventions the study team including the 3 presenters of the Patient Talk would like to bring a focus group together with first degree relatives (siblings and children of IBD patients or parents of children at risk) to assess preferences and fears towards prediction tools and preventive strategies.

Fatigue and IBD

Last year and in line with our priority theme of well-being we have worked on a project that aims to raise awareness around the issues of Fatigue and IBD.

People with Crohn's disease or ulcerative colitis are at risk for experiencing fatigue which can have a huge impact on their daily life. The symptoms of fatigue are often overlooked or mistaken as an effect of the disease itself.

We have prepared a short clip with the aim to raise awareness around the impact on the quality of life for people experiencing fatigue and IBD.



Furthermore, a dedicated page of our website provides more information and includes links to useful resources on this topic. For more information please visit: www.efcca.org/en/ibd-and-fatigue

ATLAS project

EFCCA has been involved in the ATLAS programme that was formed in 2016 as a response to a lack of awareness of Intestinal Failure (IF) and poor harmonisation of standards of care across Europe.

In 2021 the Atlas project came to an end. In the past two years 25,000 visitors got useful information on intestinal failure on the website www.atlasif.eu while a new version of "In their Shoes programme" for Short Bowel Syndrome was created and the project contributed to raise awareness on intestinal failure and SBS among HCPs and journalists.

Moreover, the subproject ATLAS of Variance got 3 abstracts accepted to ESPEN (European Society of



Clinical Nutrition and Metabolism), and a publication will follow. All the assets created to date – e.g. website and content including information material and dashboards will still be publicly available for up to a further 2 years.

Patients' perceptions of surgery for inflammatory bowel disease

Surgery is indicated in selected patients with inflammatory bowel disease (IBD). However, due to a negative perception, surgery may be delayed, leading to possible unfavourable outcomes.

The aim of this work was to investigate patients' perceptions of surgery and the impact on reported outcomes. The study, which was led by Professor

Antonino Spinelli found that despite the negative perception of surgery and the delayed involvement of surgeons as a source of information and in the decision-making process, the majority of respondents experienced positive outcomes from surgery, including improvement QoL and acceptance of the stoma.

Read study: www.doi.org/10.1111/codi.15813

Advocacy

EFCCA carries out advocacy work with EU institutions and international organisations such as WHO to move from a therapy-focused approach to a more patient/person-focused approach, ensuring that concerns, needs and priorities of people living with IBD are included in the decision-making process for policies and other related health initiatives.

Patient's perspective on the impact of perianal fistula in Crohn's disease on quality of life

The results of the survey conducted in 2019 in partnership with Takeda have been presented at the latest ECCO Congress in July 2021 and are in the process of publication.

We organised an EFCCA Patient Talk on 9 September 2021 to share the main findings of this study which collected 820 responses across 33 countries.

Our guest speaker and lead author of the study, Prof. Antonino Spinelli, Director of the Division of Colon and Rectal Surgery at Humanitas and Professor of Surgery at Humanitas University in Rozzano in Milan (Italy), introduced the subject speaking about the burden of perianal fistulas in Crohn's disease and stressing the importance of gathering patients' feelings and perspectives in clinical practice.

The results clearly showed that from the patient perspective, perianal fistulas severely impact the overall quality of life, relationships with family and friends, intimacy and social and work life in addition to the existing impact of Crohn's disease. The survey also brought to light differences in symptoms experienced by those with Crohn's disease with and without perianal fistulas, but also differences in symptoms experienced by men and women.

EFCCA Patient Talks

Free Webinar

Results of Fistula survey

Join our presentation on the results of "the impact of perianal fistula in Crohn's disease on quality of life" survey.

Speakers include:

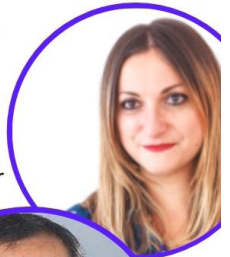
Professor A. Spinelli, Humanitas University (Milan)

Maria Stella de Rocchis, EFCCA Project Coordinator

Candida Cruz, APDI (tbc)

Register: info@efcca.org

9 September, 2021 6-7 PM (CET)



Significantly important are also the differences in symptoms experienced by men and women and the different impact of living with perianal fistula in the different life areas.

These results are important to consider when tailoring treatment strategy and patient services in a multidisciplinary approach to address individual patient needs.

To read the full results/infograph please follow this link www.efcca.org/sites/default/files/fistula_infograph.pdf

Patient Preference

Since the beginning of 2021, EFCCA has been working on the issue of patient preference. This refers to a person's evaluation of aspects - physical, psychological, and social - of health outcomes and how this influences his or her health care choices.

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

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

EFCCA will collaborate with KU Leuven to prepare a patient-friendly questionnaire, to disseminate throughout the EFCCA membership base and to promote patient participation in the study. This work will help us to determine how much importance patients attach to the characteristics discussed in the previous study and will also allow us to investigate the unmet needs of IBD patients that cannot be solved with existing therapies.

Implementation and short-term adverse events of anti-SARS-CoV-2 vaccines in Inflammatory Bowel Disease patients: an international web-based survey

As Anti-SARS-CoV-2 vaccines clinical trials did not include patients with immune-mediated conditions such as inflammatory bowel disease (IBD) the study aimed to describe the implementation of anti-SARS-CoV-2 vaccination among IBD patients, patients' concerns and side-effect profile of the anti-SARS-CoV-2 vaccines using real-world data.

This survey was funded by the Portuguese Society of Gastroenterology, through the support of its online platform for multicentric studies, CEREGA. EFCCA and all National Patient Associations distributed the survey online.

The results showed that the implementation of vaccination in those responding to the survey was high and the adverse events were comparable to the general population, with minimal impact on their IBD.

The study, whose main author is Pierre Ellul, has been published in the Journal of Crohn's and Colitis. Read article: [www.doi.org/10.1093/ecco-jcc/jjac010](https://doi.org/10.1093/ecco-jcc/jjac010)

Biosimilar knowledge and viewpoints among Brazilian inflammatory bowel disease patients

EFCCA has been involved in this study which aimed to describe Brazilian inflammatory bowel disease (IBD) patients' knowledge and perceptions regarding biosimilars and compare with viewpoints from non-Brazilian patients.

An online survey consisting of 19 questions was made available by the European Federation of Crohn's and Ulcerative Colitis Associations between July 2018 and December 2018. Brazilian patients reported higher rates of misconceptions regarding biosimilars than non-Brazilian IBD patients. Although patients still worry about different aspects regarding biosimilars, they also tend to be confident that biosimilars will have an impact on the management of their disease.

With the recent approval of many biosimilars in Brazil and the imminent widespread use of these drugs, our data raise awareness for the need of providing patient education to prevent negative expectations toward switching to biosimilars.

The results of the Study have been published in SAGE Journals May 2021 to coincide with World IBD Day.

Read article:

[www.journals.sagepub.com/
doi/10.1177/17562848211013249](http://www.journals.sagepub.com/doi/10.1177/17562848211013249)

Empowerment

EFCCA supports its members in their work and mission at national level through the exchange of best practise and capacity building activities such as educational seminars, thematic workshops, policy initiatives. EFCCA wants to invest in creating sustainable resources, training independent, self-confident patients and in increasing the collaboration with members.

EFCCA Youth Academy: Empowering young IBD representatives

In 2021-2022 we have launched for the first time the EFCCA Youth Academy addressed to our youngest patients' representatives (aged between 18 and 30). The aim of this new educational programme is to increase the representativeness of the youth group, to create a more cohesive group of leaders of tomorrow, to empower young representatives and to strengthen and expand the youth group.

The training is taking place online due to COVID-19 restrictions and held on the EFCCA e-learning platform. A first class including 30 students from 20 IBD patient associations started last November 2021 with the first teaching class called "The history of EFCCA, its mission, values and strategic priorities" presented by Our EFCCA CEO, Luisa Avedano and Deputy Director, Isabella Haaf. The idea of passing some valuable EFCCA principles to the younger generation lies precisely in the hope that some of them in the future will be able to continue the journey that began so many years ago.

In the second module students met Marco Greco, EFCCA chairman from 2008 to 2014, founder of the EFCCA Youth Group and its leader from 2003 till 2007, and Daniel Sundstein, EFCCA Youth Leader from 2021 to 2015. They talked about the journey that led to the creation of the youth group in about 50 rapid-fire questions!



SECOND TRAINING MODULE

The journey that led to the creation of the Youth Group

Testimonials from the IBD community



DOUBLE INTERVIEW WITH:

MARCO GRECO - EFCCA CHAIRMAN FROM 2008 TO 2014, FOUNDER OF THE EYG, AND ITS LEADER FROM 2003 TILL 2007

DANIEL SUNDSTEIN - EFCCA YOUTH LEADER FROM 2012 TO 2015, EYG BOARD MEMBER FROM 2009 TO 2016 AND EFCCA BOARD MEMBER FROM 2012 TO 2015





The module presented by Clara Drammeh from European Youth Forum, which is the platform of youth organisations in Europe representing over 100 youth organisations and which brings together tens of millions of young people from all over Europe, is now online and it is around subjects like good governance, youth empowerment and strategic thinking and

planning. A final module about “Team building and leadership” will be released in 2022 and then the students are invited to take part to a 3-days-of live workshop in which will learn how to engage youths, how to start an Advocacy Campaign and how to organize the next EFCCA Summer Camp that we all hope will take again place soon!

EFCCA Academy: towards the Certified Patient Award on Clinical Trials

Last 2020-2021 we have developed an exciting set of training modules on the issues of clinical trials. Various studies that have been carried out in the past to assess public awareness, perceptions, and attitudes toward clinical trials clearly show a lack of knowledge and understanding of them amongst the public in general, amongst patients and even amongst some patients that are already participating in a clinical trial.

Information about clinical studies/trials is at times confusing, too technical and beyond the understanding of a layman. Finding reliable and verified information about clinical studies is another issue.

The Academy training modules dealt with the majority of these issues and gave the opportunity to 14 students from 12 IBD patient associations to benefit from it. At the end of the educational programme, we have asked them to work on a project with the aim to raise awareness around this topic in their local associations. Students have worked hard and with passion and have realized different assignments like webinar inviting local experts in clinical trials, online and offline information documents, workshops with patients and one of them also became Clinical trial Ambassador in his country.

We were very proud of the big success and for 2021-2022 we decided to re-open the Academy to another bunch of students who are now finalizing the training and they will soon be involved in some other valuable activities.



THIRD TRAINING MODULE

Breaking the myths around Clinical Trials







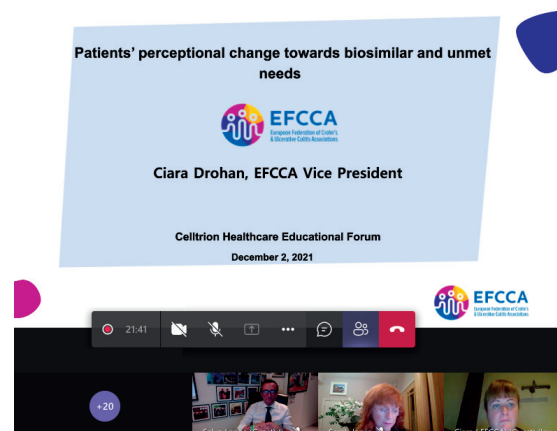
WITH LECTURES BY PROF. ARIEL LIEBERT, HEAD OF THE DEPARTMENT OF MULTISPECIALIST CARE IN GASTROENTEROLOGY, NICOLAUS COPERNICUS UNIVERSITY IN TORUN, POLAND AND STEFANIE DERZSI - PATIENT PARTNERSHIP DEPARTMENT, KT PARK - RESEARCH AND DEVELOPMENT DEPARTMENT, AMANDA TATROW - MEDICAL DEPARTMENT, JO PHIPPS - REGULATORY DEPARTMENT AND LAURA POPE - ACCESS DEPARTMENT AT ROCHE






Educational webinar – biosimilars and biobetters

EFCCA participated in an educational forum “*Biobetters: The future of biosimilars – post COVID-19*” which took place online on 2 December 2022 and which was organised by the pharmaceutical company CELLTRION. The objective of the forum was to understand the perspectives of patient representatives on key topics related to **biological medicines**, including treatment access and optimal care, and about changes in perception of **biosimilars**. The forum included a presentation by Prof. Laurent Peyrin-Biroulet on the role of biosimilars and biobetters in which he gave an overview of the impacts and potential advantages of biosimilars and biobetters and how things will evolve with biobetters and their role in the future treatment landscape.



Finally, Dr. Philip Smith discussed how IBD during the COVID-19 pandemic has been a real challenge faced by clinicians and patients and how biobetters could address unmet needs in existing biosimilars amid COVID-19, presenting real world switching case. The webinar provided a good occasion for EFCCA delegates to get a better understanding of the latest development in science as regards biologic medicines.

Horizon 2020 projects

ImmUniverse

EFCCA is a partner of the ImmUniverse project (under the Innovative Medicines Initiative, IMI) which aims to improve diagnostic and therapeutic options for patients living with ulcerative colitis and atopic dermatitis. New insights into disease severity and progression will enable personalised therapy for each individual patient.

The first annual progress report of ImmUniverse is now available for download. After a turbulent first project year highly impacted by the COVID-19 pandemic, the project team nevertheless continued unperturbed in advancing the research into a more personalised identification and treatment of ulcerative colitis and atopic dermatitis.



The foundations have now been laid in delving deeper into the planned studies during the current second year of the project. This has been reflected by the recent extensive reporting phase. To find out more, please refer to the [downloadable summary](#) of the annual progress report here.

More info: www.immuniverse.eu

IDEA-FAST

This project (Innovative Medicines Initiative, IMI) will identify digital endpoints that provide reliable, objective and sensitive evaluation of activities of daily living and Health-related quality of life (HRQoL) in Immune-Mediated Inflammatory Diseases such as IBD as well as other such as Rheumatoid Arthritis and Lupus and which will ultimately have a positive impact on the quality of life of these patients.

Our participation as patient representatives is taking shape, in particular in the Patient Engagement Group of IDEA-FAST and in the Work Package 2/6 on clinical knowledge and insight.

More information: www.idea-fast.eu



Projects in the pipeline

Beside the IDEA-FAST and IMMUNIVERSE, the two research projects in which EFCCA is involved, over the past months the Secretariat has been contacted by renowned research institutes, Universities and University centers in Europe that are interested in involving patient associations in European funded research projects (Horizon 2020, IMI and the most recent IHI programme).

Among the many requests EFCCA has expressed its interest in partnering with the following lead partners: Cork University, KU Leuven, Amsterdam UMC, Lithuanian University of Health Sciences, Cattolica del Sacro Cuore University in Rome, University of Porto. We are already in contact with some of our members

that could join the projects once they will get a clearer shape and we are confident that the collaboration will be fruitful for all.

We agreed in exploring these partnership opportunities because we believe that these projects could really represent an excellent occasion to work on patients' quality of life impact of IBD, on behavioural preventive actions and to directly involve our community in clinical decisions that can be crucial for IBD treatment. We also aim at increasing the engagement of patients and raise awareness on civil society.

We expect to have some feedback from the European Commission within the first semester of 2022 and we hope that our efforts, at least some, are rewarded.

The LUCID study: living with ulcerative colitis; identifying the socioeconomic burden in Europe

EFCCA has been involved in this study (main author Prof. Leonardo Ruiz-Casas,) which aimed to determine the socioeconomic burden of UC in adult patients in a real-world setting. In this retrospective, cross-sectional and observational pan-European study, patients with moderate or severe UC, were assigned

to different arms. The results showed that the cost and HRQoL burden were high in patients in both arms indicating unmet needs in the UC active population.

Read article:

www.doi.org/10.1186/s12876-021-02028-5

The effects of COVID-19 vaccine in patients with inflammatory bowel diseases - Outcomes of a prospective, multi center Israeli study

EFCCA has been partnering with our Israeli member – The Israel Foundation for Crohn's Disease and Ulcerative Colitis, the Division of Gastroenterology, Rabin Medical Center, Petah Tikva, and the Sackler Faculty of Medicine of Tel Aviv University on a research project about "The effects of COVID-19 vaccine in patients with inflammatory bowel diseases - Outcomes of a prospective, multi center Israeli study".

Its overall objective was to analyse the impact of Covid 19 RNA vaccines on designated IBD groups as well as its Efficacy aspects.

Prof. Iris Dotan (Director of the Division of Gastroenterology at the Rabin Medical Center, Israel, affiliated with the Sackler Faculty of Medicine, Tel Aviv, Israel) initiated then clinical research at evaluating mRNA COVID-19 vaccine responses, the sustainability of immune response, side effects and IBD course post vaccination.

The study was aiming to prospectively determine the effects of COVID19 vaccine in patients with IBD, grouped according to treatment, specifically focusing on those treated with anti-TNF drugs. The main outcome of the study was to evaluate the serologic response to each vaccine dose. Other outcomes that were assessed were the evolution of the immune response and the safety of the vaccine.

In summary, our results show that:

1. Vaccine is effective, with 100% seroconversion in the short term in all subjects, including patients with IBD treated with anti-TNF;
2. Vaccine is safe, no serious side events were detected, and no IBD exacerbation was observed in the short term;
3. There is no need to adjust the timing of anti-TNF drug administration and vaccination;
4. Patients with IBD who are treated with anti-TNF may need an earlier vaccine booster dose.

The study has been an example of collaboration and partnership between multiple IBD centers in Israel. It was conducted in collaboration with the Israel Crohn's disease and ulcerative colitis foundation (CCFI) and supported by a grant from the Leona H. and Harry B. Helmsley Charitable Trust, EFCCA, AMICI Italia, and the MOH. Mutual interest and dedication by patients, patient organizations, physicians, researchers, and organizations, coalesced into a coordinated study resulting in meaningful outcomes for patients and their care givers.

General Assembly

During our latest EFCCA General Assembly delegates voted in favour of four new patient associations from Mexico, Singapore, Russia and Ukraine joining the EFCCA network bringing our total membership to 45 associations in 44 countries.

The EFCCA General Assembly which brings together representatives from Crohn's and Colitis patient associations was held - due to the current pandemic - for the second time running on-line on 29 May 2021. During this annual meeting delegates approve the EFCCA Annual and Financial Reports as well as our yearly work plan. In addition, elections to the EFCCA membership and the EFCCA board are held.

Elections to the EFCCA Executive Board are held annually. In 2021 we have welcomed Menne Scherpenzeel as new board member. Menne is the CEO of the Dutch patient association Crohns and Colitis NL. Salvo Leone, EFCCA chairman, took the opportunity to thank out-going board member Natasa Theodosiou from the Cyprus association, for all her work and commitment during the years she served on the EFCCA board.

Other institutional matters were presented and discussed. All documents can be consulted by EFCCA members in the private area of the EFCCA website.



Executive Board

Following elections to the board during the EFCCA General Assembly last May 2021 the newly elected board has met online on the following occasions:

- 14 March 2022, emergency meeting to discuss the situation in Ukraine and how to support our member association in Kyiv.
- 14 January 2022, main topics to be discussed were our strategic plan, the next General Assembly, and the first-trimester activity plan.
- 7 October 2021, discussions on current project,

Academy update, last 2021 trimester activities and first steps 2022: World IBD Day, GA and Strategic Plan

- 17 June 2021 to discuss various issues including several on-going projects, development of a new EFCCA strategy plan and other institutional matters.
- Furthermore, the Petit Comité consisting of the President, Vice President, Treasurer, CEO and Deputy Director held several ad-hoc meetings to discuss urgent issues arising.

EFCCA Staff

EFCCA has a small staff headed by Chief Executive Officer (CEO) **Luisa Avedano** who is responsible for the overall implementation of the EFCCA work plan and its institutional representation.

Isabella Haaf, Deputy Director is assisting with the overall implementation of the EFCCA work plan with a main focus on communication and international relations in particular the coordination of World IBD Day.

Veronica Pisco, assistant, based in the EFCCA's headquarter in Brussels has provided administrative support to the whole EFCCA network as well as representing EFCCA in meeting and conferences held within the European institutions. Her contract has terminated December 2021 and we are currently in the process of hiring a new assistant. We want to thank Veronica for her support and dedication, and we wish her a happy future in Switzerland where she has relocated.

Maria Stella De Rocchis European Project officer has joined EFCCA end of 2019 and has been working on the development of the training programmes of the EFCCA Academy as well as managing the Fistula survey project.

Eva Izquierdo Sanchez has been supporting us with our social media activities (Facebook/Twitter) and **Antonella Montanari** has been supporting around World IBD Day and during the General Assembly.

Our former colleague **Andrea Broggi** has been working with us as an external consultant on legal issues and advisor on several EU projects.

Michele Pasino, Mario de Reviziis, William Ronco from **Officine Digitali** are in charge of our IT support, online training platforms and video recordings.

Youth Group

The Youth Group has experienced various challenges in the management of the group. The EFCCA board has been in discussions with the youth group to overcome these challenges and there has been a request for a structured long-term training programme for youth representatives. As a response we have designed a Youth Training programme address to young representatives (aged between 18 and 30) from our members.

The aim of this new educational programme is to increase the representativeness of the youth group, to create a more cohesive group of leaders of tomorrow, to empower young representatives and to strengthen and expand the youth group.

You will find detailed information about this programme on page 17.

List of members as of 2021

Austria

OMCCV - www.oemccv.at

Belgium

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

Bulgaria

BCUCA - www.babkuk.org

Croatia

HUCUK - www.hucuk.hr

Cyprus

CYCCA - www.cycca.org

Czech Republic

Pacienti IBD - www.crohn.cz

Denmark

CCF - www.ccf.dk

Estonia

EPSS - www.ibd.ee

Finland

CCAFIN - 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

ISCC - 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

LMF - www.lmf norge.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.crohnclub.sk

Slovenia

SAIBD - www.kvcb.si

Spain

ACCU - www.accuesp.com

Sweden

MOT - www.magotarm.se

Switzerland

SMCCV - www.smccv.ch
Crohn Colite Suisse - 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

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.gofulllife.com.ua

Sponsors

EFCCA is funded by its national members that contribute with an annual fee based on their number of registered volunteers.

EFCCA is also supported by projects that are developed in partnership with donors. EFCCA usually works with a multi- stakeholder partnership for its projects in order to ensure its independence.

EFCCA supports a policy of full transparency regarding its funding sources. The EFCCA transparency rules can be downloaded from the EFCCA website in the “Funding” section.

We would like to thank the following donors who have supported us in several activities that are mentioned in this report.

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European Federation of Crohn's
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