Results

Project Information

PIBD-SETQuality

Grant agreement ID: 668023

Funded under
H2020-EU.3.1.
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Overall budget
€ 5 996 000

EU contribution
€ 5 996 000

Coordinated by
UNIVERSITE DE PARIS
France

Deliverables

Documents, reports (17)

Generation of new risk stratification algorithms for UC
The evolution of patients over at least 3 years in the inception cohort WP7 will be prospectively analysed with the aim of identifying new predictors for severe disease evolution This deliverable will help to identify additional predictive factors

Generation of new risk stratification algorithms for CD
The evolution of patients over at least 2 years in this inception cohort WP7 will be prospectively analysed with the aim of identifying new predictors for severe
disease evolution. This deliverable will help to identify additional predictive factors.

450 patients recruited

This deliverable allows the extraction of sufficient and relevant prospective data needed for a first independent validation of the risk algorithms WP12 as well as the health economic evaluations WP8 and microbial immunological genetic testing WP91011.

900 patients recruited

Main deliverable of this inception cohort data analysis of at least 900 patients with a followup of 13 years equal approx 1500 patient years.

Final analysis of efficacy, side effects and dropout rate in relation to drug monitoring results

After completion of followup of patients in the azathioprine or adalimumab arm the PKPD data will be analysed for correlation of drugab levels and efficacy data side effects or dropout rates.

1st patient recruited

The inclusion of the first patient in this registry indicates that the system is fully operational.

Design of new assays to further discriminate patient categories and therapy responsiveness.

Based on D93 new assays will be designed and validate to discriminate different patient categories. This deliverable will result potentially in a new functional test which might give raise to a new European patent.

Final Analysis of TUMMY-CD performance in the risk-stratified RCT (at least in a subgroup of patients)

The TUMMY-CD is integrated in the RCT WP3 and thus its performance can be compared to endoscopic and clinical parameters within the RCT. This deliverable will allow to further validate the use of a PRO and to elaborate future strategies of patient reported outcome evaluations.

Annual summary of incidence and prevalence of rare complications

Annual analysis and report of AE and SAE allow to produce an incidence/prevalence analysis within the PIBD cohort. (M24, 36, 48) Lead beneficiaries: QMUL, ERASMUS, PIBDnet.

Final report on genetic risk profiling of PIBD patients with rare and severe adverse events and potentially proposal of a risk-minimization algorithm based on these molecular data

This deliverable will report on all genetic analyses completed within PIBD Set Qualtiy. These results will be reported scientifically and there might be also a potential for a new European patent.
Implementation of the project website
This will allow to generate a functional electronic interactive tool for all aspects of PIBDSETQuality. The communication of PIBD-SET Quality activities/projects will be achieved by the creation of a specific website (within the PIBDnet portal) allowing a large visibility with in the PIBD community. Communication beyond including press media is planned. Specific attention will be given to the frequent updating of the website content. A periodic newsletter will be also published on the project website.

Modelling of health economic impact according risk stratification in paediatric CD
This deliverable will produce a model of the health economic impact comparing different treatment strategies based on the risk of severe disease progression in paediatric CD. This tool will allow the consortium to add to efficacy and safety data also knowledge on the health economic impact of different treatment algorithms. This will be reported via scientific publications M4448.

Internal annual report related to WPs
This is an important yearly deliverable allowing to follow closely the progress of the WPs and it will allow to perform interim quality analyses. (M12, 24, 36, 48)

Final report on microbiome markers
Based on D102 new assays will be designed and validated to discriminate different patient categories. This deliverable will result potentially in new analytic test which might give raise to a new European patent.

Clinical Research Tool Demonstration (Demonstrator)
This deliverable will document how the clinical research tool in the PIBD cloud environment has aided the aims and objectives of the PIBD project.

"Kick-off meetings and annual meetings"
First and scheduled follow-up face-to-face meetings, allowing an efficient organisation and thorough realization of the different WPs. (M1, 12, 24, 36)

Midterm recruitment report
Analysis based on approximately 50 of the study population recruited into the clinical trial. This report includes an overview of recruited subjects by study sites potential recruiting problems and if applicable a detailed description of implemented and planned measures to compensate delays in the study subject recruitment. This deliverable is an additional step to increase the quality and safety of the RCT.
Protocol for a multinational risk-stratified randomised controlled trial in paediatric Crohn’s disease: methotrexate versus azathioprine or adalimumab for maintaining remission in patients at low or high risk for aggressive disease course

Author(s): Rachel E Harris, Marina Aloi, Lissy de Ridder, Nicholas M Croft, Sibylle Koletzko, Arie Levine, Dan Turner, Gigi Veereman, Mattias Neyt, Laetitia Bigot, Frank M Rüemmele, Richard K Russell
Published in: BMJ Open, Issue 10/7, 2020, Page(s) e034892, ISSN 2044-6055
DOI: 10.1136/bmjopen-2019-034892

International prospective observational study investigating the disease course and heterogeneity of paediatric-onset inflammatory bowel disease: the protocol of the PIBD-SETQuality inception cohort study

Author(s): Martine A Aardoom, Polychronis Kemos, Irma Tindemans, Marina Aloi, Sibylle Koletzko, Arie Levine, Dan Turner, Gigi Veereman, Mattias Neyt, Richard K Russell, Thomas D Walters, Frank M Rüemmele, Janneke N Samsom, Nicholas M Croft, Lissy de Ridder, PIBD-SETQuality consortium and PIBD-NET
Published in: BMJ Open, Issue BMJ Journals, 2020, ISSN 2044-6055
DOI: 10.1136/bmjopen-2019-035538

Identifying Health Economic Considerations to Include in the Research Protocol of a Randomized Controlled Trial (the REDUCE-RISK Trial): Systematic Literature Review and Assessment

Author(s): Mattias Neyt, Annick Christiaens, Marina Aloi, Lissy de Ridder, Nicholas M Croft, Sibylle Koletzko, Arie Levine, Dan Turner, Richard K Russell, Frank M Rüemmele, Gigi Veereman
Published in: JMIR Formative Research, Issue 5/1, 2021, Page(s) e13888, ISSN 2561-326X
DOI: 10.2196/13888

P584 Rare and severe complications in children with paediatric-onset IBD; the international PIBD SETQuality Safety Registry by PIBDnet

Author(s): M Aardoom, P Kemos, F Rüemmele, N Croft, L de Ridder
Published in: Journal of Crohn’s and Colitis, Issue 12/supplement_1, 2018, Page(s) S403-S404, ISSN 1873-9946
DOI: 10.1093/ecco-jcc/jjx180.711

P785 Designing the first pan-European paediatric IBD database to allow the study of incidence and prevalence of UC, CD, and their rare and severe complications

Author(s): P Kemos, M Aardoom, F Rüemmele, L de Ridder, N Croft
Published in: Journal of Crohn’s and Colitis, Issue 12/supplement_1, 2018,
The Incidence and Characteristics of Venous Thromboembolisms in Paediatric-Onset Inflammatory Bowel Disease: A Prospective International Cohort Study Based on the PIBD-SETQuality Safety Registry


Published in: Journal of Crohn's and Colitis, 2021, ISSN 1873-9946
DOI: 10.1093/ecco-jcc/jjab171

Dissecting the Heterogeneity in T-Cell Mediated Inflammation in IBD

Author(s): Irma Tindemans, Maria E. Joosse, Janneke N. Samsom

Published in: Cells, Issue 9/1, 2020, Page(s) 110, ISSN 2073-4409
DOI: 10.3390/cells9010110

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