DIVA

Data Insights for Added Therapeutic Value

EFCCA Conference

Vienna, 12 October 2024

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EFCCA
European Federation of Crohn's & Ulcerative Colitis Associations

Setting the scene

1. The new Pharmaceutical strategy promotes research, but also assesses certain market failures.

2. Until now, unmet needs were mainly focused on patients related to financially related aspects.

3. We need to promote the generation, collection and use of evidence-based patient experience data for benefit-risk decision-making; (EMA framework).

4. **This changes how we justify an estimate the value of therapeutic proposals.**

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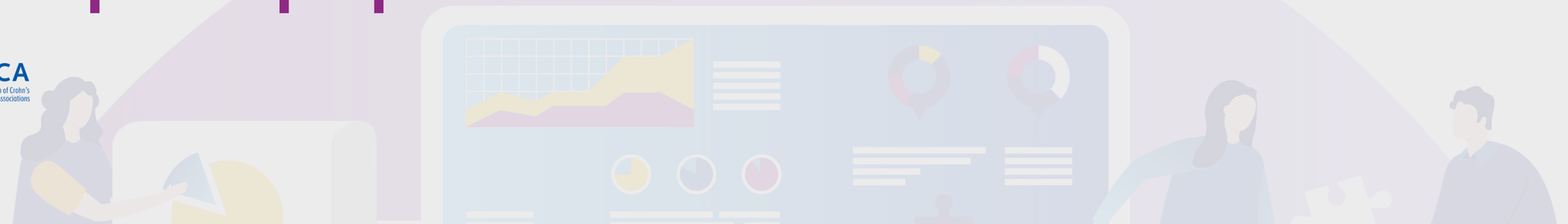
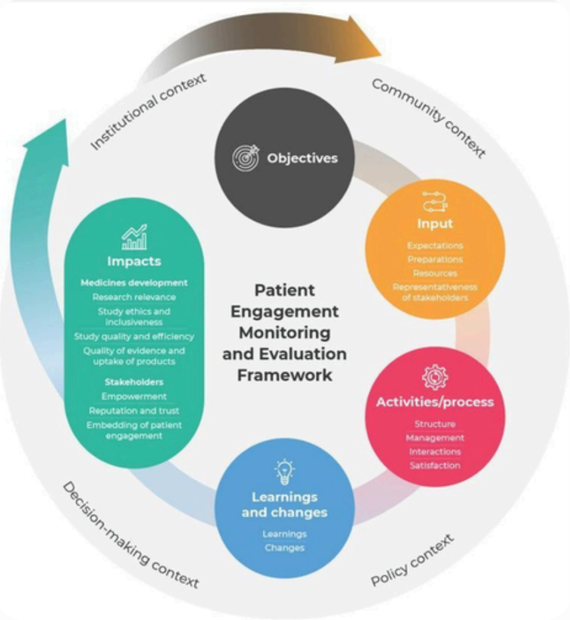


A new role for patients' associations:

EFCCA opinion matters

The **new EFCCA's roadmap and related methodological approach** are a clear shift of the role of the patient.

A much more proactive aimed at identifying an addressing the real needs of patience and healthcare systems.



EFCCA **must give** evidence based answers to stakeholders such as regulators, policy makers, pharmaceutical industries and healthcare professionals.

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EFCCA realised that **data** are gold...

and that there was a **limited availability** of accessible data on IBD, starting from Clinical Trials

From May to September 2022, several brainstorming sessions were held with Board members and staff to conduct a **feasibility study** in line with the consultations and core priorities of EFCCA 2023-2027 Strategic Plan.

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How DIVA was born

In **2022** a **draft project** was presented to different stakeholders

The proposal was enthusiastically **welcomed**

In October 2022, at UEGW in Vienna, we introduced **DIVA**, our new methodological approach, to a multidisciplinary audience, that confirmed that we were on the right track

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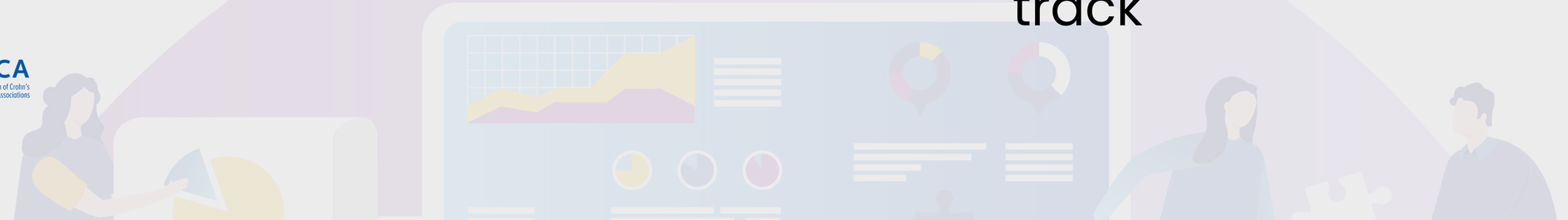

DIVA in a nutshell

Evidence-based data is crucial when discussing with **stakeholders** like policymakers and pharmaceutical companies.

This ensures that decisions are grounded in the **latest** and **most reliable** information.

All EFCCA representatives know **how challenging** it is to discuss unmet needs and patient priorities without relevant data.

Very often, it is only possible to share **personal experiences**, which are not necessarily representative of the patient community.

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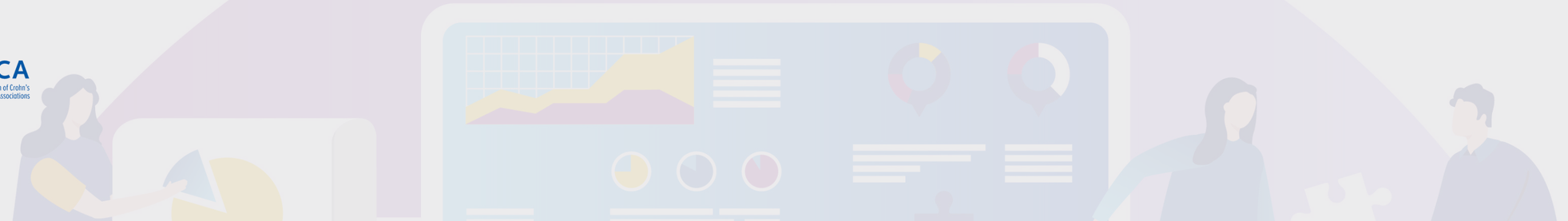
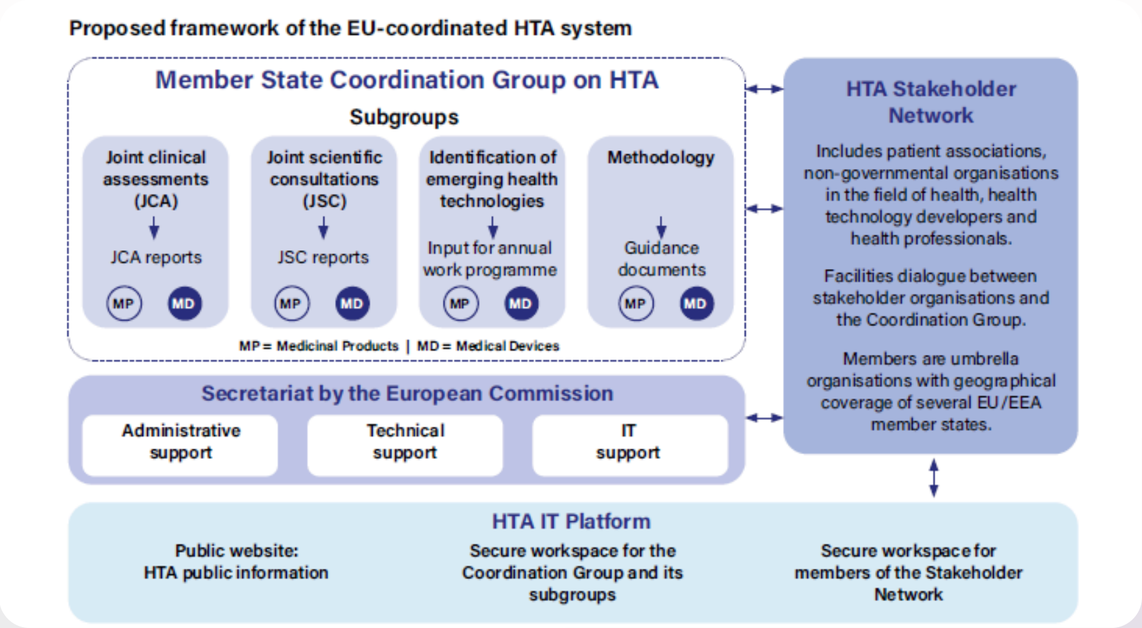


EMA Engagement Framework



Also, EMA and EC is asking to do so!

*"EMA is committed to ensuring that **the patient voice is included** in the different regulatory activities of a medicine's lifecycle, which improves the quality of and trust in the regulatory decisions and in new medicines placed onto the EU market."*

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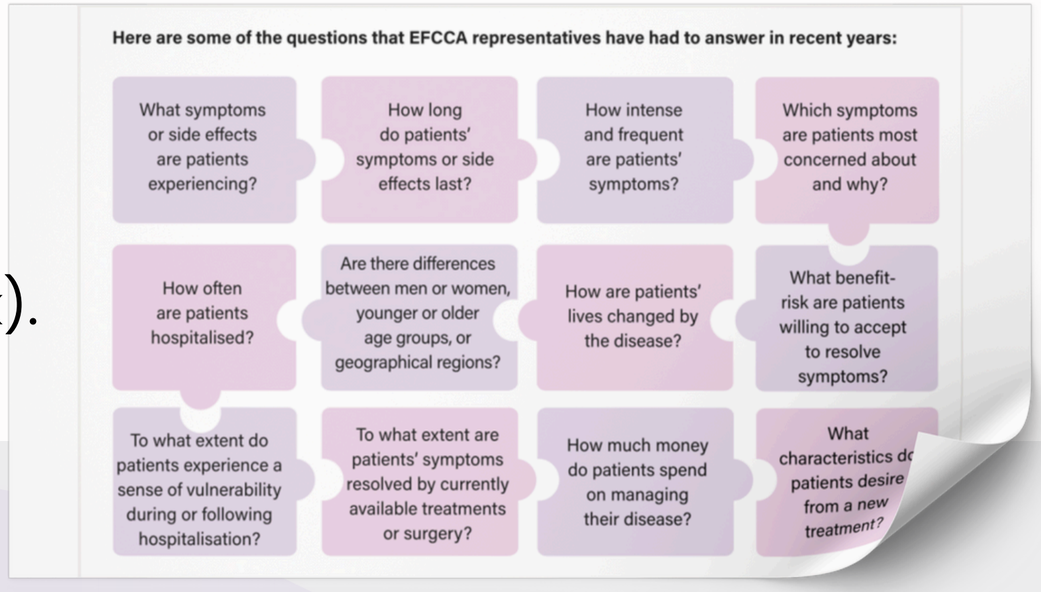
A new role for patients' associations:

EFCCA opinion matters!

We are promoting the generation, collection and use of evidence-based patient experience data for benefit-risk decision-making; (EMA framework).

EFCCA wants to give evidence-based answers to stakeholders such as regulators, policy makers, pharmaceutical industries and healthcare professionals.



EUnetHTA: template for asking patients associations

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How EFCCA aims to respond to this new role?

With **DIVA**: **D**ata **I**nsights for Added therapeutic **Va**lue

- DIVA aims to identify and address the **real needs** of IBD patients.
- It makes use of **publicly available data** and **internal EFCCA data** to analyse and interpret the IBD patient communities' unmet needs.
- Its objective is to provide **harmonised opinions and recommendations** to stakeholders (regulators, policy makers, pharmaceutical industries and healthcare professionals).

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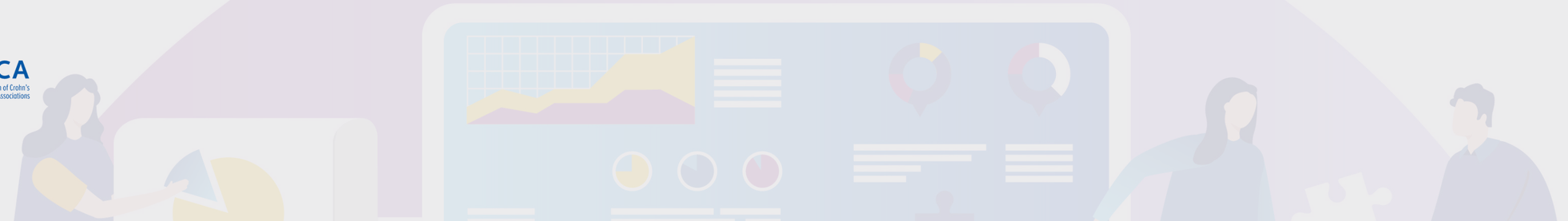
DIVA 2023-2024 Main Features

- IBD **clinical trials** available in EFCCA countries
- **Drugs** approved by EMA
- **Interactive AI** to consult IBD scientific literature and content published by EFCCA and EFCCA members (**chatIBD** in several languages)
- **Direct monitoring** of symptoms and side effects reported from patient-reported testimonials



DIVA 2025... What's next?

2025

The next step that will help to close the circle will be to **cross-reference all the information** that patients report to us in real time to continue supporting researchers and also to continue evaluating the value of innovation based on what patients really need.

We are nearly there. Stay tuned!

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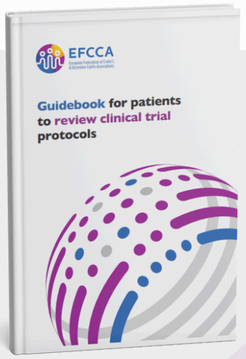
DIVA 2023-2024 Deliverables

October 2023

- Launch of the Guidebook for patients' to review clinical trial protocols



April 2024

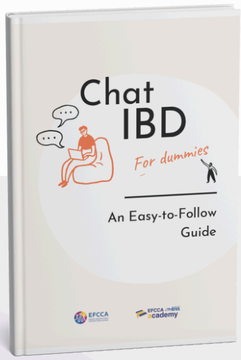
- DIVA Academy

March 2024

- Health Tecnhnology Assessment (HTA) Guidebook

July 2024

- ChatIBD for dummies



December 2024

- Exercise book?

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ChatIBD for dummies

- We are aware that, being a new tool, DIVA may be **somewhat technical** for some users
- Therefore, we created "ChatIBD for dummies," a **simple user guide** aimed at DIVA Academy students

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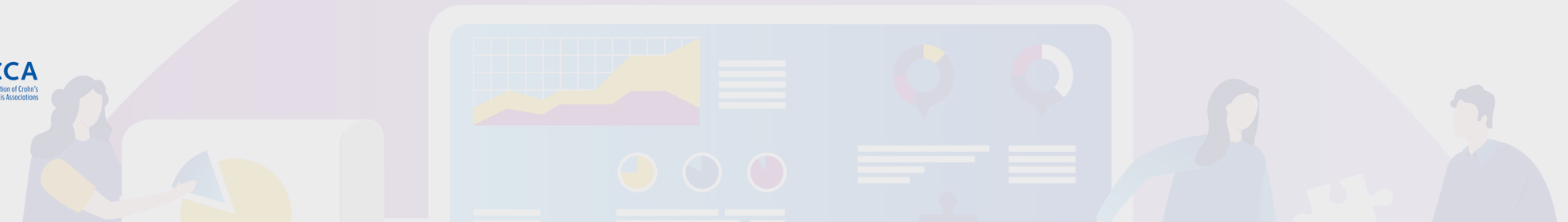
How to enhance DIVA?

How can a patient association support EFCCA in feeding and enhancing DIVA to **increase national data availability**?

- **Testing** the tool
- Sharing your **experiences**
- Work in connection with **the DIVA team** to make their data analysis available at a national level
- Participating in **DIVA activities and initiatives**
- Give availability and share publicly available **national data bank**



Thank you!

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