The European Cystic Fibrosis Society Patient Registry's Data Quality programme

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Background
The European Cystic Fibrosis (CF) Society Patient Registry collects demographic and clinical data from consenting people with CF in Europe. The Registry's database contains data of over 49,000 patients from 38 countries. High quality data is essential for use in annual reports, epidemiological research and postauthorisation studies.

Methods
A validation programme was introduced to quantify consistency and accuracy of data-input at source level, and verify that the informed consent – required to include data in the Registry – has been obtained in accordance with local and European legislation. Accuracy is defined as the proportion of values in the software that match the medical record, and consistency as definitions used by the centre that match those defined and required by the Registry. The data fields to verify: demographic, diagnostic, transplantation, anthropometric and lung function measurement, bacterial infections, medications and complications. The number of countries to validate: 20% of the total countries per year, max. 5 countries/year. In the selected country ≥10% of the centres are to be visited and 15-20% of patients' data validated. The visits are limited to centres with ≥50 patients.

Results
In a one day visit the aim of the programme was explained to the centre, the data included in the Registry were compared with the medical records, the outcomes and recommendations discussed, and a final report provided to the centre. Challenges proved to be: informed consent (re-consent at adult age or when the patient moved centre), mutation information (genetic laboratory report missing), different interpretations of the definitions. The outcomes of the validation visits are presented in Figure 1.

Conclusions
Validation visits are essential to optimise data quality at source, ensure centres are aware of the importance of correct informed consent and encourage dialogue to gain insight in how procedures, software, support and training can be improved.

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Figure 1

Variable type	Variables verified	Correct (= accurate and consistent) Total (range for each country)	Comment
Demographics	Birth date (month and year only) Gender	98.8% (96.2 – 100%) 99.8% (99.5 – 100%)	
Genetic information	Mutation	77.4% (55.2 – 91.7%)	No source data 21.4% (4.1-44.5%); Incorrect data 0.9% (0.0-5.1%)
Transplantation	Organ (Lung, Liver) Year of transplant	99.8% (99.1 – 100%)	
Anthropometrics	Weight Height	92.2% (77.5 – 97.5%) 92.8% (81.6 – 97.5%)	Definition criteria in selected centre(s) inconsistent with Registry definition: "height and weight at best FEV1% pred of the year"
Lung function	Best FEV1% pred of the year	86.4% (38.8 – 92.6%)	Definition criteria in centre(s) inconsistent with the ECFSPR definition
Medication	Inhaled antibiotics DNAse Pancreatic enzyme use	96.1% (93.9 – 98.6%) 98.1% (96.3 – 99.3%) 97.6% (93.8 – 99.3%)	
Microbiology	Chronic Pseudomonas aeruginosa infection Chronic Burkholderia Spp infection	95.0% (85.7 – 99.3%) 97.0% (85.7 – 99.3%)	
Complications	Liver disease Major Haemoptyis Diabetes treated with daily insulin	86.8% (84.7 – 91.8%) 94.6% (86.4 – 100%) 97.2% (93.8 – 100%)	Uncertainty regarding the definition of "liver disease w/o cirrhosis"

Legend: Green > 95%, Blue 90-95%, Red: < 90%