Summary research protocol

Title	Multicenter patient-reported outcome registry for acute DVT
Short title	PRORIT-PE
Date	15-02-2023
Principal Investigator(s)	
Coordinating researcher(s)	
Collaborations	Brightfish B.V. (BF), Boston Scientific International S.A. (BSCI)
Background	Although difficult to determine exactly, in the United States alone 100-200 thousand patients are (clinically) diagnosed with an pulmonary embolism. (PE) One out of three will have a recurrence within 10 years and some will develop a post-PE impairment. Much research has been done on the clinical aspects, treatment of and risk factors for PE. Despite this impressive amount of scientific information, real-world evidence regarding the Quality-of-Life effects of PE is still scarce and fragmented. BSCI recognizes this lack of information and wants to initiate and support Quality-of-Life and patient-reported outcomes collection in PE patients.
Purpose	**The implementation and evaluation of disease-specific patient-reported outcome measures (PROMs) for pulmonary embolism.** The following sub-goals were defined. 1. Using the PROMs at an individual patient level in the consulting room to gain (even) better insight into complaints and problems; 2. Using aggregated PROM data to understand quality of life in PE patients, before and after treatment; 3. To use aggregated PROM data for internal quality assessment of treatment for patients with PE; 4. Implementation of an outcome set for PE, possibly at a national level or in societal guidelines for external quality assessment of treatment for patients with PE.
Approach	Implementation and collection of an a PE PROM set will take place in collaboration with selected clinics. In addition, since the ICHOM standard outcome set for venous thromboembolism is largely used, participation in the ICHOM global benchmark is possible for the selected clinics. Patients and clinicians will be closely involved in the implementation of the PROM tool. To this end BSCI will collaborate with BF, a specialised platform for data collection and processing. Data will be collected in a standardised way and case-mix analysis will be applied to define the PROM set as an indicator of quality.

Data set (case-mix)

Case-Mix Variables

Patient Population	Measure	Timing	Reporting Source
Demographic Factors			
All patients	Year of birth	Baseline	Clinical
All patients	Sex	Baseline	Clinical
All patients	Race	Baseline	Patient-reported
All patients	Ethnicity	Baseline	Patient-reported
All patients	Level of education	Baseline	Patient-reported
Baseline Health Status			
All patients	BMI	Baseline; 1 year and annually*	Clinical
All patients	Previous history of VTE	Baseline	Clinical
All patients	Comorbidities	Baseline; 1 year and annually*	Patient-reported
All patients	High-Risk/Massive PE	Baseline	Clinical
All patients	Phlegmasia	Baseline	Clinical
All patients	Unprovoked VTE	Baseline	Clinical
Treatment-related Factors			
All patients	Antithrombotic Treatment	Baseline; 3 months and 6 months; 1 year and annually*	Clinical
All patients	Underwent interventional treatment for VTE	Baseline; 3 months and 6 months; 1 year and annually*	Clinical

Data set (PROM)

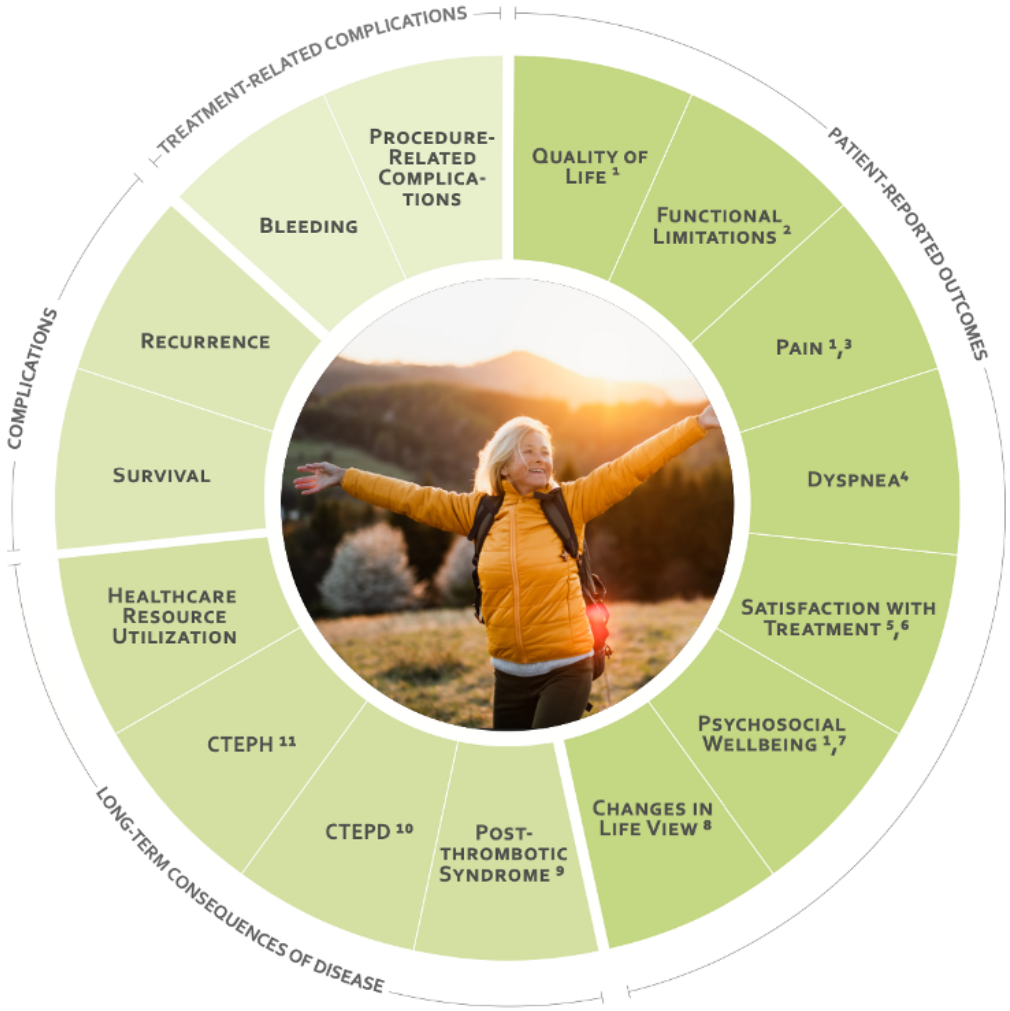
Patient-Reported Outcome Measures

Patient Population	Measure	Timing	Reporting Source
Patient-Reported Outcome Measures: Core Set			
All patients	Functional Limitations	Baseline; 3 months and 6 months; 1 year and annually*	Patient-reported
All patients	Quality of Life	3 months and 6 months; 1 year and annually*	Patient-reported
All patients	Treatment Satisfaction	3 months and 6 months; 1 year and annually*	Patient-reported
All patients	Changes in life view	3 months and 6 months; 1 year and annually*	Patient-reported
Patient-Reported Outcome Measures: Optional Set**			
All patients	Pain	Baseline; 3 months and 6 months; 1 year and annually*	Patient-reported
All patients	Dyspnea	Baseline; 3 months and 6 months; 1 year and annually*	Patient-reported
All patients	Psychosocial wellbeing	Baseline; 3 months and 6 months; 1 year and annually*	Patient-reported
All patients	Treatment Satisfaction	3 months and 6 months; 1 year and annually*	Patient-reported

Data set (clinical)

Clinical Outcome Measures

Patient Population	Measure	Timing	Reporting Source
Clinical Outcome Measures			
All patients	Healthcare Resource Utilization	Baseline; 3 months and 6 months; 1 year and annually*	Clinical
All patients	Chronic Thromboembolic Pulmonary Disease	3 months and 6 months; 1 year and annually*	Clinical
All patients	Chronic Thromboembolic Pulmonary Hypertension	3 months and 6 months; 1 year and annually*	Clinical
All patients	Post-Thrombotic Syndrome	3 months and 6 months; 1 year and annually*	Clinical
All patients	Recurrence	Baseline; 3 months and 6 months; 1 year and annually*	Clinical
All patients	Vital Status	Baseline; 3 months and 6 months; 1 year and annually*	Clinical
All patients	Bleeding	Baseline; 3 months and 6 months; 1 year and annually*	Clinical
All patients	Procedure-related complications	Baseline; 3 months and 6 months; 1 year and annually*	Clinical

Used questionnaires	 Used instruments: 1. Measured using the PROMIS Scale v1.2 – Global Health, PEmb-QoL, and VEINES-QOL questionnaires 2. Measured using the PROMIS Short Form v2.0 – Pain Intensity – 3a 3. Measured using the PEmb QoL and PROMIS Short Form v1.0 – Dyspnea Severity – 10a 4. Measured through the question: “Are you satisfied with your VTE treatment?” 5. Measured using the Anti-Clot Treatment Scale 6. Measured using the PHQ-9 and GAD-7 questionnaires 7. Measured through the question: “Have you experienced a change in your expectations, aspirations, values, or perspectives on life opportunities since the diagnosis of Venous Thromboembolism?” 8. Chronic Thromboembolic Pulmonary Disease 9. Chronic Thromboembolic Pulmonary Hypertension
Study population	Patients with one of the following diagnosis: - Pulmonary embolism and interventional treatment

Inclusion criteria	– 16 years of age or older – Competent
Exclusion criteria	- Did not give permission to be approached for scientific research - No available email address

Planning	**Phase 1: September 2023 – January 2024** **Implementation period** – Onboarding and selecting participating clinics – Legal requirements (data processor agreements, etc.) – Optional: create steering committee with key person from each participating clinic – Implementation of the digital pathways for data collection in selected clinics – Introduction and instructions for the digital pathway platform (BF) in selected clinics – Dry-run and go-live **Phase 2: 2024** **Data collection period** – Collect outcomes at participating clinics. – Optional: data delivery to ICHOM global benchmark **Phase 3: 2025** **Data analysis period** – Case mix analysis – Evaluating and analysing outcomes – Evaluate the outcome set