



Report
**DIGITAL HEALTH
AND DATA
COLLECTION
EFCCA
SYMPOSIUM**

Vienna 14 February 2020, ECCO Congress



EFCCA
European Federation of Crohn's
& Ulcerative Colitis Associations



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FOREWORD

Digital tools and technologies are rapidly transforming healthcare systems and have a huge potential in patients' treatments and life.

In the past two years, the European Federation of Crohn's & Ulcerative Colitis Associations (EFCCA) has been in the forefront of the discussion on how digital health and big data can contribute in delivering more personalised care and offering a higher quality of life for patients with IBD.

This report summarizes the discussions made during the symposium on **Digital Health and Data Collection** organised by EFCCA and which took place during the ECCO Congress on 14 February 2020 (Vienna, Austria).

The symposium convened for the first-time representatives from the IBD patient community, physicians/Health Care Providers and the pharmaceutical industries to initiate an open discussion on how digital technologies can bring benefits and opportunities for all.

EFCCA believes that a multi-stakeholder approach and collaboration can represent an opportunity to achieve a more harmonic combination between the quality of care and quality of life data of IBD patients.

Patient centred care, which is considered the standard in Europe, means giving patients a central role in the digital "revolution" in health care as well as the data collected from patients.



It means involving them in the whole process that starts from the design of the structure of the data base, goes through the data collection and ends in data analysis. Analysing data from the patient's perspective can become a powerful and unique way to achieve earlier diagnosis, better care strategies and identify patterns in health outcomes in partnership with medical societies and all relevant stakeholders.

We are pleased that this first meeting has been such a success, but we must now continue with this important work, we must widen this stakeholder discussion involving also representatives from the payers and the regulatory bodies and we must ensure to bring the entire IBD community on board. We are confident that together we can make a difference for the lives of people with IBD.

Isabella Haaf
EFCCA Deputy Director



Introduction

The IBD patient community is getting increasingly involved in the debate related to e_health and the proactive role they can play in collecting, managing and owning their data could lead to stronger empowerment and a more precise definition of unmet needs and patients' priorities.

Digital health and more importantly data collection can be the most suitable solution. Generally speaking, patients are willing to share data related to their health conditions and quality of life, but it is crucial that appropriate data protection, privacy rules as well as the full control of the whole data collection process is co-designed and defined.

Empowering patients and patient associations can lead to more commitment and to target that portion of the IBD patient community that is still not fully engaged and aware of the role it can play in research and personalised medicine.

Patient data ownership is then the most effective answer and patients are the more suitable players to assure equal access to knowledge and information and to avoid discrimination in the use of outcomes and analysis. By assuming the full control of data patients can strongly contribute in defining research activities, reducing the time of diagnosis and prioritising key messages and outcomes.

It is within this framework that EFCCA has decided to organise a symposium on Digital Health and data collection bringing together representatives from the IBD patient community, physicians and industries to start discussions on this important issue and to see how a multi-stakeholders and industry alliances can bring benefits and opportunities for all.

Setting the scene

The keynote speaker of the symposium, Professor Claudio Fiocchi (Cleveland Clinic, USA) has a longstanding commitment to research and education in the field of Inflammatory Bowel Diseases and has published numerous peer reviewed publications in scientific journals as well as book chapters and abstracts.

Whilst providing the context for the symposium's discussion Professor Fiocchi proposed an integrated, holistic approach to IBD which holds significant promise for improving both our understanding and treatment of the disease. Only by considering the complexity of the disease and the diversity of each patient will we be able to achieve successful IBD therapies.

More specifically, with the regard to the topic of digital health and data collection Professor Fiocchi sees Patient-Reported outcomes (PROs) as an important contribution to boost progress in IBD and stressed that data including biomedical big data has become one of our most valuable resource.

By merging computing and medical technologies, we will see exciting breakthroughs for Inflammatory Bowel Disease. Artificial intelligence (AI), machine learning and deep learning are the new tools to understand IBD and advance its therapy. For example, Artificial Intelligence (AI) systems have shown to improve diagnostic accuracy of 95% for common ailments.

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“The world’s most valuable resource is no longer oil, but data.”



Professor Claudio Fiocchi

Other successful digital interventions aimed specifically at IBD and involving the collection of patients' biomedical data have allowed physicians to move from traditional generic therapy to a more comprehensive precision therapy.

To conclude with his presentation Professor Fiocchi highlighted some of the barriers to digital medicine with interoperability being an important element.

“Interoperability is a prerequisite for the digital innovations envisioned for future medicine.”

*Professor,
Claudio Fiocchi*

The fact that there are a wide range of databases, compatible systems and proprietary software means that it is difficult to exchange, analyze and interpret data in a meaningful way, making “Interoperability a prerequisite for the digital innovations envisioned for future medicine.”

SYMPOSIUM OPENING

Opening of the symposium:
Professor Silvio Danese, ECCO President and
EFCCA Chairman, Salvo Leone



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“For the first time today, an event organized by the patient community takes place during an important medical congress.

This is a signal that the relationship between EFCCA and ECCO is growing and is taking on a deeper value and significance.”

*EFCCA Chairman,
Salvo Leone*

The Patient Perspective

The IBD patient community is getting increasingly involved in the debate related to e_health and the proactive role they can play in collecting, managing and owning their data could lead to stronger empowerment and a more precise definition of unmet needs and patients' priorities.

Digital health and more importantly data collection can be the most suitable solution to the above-mentioned needs and patients clearly want to be involved in the development of digital health solutions. It is important though to **generate evidence** that shows the positive impact that any given digital solution has on the patients' quality of life and general well-being.

For digital health to be as useful as it can be, it needs to involve the widest range of patients to collect data on health markers. This will allow scientists with the help of big data systems and artificial intelligence to deliver precision medicine.

Therefore, ensuring **all-inclusive access** to these technologies especially by groups of patients that are more reluctant to use these is of paramount importance. Empowering patients and patient associations can lead to more commitment and to target that portion of the IBD patient community that is still not fully engaged and aware of the role it can play in research and personalised medicine.

It is important that **barriers to all-inclusive access** such as digital illiteracy, economic level, education, chronic conditions, disabilities etc. should be appropriately addressed and overcome in order to have meaningful and impactful digital health solutions.

Generally speaking, patients are willing to share the data related to their health conditions and quality of life, but it is essential that appropriate **data protection, privacy rules** as well as the full control of the whole data collection process is co-designed and defined by and with patients.

Involving patients in all stages of the development of digital technology will better ensure that these tools are successful and impactful.

When patients are involved from the early stages of the development process, they can easily flag difficulties that will lead to a slow uptake of a given tool and at the same time they can show patient preferences and real-life needs which will make the device more accessible and more likely to be used.

Evidence from the following digital health projects that have been developed by patients or that have involved patients from the early design stage show very positive results and are an encouraging model to pursue.

PATIENT PERSPECTIVE



MICI CONNECT (IBD CONNECT)

An excellent example of a digital tool developed by patients is the MICI Connect (IBD Connect) platform.

This platform was created by the French IBD association AFA Crohn RCH France and offers services and a support program from patients, for patients. It is a collection of tools to better understand and manage the disease. Several paths are proposed allowing each user to progressively assimilate the information needed daily with the disease.

The patient may also follow his or her progression with the disease through some useful scores for consultations with health professionals such as fatigue, quality of life, number of stools, etc. and add this data to his or her health journal.

“1 in 2 patients thought that the (MICI Connect) platform had allowed them to avoid hospitalization.”

What makes the tool original is the fact that it was designed and built by the patients themselves, in answer to their own individual problems and needs in everyday life.

In a follow up survey to the MICI Connect App 84% of its users were satisfied with the tool and would recommend it to someone else. 68 % felt reassured about their disease and 1 in 2 patients thought that the platform had allowed them to avoid hospitalization.



Bastien Corsat representing MICI Connect

PATIENT PERSPECTIVE

MYIBDCOACH

Another good example of showing the importance of patient involvement in the design and development of digital health tools is myIBDcoach. MyIBDcoach was developed in partnership with patients, dietitians, IBD nurse-specialists, and gastroenterologists.

MyIBDcoach enables continuous home-monitoring of patients with IBD and enhances disease knowledge and communication between patients and health care providers.

A feasibility study of myIBDcoach was carried out in order to evaluate the effects of myIBDcoach compared to standard care on healthcare utilisation and patient-reported quality of care PRQoC.

The result showed a high satisfaction and compliance of patients and health care providers. Interestingly, the results also showed a 36% reduction in outpatient visits, a 31% reduction in telephone consultations and a 50% reduction in hospitalisations and increased adherence to medication.



Dr Marieke Pierick, Maastricht University Hospital

The Physicians and Health Care Professionals' Perspectives

In her presentation made at the Symposium, MD Catarina Fidalgo (Hospital Beatriz Ângelo & Hospital da Luz, Portugal) provided some interesting reflections and viewpoint on the issue of digital health and data collection from the physicians' viewpoint.

Given the huge financial costs around IBD care from diagnosis to risk stratification, treatment, complications and recovery,

physicians and HCPS rely heavily on quality data to decide where there are high value interventions and where not.

Unfortunately, getting good quality data is not easy.

Sometimes it is a lack of access to such data (be it government, insurance or clinical trial data) or there is data that is conflicting or unclear.



Dr Catarina Fidalgo, Hospital Beatriz Ângelo & Hospital da Luz

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There is a lack of clear definitions or outcome measures available to establish quality of care standards for IBD patients

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This lack of clear definitions or outcome measures available to establish quality of care standards for IBD patients has led the **European Crohn's and Colitis Organisation (ECCO)** to work on the construction of a list of criteria summarising current standards of care in IBD.

The list is based on scientific evidence, interdisciplinary expert consensus and patient-oriented perspectives. It represents the position of ECCO regarding the optimum quality of care that should be available to patients.

Considering that healthcare systems and regulations vary between countries it might be necessary to adapt it at local and national levels and it is recognised that not all criteria that have been identified as optimal will be available in every unit.

An initiative of ECCO, the **“United Registries for Clinical Assessment and Research” (UR-CARE)** database is an online international registry capturing IBD patients' records in an easy and comprehensive way.

UR-CARE is designed for daily clinical practice and research studies and is available to study groups as well as to individual centres.

Another issue MD Fidalgo highlighted was the incompatibility of Clinician Rated Outcome Measures (CROMS), Patient Reported Outcome Measures (PROMs) and Patient Reported Experience measures (PREMs). Furthermore, none of the 20 existing PRO tools for disease activity meet the FDA criteria for tool quality and only 2 of them involved patient representatives in the process.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) perspective

Pharmaceutical companies in Europe are recognizing that digital technologies are driving a radical transformation of our healthcare systems and that in order to support health innovations there is a need for connecting and collaborating with all relevant stakeholders.

In its manifesto “Building a healthier future for Europe” the EFPIA calls for the need to “drive the evolution towards patient-centered and outcomes-focused healthcare systems to allow national governments to recognise and reward innovation based on the value it brings to patients and society. This includes assessing and benchmarking EU Health Systems by using patient-relevant outcomes, with the support of digital solutions and a European harmonised distributed health data network”.

Speaking on behalf of the European Federation of Pharmaceutical Industries and Associations (EFPIA) Ms Meni Styliadou and Pr Tanja Stamm, PhD (Head of Section for Outcomes Research at Vienna University) presented the H2O (Health Outcomes Observatory) a European project funded by the Innovative Medicines Initiative.

The project will empower patients with tools to measure their outcomes in a standardised manner creating transparency of health outcomes.

The overall objectives of H2O will be to make health outcomes transparent to patients and other stakeholders in order to improve clinical care, to enhance medical research and to support moves to value-based healthcare while also creating an ethically and legally appropriate model for the collection and management of patient health data.

Patients will create information and use this with their health care professionals in routine clinical care; researchers and policy makers will use the new data to improve policy and decision making.

An umbrella organization at the European level will ensure interoperability and reproducibility at international level.



Meni Styliadou (left) and Tanja Stamm

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**Drive the evolution
towards patient-centered
and outcomes-focused
healthcare systems
to allow national
governments to recognise
and reward innovation
based on the value it
brings to patients and
society...**

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Discussion points

Following these presentations and discussions during the Question and Answers session we have identified the following elements/barriers that we aim to further discuss with all multi stakeholders and industry alliances.

INTEROPERABILITY

The interoperability of digital medicine. The fact that there are a wide range of databases, compatible systems and proprietary software means that it is difficult to exchange, analyse and interpret data in a meaningful way. Interoperability is seen as one of the key elements to ensure meaningful digital health outcomes.

TRUST

Concerns about user's data privacy, the ownership data and data protection need to be taken into consideration in order

to encourage greater use of the most impactful technologies. **Data collection and protection under institutional umbrella.**

ALL INCLUSIVENESS

In order for digital technologies to have a meaningful impact on the improvement of health and healthcare these technologies need to be accessible to everyone. Digital literacy, economic income level and education are some of the aspects that need to be taken into consideration.

DISCUSSION POINTS

PATIENTS AS EQUAL PARTNERS

Digital solutions that are “made by patients” are more likely to address these barriers and to be used by patients and therefore it makes sense to involve patients early and in a systematic manner in the development of digital technologies.

DATA COLLECTION AND DATA OWNERSHIP

Patients’ engagement can be of paramount importance not only in the collection of their data. Patients can also play a crucial role when it comes to data analysis issued from quality of care and patient-reported outcomes. The ownership of these data combined with a greater involvement in the analysis of clinical data may be a possible path and lead to a more patient-centred approach and deliver more personalised care.

STANDARDISATION

There is a need for standardized dataset for IBD that should be endorsed by ECCO, EFCCA and CCFA as well as agreed and accepted outcome measures including CROs / PROMs / PREMs for benchmark and outcome research.

SLOW UPTAKE

In many countries across Europe the uptake of digital solutions is slow and HCPs are reluctant to use them in daily practise. Patients do not yet see any direct benefits which often results in desisting from using such tools.

There is a **need to engage and raise awareness with health care providers and the patient community** to ensure that they are well informed of the benefits that digital health can deliver.

Step forwards

The Symposium has been a unique meeting in bringing together major stakeholders to discuss the issues around digital health and data collection. It has provided us very useful insights into the variety of aspects of this topic and will allow us to foster a meaningful exchange of ideas and common strategies.

It is foreseen to continue with this dialogue, and we will look into involving further stakeholders such as the payers (through the International Association of Mutual Benefit Societies (AIM) as well as the regulators such as the European Medicines Agency.

We strongly believe that such a multi stakeholder approach is needed in order to create synergies and ensure that digital technologies are developed in the most efficient and effective way whilst taking into consideration their relevance to patients.



EFCCA wishes to thank the Congress partners and sponsors:



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