Hillerød, 23 December, 2025

Ansøgning om støtte til etablering af biobank og regulatorisk godkendelse

Kære Colitis-Crohn Foreningen – Foreningen for tarmsyge,

Vi ansøger hermed om økonomisk støtte til gennemførelse af et forskningsprojekt om optimal timing af vaccination hos patienter med inflammatorisk tarmsygdom (IBD).

Projektet har til formål at undersøge, om patienter med IBD, som er i stabil remission under biologisk behandling, opnår et lige så godt immunrespons på pneumokokvaccination som nydiagnosticerede patienter uden immundæmpende behandling. Resultaterne kan få direkte betydning for fremtidige vaccinationsanbefalinger og dermed bedre beskyttelse mod alvorlige infektioner hos mennesker med IBD.

Projektet gennemføres af en tværfaglig arbejdsgruppe bestående af **læge, ph.d., lektor Mette Bennedsen** og **professor, overlæge Pia Munkholm** fra Gastromedicinsk Afdeling, Nordsjællands Hospital, samt **Zitta Barrella Harboe, professor i infektionsmedicin**, Lungemedicinsk og Infektionsmedicinsk Afdeling, Nordsjællands Hospital.

Vi søger **50.000 kr.** til etablering af en forskningsbiobank, som muliggør opbevaring og analyse af biologisk materiale over tid. Alternativt søger vi **100.000 kr.**, hvis det er muligt, til både etablering af biobank og dækning af udgifter i forbindelse med ansøgning via **CTIS**, det nye europæiske system for vurdering i de videnskabsetiske komitéer.

Støtten vil være afgørende for at sikre, at projektet kan gennemføres i overensstemmelse med gældende etiske og regulatoriske krav og med et solidt videnskabeligt grundlag.

Vi håber, at foreningen vil finde projektet relevant for mennesker med tarmsygdomme, og takker på forhånd for jeres overvejelse.

Med venlig hilsen

Zitta Barrella Harboe, infektionsmediciner

Optimal **T**iming for **V**accination with the 21-valent pneumococcal conjugate vaccine in immunosuppressive-naïve vs biologic-treated IBD patients in remission supported by the **C**onstant **C**are platform (**OPTIVACC-study**)

I. Introduction

Patients with inflammatory bowel disease (IBD) are recommended to receive pneumococcal and other vaccines ideally before starting immunosuppressive therapy, when vaccine responses are expected to be optimal (1,2). In clinical practice, however, many patients are initiated on immunosuppressive treatments to control symptom burden and do not receive the recommended vaccines. This results in a substantial prevention gap, where patients at increased risk of severe infections remain under-vaccinated (3).

An additional layer of complexity is the dynamic nature of IBD activity. Many patients receiving biological treatment maintain reasonable clinical and biochemical control, as reflected by low symptom scores and fecal calprotectin levels. It is biologically plausible that, under these conditions, vaccine responses could be preserved despite ongoing low levels of immunosuppression.

A telemedicine application, Constant Care (4–6) is currently used in patients with IBD to monitor symptoms and assess intestinal inflammation via fecal calprotectin measurements. The platform supports individualized disease management by increasing patient engagement and enabling nearly real-time adjustments to treatments based on patient self-reported outcomes and biomarkers. It is unknown whether, in this state of controlled inflammation, their vaccine responses are comparable to those of immunosuppressive-naïve patients.

II. Clinical research question

Do patients with IBD receiving immunosuppressive treatments, who have low symptom scores and low fecal calprotectin levels, respond as well to a pneumococcal conjugate vaccine as patients with IBD who are naïve to immunosuppressive treatment?

III. State of the Art

Vulnerability to pneumococcal disease in IBD patients

Patients with inflammatory bowel disease (IBD) are at increased risk of invasive pneumococcal disease (IPD) compared with the general population. In an extensive Danish population-based cohort study including more than 74,000 individuals with IBD (7), both Crohn's disease and ulcerative colitis were associated with a significantly elevated risk of IPD. The highest risk was observed among patients with Crohn's disease (hazard ratio [HR] 1.99), while patients with ulcerative colitis had an approximately 1.5-fold increased risk (HR 1.46).

Notably, the risk was particularly high during the first year after diagnosis but remained elevated for many years thereafter compared with matched population controls (7).This increased susceptibility occurred regardless of immunosuppressive therapy and was already

detectable before the diagnosis of IBD, indicating that the underlying immune alterations intrinsic to IBD itself contribute to infection vulnerability (7).

Pneumococcal vaccines in preventing IPD in IBD patients

Pneumococcal conjugate vaccines elicit T-cell-dependent immune responses that generate durable immunological memory. The newly licensed 21-valent pneumococcal conjugate vaccine (PCV21)(8), provides the broadest serotype coverage to date in adults in Denmark; however, its immunogenicity in patients with IBD, including those who are immunosuppressed, has not yet been explored (9).

Previous studies have demonstrated substantial variability in vaccine responses among patients with IBD receiving different forms of immunosuppressive therapy (10). A randomized controlled trial had previously shown that patients with Crohn disease treated with immunosuppressive drugs alone or in combination with TNF-alfa antagonists had an impaired antibody response following pneumococcal vaccination compared to patients not receiving any of these treatments(11). However, the extent to which biologic therapy may influence PCV21 responses, particularly in patients with low inflammatory burden and biochemical remission, remains insufficiently understood.

Therefore, it is essential to examine how the immunogenicity of this vaccine varies among patients with IBD presenting with different clinical manifestations and levels of immunosuppression. To address this knowledge gap, the OPTIVACC study compares vaccine responses between these two clinically distinct IBD populations. The trial integrates digital disease monitoring through the Constant Care platform, providing precise documentation of symptoms, flare patterns, clinical stability, adverse events**,** and biochemical remission over time.

IV. Objectives

The **primary objective** is to determine whether the proportion of patients achieving a pneumococcal IgG geometric mean concentration (GMC) > 1 µg/mL at Day 28 ± 2 days following PCV21 vaccination is non-inferior in biologic-treated IBD patients in stable clinical and biochemical remission compared with immunosuppressive-naïve, newly diagnosed IBD patients.

The **secondary objectives** are to provide a comprehensive immunological characterization of the pneumococcal vaccine response in both study groups, including:

- Evaluation of serotype-specific IgG responses to 12 pneumococcal serotypes
- Assessment of functional antibody responses using opsonophagocytic activity (OPA)
- Characterization of antibody Fc glycosylation profiles in the long term (> 6 months after vaccination), including sialylation/desialylation patterns.

V. Hypothesis

The **main hypothesis** is that biologic-treated IBD patients in clinical and biochemical remission have noninferior pneumococcal vaccine responses, as measured by the proportion of

participants achieving an IgG GMC >1 µg/mL, compared with immunosuppressive-naïve IBD patients.

The **secondary hypotheses** supporting these objectives are:
- Serotype-specific IgG responses in biologic-treated IBD patients in remission will be similar in magnitude to those observed in immunosuppressive-naïve patients.
- OPA functional activity will not differ significantly between biologic-treated patients in remission and immunosuppressive-naïve patients.
- Fc glycosylation patterns of pneumococcal-specific antibodies will be comparable between the two groups, indicating similar qualitative antibody responses.

VI. Outcomes

Primary Outcome: Proportion of participants achieving IgG GMC > 1 µg/mL across PCV21 serotypes at Day 28 ± 2 days after vaccination.

Secondary Outcomes (descriptive):
- Serotype-specific IgG concentrations for 16 pneumococcal serotypes at Day 28 ± 2 days, 6 months, 12 months, and annually for 5 years.
- OPA titers for the 4 representative PCV21 serotypes at the same time points.
- Fc glycosylation profiles of pneumococcal-specific IgG antibodies at the same time points

VII. Methodology

Study Design

Multicenter, Prospective, two-arm, non-inferiority immunogenicity study in adults with IBD. All participants receive a single intramuscular dose of PCV21 at baseline. The two study arms are defined by treatment status and inflammatory state at enrollment:

Arm 1: Immunosuppressive-Naïve, Newly Diagnosed IBD Patients
Participants must have received an IBD diagnosis within the previous 3 months and must not have been treated with systemic immunosuppressive therapies (including biologics, thiopurines, methotrexate, JAK inhibitors, or systemic corticosteroids). This arm represents a population with intact systemic immune function but potentially variable inflammatory activity.

Arm 2: Biologic-Treated IBD Patients in Clinical and Biochemical Remission
Participants must have received stable maintenance biologic therapy for at least 3–6 months and must be in documented remission, defined by 1) low symptom scores reported via Constant Care and 2) low fecal calprotectin levels (<250 µg/g). Patients with recent steroid use (>10 mg prednisolone equivalent within 4 weeks) or recent therapy escalation are excluded. This arm captures a population in remission who are undergoing ongoing immune modulation with biologic therapy.

Study Procedures and Follow-Up

All participants undergo baseline assessments at the time of PCV21 vaccination, including symptom reporting, fecal calprotectin measurement, and venous blood sampling for quantitative and functional levels across 16 pneumococcal antigens included in PCV21.

Follow-up visits occur at: 1) Day 0 (vaccination day) 2) Day 28 ± 2 days 3) 6 months after vaccination 4) 12 months after vaccination 5) annually thereafter for a total follow-up period of 3 years. At each follow-up visit, blood samples are collected for immunogenicity assays, and disease activity data are collected via the Constant Care platform. Participants continue to report symptoms weekly as a part of their standard of care, and flare alerts are automatically generated if symptom scores exceed predefined thresholds.

Immunological Analyses

Main immunological outcome: Measurement of serotype-specific pneumococcal antibodies. We define arbitrary response to vaccine, if we measure GMC IgG > 1 µg/mL for the combined serotypes at baseline and day 28 ± 2 days.(12). This analysis is also used for measuring the secondary immunological outcome of serotype-specific IgG Quantification.

Functional assays (secondary immunological outcomes in a random subset of samples): 1) Opsonophagocytic Activity (OPA) (13) (UCPH, to be established) 2) Antibody Glycosylation Profiling (14) (DTU, to be established).

Statistical Framework

Sample size calculation

The study is powered to test the non-inferiority of the biologic-treated remission group relative to the immunosuppressive-naïve group. A non-inferiority margin of 10 percentage points is applied to the difference in responder rates (defined as the proportion of participants achieving a GMC >1 µg/mL). Assuming an 85% responder rate in both groups(16), a two-sided α of 0.5 and 80% power, approximately 316 participants are required. Allowing for roughly a 10% drop off over the follow-up period, the target enrollment is 347 participants in each arm (total N ≈ 350) (17).

Expected Impact

To our knowledge, this is the first study to evaluate the impact of disease activity on IBD patients undergoing immunosuppressive treatment, and the first to provide a long-term evaluation of PCV21 immunogenicity in two clinically relevant IBD populations. It will clarify whether biologic-treated patients in biochemical remission retain preserved vaccine responses and whether objective markers of disease stability (e.g., low calprotectin) can guide the timing of vaccination. The results have the potential to directly influence national vaccination guidelines for IBD patients, support a personalized vaccination strategy based on inflammatory state rather than medication status alone, and contribute to a better understanding of vaccine responses under biologic immunomodulation.

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Estimated Budget

Item	Laboratory	cost per unit	Number of times	Number of participants	total number of analysis	Total (DKK)
Immunological assays						
*IgG pneumococcal antibodies**	Statens Serum Insitut	550	6	350	2100	1155000
Opsonophagocytosis assay	University of Copenhagen	600	2	75	150	90000
Glycosylation assay	DTU	1500	2	50	100	150000
PMC extraction and flow cytometry	NOH	1000	2	50	100	100000
Other						
Biobanking	Once					50000
Shipping of samples	Once					5000
CTIS application for the protocol	Once					50000
Total						1600000

*sampling dates: baseline, 28 days, 6 months, 12 months, y2,y3 (6)

København 31.12.2025

Til CFF Forening

Afdelingsledelsen ved Lunge og Infektionsmedicinsk Afdeling, Nordsjællands Hospital, tilkendegiver hermed sin opbakning til at der ansøges midler til projekt omhandlende vaccine respons efter pneumokok vaccination hos patienter med inflammatoriske tarm sygdom. Projektet gennemføres i samarbejde mellem vores afdeling og Gastromedicinsk afdeling på Nordsjællands Hospital.

Afdeling accepterer at fungere som organisatorisk og faglig forankring sted for projektet vedr. vaccination, og støtter gennemførslen af projektet inden for afdelings rammer i samarbejde med vores gastroenterologer. Afdelingsledelse vurderer, at projektet er fagligt relevant og foreneligt med afdelings kliniske of forskningsmæssige aktiviteter.

Venlige hilsner

Cheflæge Christian Søborg MD, PhD, MPG

Lunge og infektionsmedicinsk afdeling, Nordsjællands Hospital

Lægmandsresume **OPTIVACC-studiet**

Personer med inflammatorisk tarmsygdom (IBD), som fx Crohns sygdom eller colitis ulcerosa, har øget risiko for alvorlige infektioner - blandt andet lungebetændelse forårsaget af pneumokokker. Derfor anbefales det, at de bliver vaccineret, helst før de starter behandling, der dæmper immunforsvaret. I praksis sker dette dog ofte ikke, fordi mange patienter hurtigt starter medicinsk behandling for at få sygdommen under kontrol. Resultatet er, at mange patienter ikke får de anbefalede vaccinationer, selvom de har øget infektionsrisiko.

Samtidig ved man, at mange IBD-patienter i dag behandles med biologisk medicin og kan være stabile i lange perioder med få symptomer og lav betændelsesaktivitet i tarmen. Det rejser et vigtigt spørgsmål: Kan disse patienter stadig danne et godt immunrespons på en vaccine, selvom de er i behandling, hvis deres sygdom er velkontrolleret?

I Danmark anvendes den digitale platform *Constant Care* af mange IBD-patienter. Her rapporterer patienterne løbende deres symptomer og afleverer afføringsprøver, som måler betændelse i tarmen. Det giver et præcist billede af, om sygdommen er i ro. Denne viden kan bruges til at undersøge, om tidspunktet for vaccination kan tilpasses patientens sygdomsaktivitet frem for alene deres medicin.

Forskningsspørgsmål

Studiet undersøger, om IBD-patienter, der får biologisk behandling og har ro i sygdommen (få symptomer og lav betændelse i tarmen), reagerer lige så godt på en ny pneumokokvaccine som nydiagnosticerede patienter, der endnu ikke er startet på immundæmpende behandling.

Studiets opbygning

Alle deltagere får én dosis af den nye 21-valente pneumokokvaccine. Der indgår to grupper:

1. **Nydiagnosticerede IBD-patienter**, som ikke har fået immundæmpende behandling.
2. **IBD-patienter i biologisk behandling**, som har stabil sygdom med lave symptomniveauer og lav betændelse målt i afføring.

Efter vaccinationen følges deltagerne med blodprøver, som måler, hvor godt kroppen danner antistoffer mod pneumokokker. Samtidig følges sygdomsaktiviteten via Constant Care. Opfølgningen strækker sig over flere år for at se både den kortsigtede og langsigtede effekt af vaccinen.

Hvad håber man at finde? Hypotesen er, at patienter i biologisk behandling, men med velkontrolleret sygdom, danner et lige så godt immunrespons på vaccinen som patienter, der endnu ikke er i behandling. Hvis dette bekræftes, kan det få stor betydning for fremtidige anbefalinger om vaccination af IBD-patienter.

Betydning

Studiet kan bidrage til mere fleksible og individuelle vaccinationsstrategier, hvor man i højere grad ser på sygdommens aktivitet frem for alene på typen af medicin. Det kan hjælpe med at lukke det nuværende vaccinationsgab og bedre beskytte IBD-patienter mod alvorlige infektioner.

Curriculum vitae

Personal information
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Scientific focus areas
Vaccine-preventable diseases and immunization in high-risk adults, focusing on the elderly and immunocompromised.

Education

01/2025:	Clinical Trials Certificate Program, Johns Hopkins University, US
2024-2025:	Refreshed Course of Vaccinology (ARVAC), International Collaboration on Advanced Vaccinology Training (online)
08/2023:	Advanced Course in Immunology (FOCIS), Rouen, France
06/2023:	Research Leadership Program, University of Copenhagen
05/2022:	Advanced Course of Vaccinology (ADVAC), International Collaboration on Advanced Vaccinology Training, Annecy, France
04/2016:	Diploma in Tropical Medicine, Gorgas Institute of Tropical Medicine, Peru
12/2017:	Specialization in Internal Medicine/Infectious diseases, Danish Health Authority
04/2010:	Ph.D., Faculty of Health and Medical Sciences, University of Copenhagen (UCPH) Title: "Epidemiology of Invasive Pneumococcal Disease and Mortality in Denmark"
2001, 2003:	MD, Universidad Católica de Chile, Santiago de Chile/ Degree in Denmark (UCPH)

Employment

04/2024-	Clinical Professor, Institute for Clinical Medicine, UCPH
11/2021-04/2024:	Clinical Research Associate Professor, Institute for Clinical Medicine, UCPH
02/2021-10/2021:	Clinical Associate Professor, Institute for Clinical Medicine, UCPH
02/2021-01/2024:	Head of Infectious Diseases Unit, Department of Pulmonary and Infectious Diseases, Copenhagen University Hospital, North Zealand, Denmark, (NOH)
01/2018-01/2021:	Consultant, Department of Pulmonary and Infectious Diseases, NOH
08/2020-06/2023:	Senior researcher, Infectious Diseases Department, vaccination clinic for solid organ transplant candidates, Rigshospitalet
03/2010-:	Senior researcher, Diagnostics & Infection Control, Statens Serum Institute
04/2012-12/2017:	Clinical residency (Rigshospitalet, Hvidovre, NOH)
01/2006-3/2010:	Ph.D. fellowship, Statens Serum Institut and UCPH
2005- 2020:	Several medical humanitarian aid missions in Ethiopia, Uganda, and Myanmar (Médecins Sans Frontières, UN – approximately 5 years in total)

Other scientific qualifications

2025:	Chair, Clinical Academic Group for Translational Vaccine Research in High-Risk Adults (CAG-VAX), Greater Copenhagen Health Science Partners.
2025:	Appointment Committee, BRIDGE Translational program, University of Copenhagen
2024-:	Chair, European Society of Clinical Microbiology and Infectious Diseases (ESCMID) vaccine study group (EVASG)
2022-:	Member, vaccination council (National Immunization Technical Advisory Group), Danish Health Authority (nominated by the Infectious Disease Society)
2022-2025:	Member, scientific ethical committee of the Capital Region of Copenhagen. Representing the UCPH, Faculty of Medical Sciences, Department of Clinical Medicine
2022-:	Board member, Graduate Program in Immunology and Infectious Diseases, UCPH
2021-:	Associate editor, European Clinical Respiratory Journal
2021-:	Reviewer for grant applications for ESCMID, program co-organizer for ESCMID annual meeting (ESCMID)
2020-:	Executive board member (secretary), EVASG
2005-:	Regular reviewer for medical journals (e.g., Lancet, Clinical Infectious Diseases, Vaccine).

Positions of trust

2023-:	Board member, Danish Infectious Disease Society
2020-:	Volunteer physician, Caritas Denmark, a clinic for socially marginalized people
2019-2021:	Board member, patients' association Fight Against Meningitis
2004-2009:	Board member, medical humanitarian organization Médecins Sans Frontières

Management experience

2021-:	Leader of an independent research group on vaccine-preventable diseases and immunization of at-risk adults, focusing on the elderly and immunocompromised attending secondary-level healthcare. Currently, the group consists of 2 Ph.D. students, four medical students (master thesis), two medical students (bachelor thesis), one postdoc (part-time)
2023-2024:	Organizer ESCMID Postgraduate Education Course "Updates on vaccine immunology, new vaccine candidates and platforms", to be held in Copenhagen, May 2024.
2023-2024:	Co-organizer, Postgraduate Course on Vaccinology, UCPH
2021-2024:	Head of Infectious Diseases, Department of Pulmonary Medicine and Infectious Diseases, Copenhagen University Hospital, North Zealand
2011-2012:	Program Management Officer, the Global Fund to fight AIDS, TB, and Malaria. Myanmar

Funding

Granted nearly 15 million DKK (2 M EUR) as a principal applicant during the last 4 years. In addition, approximately 2 million DKK from other minor private foundations and nearly 40 million DKK as a co-applicant

Most recent grants as a principal applicant:

2025:	Greater Copenhagen Health Science Partners (CAG:VAX - Clinical Academic Group for Translational Vaccine Research in High-Risk Adults) (3.000.000 DKK)
2024:	Independent Research Fund Denmark (2.600.000 DKK). Project name: "Vaccine responses following simultaneous Immunization for optimizing disease prevention in vulnerable adults."
2024:	Copenhagen University Hospital, operational grant (1.500.000 DKK). Project name: "Implementation of a Vaccination Clinic for Immunocompromised Patients in North Zealand: A pilot study "
2022:	Danish Cancer Society, research grant (2.000.000 DKK). Project name "Vaccination coverage and vaccine-preventable diseases in cancer patients".
2021:	Independent Research Fund Denmark, scholarship grant (150.000 DKK)
2020:	Lundbeckfonden, research grant (1.000.000 DKK) Project name: "Differences in Clinical, Virologic, and Immunological Characteristics in patients with SARS-CoV-2 and Influenza Infections".
2019:	Independent Research Fund Denmark (1.400.000 DKK) Project name: "Vaccine preventable diseases in immunocompromised adults."

Awards

2016:	Danish Research award Fritz Kauffmann (microbiology and infectious diseases)
2014:	International Research award Robert Austrian (pneumococcal vaccinology)

Research

126 peer-reviewed publications in international journals, one national guideline on vaccination, and one ESCMID guideline on vaccination of immunocompromised (ongoing). H-index 27 (Scopus). ORCID: https://orcid.org/0000-0001-5552-0095

Other

1985-1994:	National Music Conservatory, Piano solist education, Santiago de Chile.