

GRANT APPLICATION 2021

Pharmacovigilance (PMV) study, on secondary use of data, to monitor the safety and efficacy of Lumacaftor/Ivacaftor in 2-5 year old F508del homozygote CF patients (study period 2018-2024).

APPLICANT Name

Name contact person responsible for the application

Rita Padoan

Position/role in the organisation

Country Coordinator

Name Centre/National Registry

Italian Cystic Fibrosis Registry

City

Rome

Country

Italy

Email

ritaf54@gmail.com

Telephone (mobile)

+39 4990 4369

Country

Italy

Mandate

Indicate the number of centres that you are representing: 29

RECIPIENT Name

Official legal entity of the organisation

Lega Italiana Fibrosi Cistica Onlus

Legal form of recipient

Dr. Gianna PUPPO FORNARO

Recipient contact name

Gianna PUPPO FORNARO, Rita Padoan, Marco SALVATORE

Email

Email recipient

info@registroitalianofibrosicistica.it

Country recipient

Italy

ACCOUNT HOLDER Name

Lega Italiana Fibrosi Cistica OdV

Bank account number (IBAN) of account holder

IT98 M030 6909 6061 0000 0151 634

Indicate a reference to track the payment

Mr. Angelo Guidi

Country

Italy

Type of grant requested

Direct

Description of use of the grant (max. 10 lines)

The main aim of Italian Cystic Fibrosis registry (ICFR) is to contribute to the improvement in CF patient's health care and clinical management through: i. the estimates of CF prevalence and incidence in Italy; ii. the analyses of medium and long term clinical and epidemiological trends of the disease; iii. the identification of the main health care needs at regional and national level to contribute to the Health Care programmes and to the distribution of resources. ICFR aim at participating to pharmacovigilance study (PMV) project as a comparator. Total number of patients included in Italian Registry in 2020 is 5841 (excl. Lost to follow-up). Grants will be mainly used i) to improve quality of management of data at both central and local level and ii) to update software for data exchange. Actually, 29 centers are involved in registry activities; our aim is to distribute major part of funds from PMV activities among all centers on the basis of the number of patients in care at each single center. A dedicated ICFR bank account is in place since many years; the account is administered by the Italian CF patient league (LIFC, central partner of registry activities). For PMV purposes, LIFC will administer and supervise in an impartial way the funds from PMV study.