



Characterization of individuals with cystic fibrosis in Norway

Cystic fibrosis (CF) is a progressive genetic disorder caused by pathogenic variants in the CFTR gene. It is associated with substantial morbidity and premature mortality. This DARWIN EU® study aimed to characterize people with CF and estimate the incidence of comorbidities. Also, it provides context for safety evaluations of CFTR modulators and future real-world studies. Here, we highlight results for Norway.

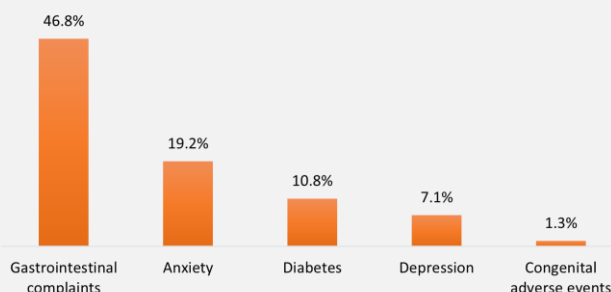
Study overview

- Design: Cohort study using routinely collected data from 11 data sources in nine European countries.
- Population: Individuals with CF in Norway (2015-2023) with ≥ 1 year of prior observable data and 180 days follow-up (N = 3,314)
- Patient demographics and comorbidities, CFTR modulator utilization, and incidence of selected comorbidities (cataract, depression, anxiety, and pulmonary exacerbation).

CF patient characteristics in Norway

- Norway contributed to the largest CF cohort and the largest number of CFTR modulator initiators to the study.
- Among CF patients, 35.2% were aged ≤ 17 years. The median age was 37 years (IQR 9–65).

Comorbidities in individuals with CF before recorded diagnosis

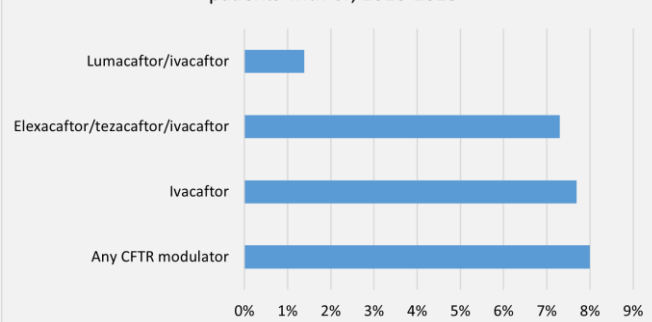


- Comorbidities after first CF diagnosis (incidence per 1,000 person-years) showed an overall decline: cataract decreased from 16.7 (2018) to 15.3 (2023), depression from 4.6 (2019) to 4.0 (2023), anxiety from 51.7 (2016) to 22.5 (2017) (similar rates thereafter), and pulmonary exacerbation from 135.3 (2018) to 55.2 (2023).

CFTR modulator utilization in Norway

- In Norway, 8.0% of individuals with a diagnosis of CF had any CFTR modulator treatment recorded, between 2018-2023.

Prevalence of CFTR modulator use among Norwegian patients with CF, 2018-2023



- Ivacaftor appears in nearly all modern regimens and as monotherapy for gating mutations, making it the most prevalent single substance.
- Like in many EU countries, the triple combinations (elexacaftor + tezacaftor + ivacaftor) tend to dominate use because they cover a large share of genotypes eligible for modulators, but actual prevalence varies a lot by genotype mix, age, and national reimbursement.
- The least frequently used CFTR modulator combination was ivacaftor/tezacaftor (0.2%), like in most other datasets.

Data & Methods notes

- The cohort entry date is the earliest recorded CF diagnosis during the study period and should not be interpreted as the true clinical diagnosis date.
- Key CF markers (e.g., sweat chloride, genotyping) were unavailable, some clinical monitoring variables (e.g., BMI) were not available in Norway.

How was this useful?

Norway was the largest contributor in the multi-database study, with 31.8% of CF cases and 34.2% of CFTR modulator initiators. Norway-specific results provide reference benchmarks for CF patient characteristics and drug utilization. Incidence rates for the four assessed comorbidities generally declined over time. Future work should improve data capture of key CF clinical variables and standardize outcome definitions to enhance comparability and support regulatory-grade real-world evidence.

Access to the full report

[DARWIN EU® - RR Characterisation of individuals with cystic fibrosis in Europe](#)

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