

### **TEMPLATE FOR ECFS WORKING GROUP REPORTS**

Please use this template for your annual working group report. Please use black ink, Calibri font size 11. For more information, please read the ECFS working group Terms of Reference document

Year of report: 2024 – 2025

Name of Working Group:  
Mental Health in the Era of CFTR Modulators Working Group (formerly, Mental Health Working Group)

Date of initial approval of working group:  
October 2022

Contact details of coordinator, vice coordinator and assistant (if applicable) including ECFS membership numbers:

Coordinator name: Dr. Eddie Landau  
Coordinator name: Dr. Sonia Graziano

Long term aims of the working group (maximum 100 words) including estimated achievement date:  
The landscape of CF has changed dramatically following the introduction of CFTR modulator treatment, with concomitant changes in mental health, which are being reported in the international literature. The long term aims of the MHWG are to carefully follow up on the changes in the MH working field, to study and disseminate new developments. Of course special attention is given to the MH of pwCF who are not (yet) eligible for modulator therapy. Future goals include measuring critical side-effects and learning about their prevalence, etiology, and strategies that successfully mitigate them. Further, as ETI is prescribed for younger children, emotional, behavioural and cognitive issues have emerged. Our current International Mental Health Guidelines only address screening in children and adults beginning at age 12 years. The critical future initiative is to assess the prevalence of depression, anxiety and behaviour problems in children < 12 years. One of the main aims of this group will be to monitor and evaluate current screening practices across countries for children < 12 years, with the goal of working towards harmonizing measures to allow for broader scale outcomes research. We want to collect information about measurements used in various countries while also continuing work toward standardized measures.

- Hence, the two underlying long-term goals for the continuation of MHWG are: 1) to assess the prevalence of mental health challenges in this young age group, and 2) identify the optimal screening tool for children < 12 years. Results of TIDES 2.0 would likely lead to an updating of the International Mental Health Guidelines to include recommendations for screening and treatment guidelines for mental health in children less than 12 years of age.

Outcomes already achieved this year (2024-2025):

We currently have 19 members

This group has meetings regularly once a month, and have worked on the four main areas described below.

#### **1. Research**

The experiences of Kaftrio/Trikafta Mental Health Survey (EUROPE) in pwCF aged  $\geq 12$  years was launched for healthcare providers in Europe, after adapting it from the US version to the European health care system. A SurveyMonkey® format was created and was distributed throughout Europe by ECFS to the multidisciplinary care team. These results were presented last year at the ECFS in Glasgow. We are finishing the writing up of the data with the plan to publish the paper later in the year.

Graziano, E.C. Landau, H. Mitmansgruber, A.L. Quittner, M. Verkleij, A.M. Georgiopoulos, U. Borawska-Kowalczyk, C.J. Bathgate. EPS10.09 Positive and negative impacts of elexacaftor/tezacaftor/ivacaftor: comparison of healthcare providers' observations in Europe vs US, Journal of Cystic Fibrosis, Volume 23, Supplement 1, 2024,

Page S65, ISSN 1569-1993, [https://doi.org/10.1016/S1569-1993\(24\)00307-2](https://doi.org/10.1016/S1569-1993(24)00307-2)

### **Psychosocial professional resources and education training**

- We have developed a subgroup within the MHWG who are currently working with the ECFS Education committee setting up online syllabus and education modules related to mental health care. We work jointly with the EPSIG.
- We have been adding all of the educational handouts on modulator use and other topics to the MHWG website, with translations for European countries. In collaboration with the CFF Mental Health Advisory Committee (MHAC) in the US, US liaison Dr. Anna Georgiopoulos shared handouts on a variety of prevalent topics, including effects of modulator use in different populations and ages. These have been added on the website. These materials together with other resources such as the Mental Health screeners have been shared with medical professionals and parent associations across Europe. To date, they have been translated into various Eastern European Languages including Latvian, Macedonian Polish, Romanian, Russian, Serbian, Slovakian, Slovenian and Ukrainian; and updated on our website under tools and resources:

[https://www.ecfs.eu/mental\\_health-tools/guidelines](https://www.ecfs.eu/mental_health-tools/guidelines)

### **3. Organizing the pre-conference workshop jointly with EPSIG:**

#### **Pre-Conference Short Course:**

**The challenges of managing the neuropsychiatric and psychological effects of modulators:**

**Practical and clinical implications:** Tue 3rd June. 1400-1800.

### **4. Organizing the tomorrow's lounge:**

Tomorrow's Lounge session: **"How are we measuring mental health and quality of life impacts of CFTR modulators"** : Thursday 5th June, 12:45-13:45

### **Lunchtime Webinars**

For the past four years the MHWG and EPSIG have organized a series of three lunchtime webinars for the CF MDT.

The aim is to join up for an hour online and discuss pertinent topics related to CF, mental health and psychosocial care and that it be a useful forum for CF team members from all disciplines and from all over the world (we have participants from over 36 countries).

The topics of organised webinars for this year included:

- **Substance abuse and risk-taking behaviour 9<sup>th</sup> April 2025**
- **Perspective from different ages: from generation to generation 12<sup>th</sup> February 2025**
- **Is telehealth taking over regular face to face consultations? 27<sup>th</sup> Nov 2024**

#### **Network of Colleagues**

We have created a network of colleagues around Europe and E. Europe and also involve representatives from the CFF Mental Health Advisory Committee (MHAC) and Prioritizing Research in Mental Health (PRIME) in the US. We all meet once a month on a regular basis to discuss and achieve the aims of the MHWG. In addition, Drs Graziano and Verkleij are involved in the research group and Dr Landau is part of the education group for the CFF MHWG.

Aims for the coming years (max 50 words): 2025-2026

- Drs Eddie Landau and Sonia Graziano have completed their tenure as co-chairs on the MHWG in the era of modulators.
- Dr Urszula Borawska – Kowalczyk (Poland) and Pavla Hodkova (Czech Republic) will be carrying on as the new co-chairs (after hopeful acceptance of re-application for the renewal of the MHWG in the era of modulators).
- Continue the work on disseminating knowledge and information concerning MH and MH screening around Europe, particularly in the era of the new modulators
- Europe-wide monitoring of the assessment and evaluation of mental health and CFTR modulator side effects in children under 12 years, adolescents (for some European countries this will involve conducting the TIDES 2.0 study) and adults with CF
- Continue work on the above described educational and conference projects.
- Discuss, collaborate and contribute to the ECFS projects, conferences and online meetings.

Summary (maximum 100 words):

- Maintaining and updating the Mental Health Website including more resources and handouts as well as short- and long-term psychosocial consequences of starting ETI.
- Continue to hold zoom monthly MHWG meetings.
- Hold the Mental Health Working Group Annual General meeting during ECFS Annual Conferences (25 - 30 participants).
- Manuscript in preparation: "Positive and Negative Impacts of Elexacaftor/Tezacaftor/Ivacaftor: Comparison of Healthcare Providers' Observations in Europe vs US"
- Continue to be involved in conference activities, including pre-conference workshop, tomorrow's lounge.

Long term goals: 1) Disseminate knowledge and information across Europe on assessing the mental health of people with CF in the era of CFTR modulators 2) Evaluate the mental health and side effects of CFTR modulators in children under 12 years old, adolescents, and adults (with the aim of some European countries conducting TIDES 2.0 study, 3) translate GEMS-CF into European languages and put them on the website; 4) work toward updating the international mental health guidelines based on the introduction of ETI and new data on mental health.

Breakdown of expenses (please include total amount received as well as expenditure and, if applicable, the outstanding balance (Euros)):

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Pre-conference short course instructor's fee €700, travel (estimated €200) and accommodation for one night (estimated €150), and moderators' registration €300, catering €900: to be split equally between EPSIG and MHWG.

MHWG expenses for above €1,200 Euros

MHWG meeting at Milan Conference:

Room rental:

Catering: 650-700€

Budget amount requested for next year (please give the amount in Euros and the year):

- Organisation of meetings/networking events, minute meetings, produce newsletters/report, liaison with ECFS, CF Centres and Patient Associations
- Statistical support for analyses
- Manage website resource content
- Web-based Survey administration
- Training Workshops

**The deadline for submission to the ECFS Office is 1st May 2025.** The report will then be presented to the board prior to the summer ECFS board meeting and then a decision will be made at the next board meeting for approval before being distributed. Please email the report to: [jess.matthews@ecfs.eu](mailto:jess.matthews@ecfs.eu)