

# ESCP CRAFT Study

Cryptoglandular Anal Fistula Treatment

The new international, prospective  
combined Audit & Cohort Study



UNIVERSITY OF  
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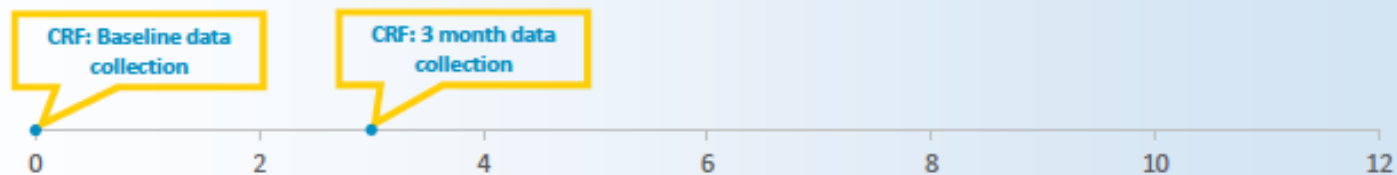


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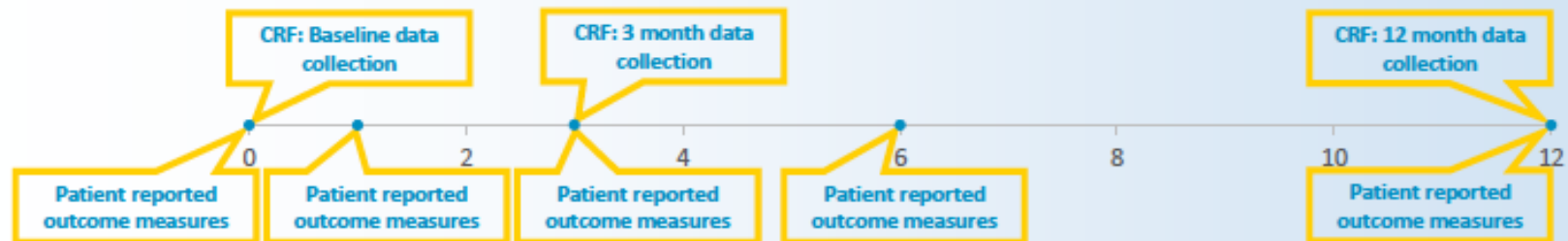


# Objectives

## CRAFT Audit: Practice variation, Short-term outcomes, FU 3 months



## CRAFT Cohort: PROMs, Long-term outcomes, FU 12 months



# Research questions

## Main question:

1. What associations can be observed between patient demographic factors, diagnostic and treatment modalities, and outcomes, as defined by the AF-COS, in real-world clinical settings?

## Further questions focusing on:

1. Demographic data & fistula types
2. Diagnostics
3. Treatment

# Data collection

- Baseline

- Demographic data
- Medical history
- Primary fistula
- Recurrent fistula

- Work-up

- MRI
- EA-US
- EAU

- Treatment

- Fistulotomy/-ectomy
- Seton
- RAF
- LIFT
- Laser
- VAAFT
- Plugs
- Autologous products

# Anal Fistula Core Outcome Set

## Clinician reported outcomes:

- Clinical fistula healing
- Radiological healing
- Recurrence
- Development of additional fistulas
- Complications & reinterventions

## Patient reported outcomes:

- Fistula symptoms
- Incontinence
- Psychological impact of treatment
- Patient satisfaction
- Quality of life

# Anal Fistula Core Outcome Set

## Patient reported outcomes

### Clinical fistula healing

- **Defined as: absence of any discharge symptoms, absence of abscess, infection or inflammation, and no recurrence or persistence of the fistula**
- **Healing is achieved after a 6 month discharge symptom free period**

### Recurrence

### Radiological healing

- Modality: MRI
- **Defined as: the complete resolution of any visible fistula tract and inflammatory mass +/- formation of fibrosis within the tract**

### Development of additional fistula

### Complications and reinterventions

- **Complications: Clavien Dindo Classification**
- **Reinterventions only refer to surgical and radiological reinterventions**



# Anal Fistula Core Outcome Set

## Patient reported outcomes

### Quality of life

- Anal Fistula Quality of Life Questionnaire (AF-QOL)
- EQ-5D

### Incontinence

- St. Marks (Vaizey) Incontinence Score

### Fistula symptoms

- AF-QOL

### Psychological impact of treatment

- AF-QOL

### Patient satisfaction

- Numerical Rating Score (NRS)

### Financial impact on healthcare systems

- Work Productivity Activity Index (WPAI )
- EQ-5D

**AF-QoL: The Anal Fistula Quality of Life Scale**

The aim of this questionnaire is to understand the impact that your fistula is having on your daily life, and the adjustments you are having to make because of it.  
The following questions ask about your fistula, the symptoms it gives you and how they have affected your life over the last 4-6 weeks. Please answer all the questions. If you are unsure about how to answer any question, just give the best answer you can.  
Do not spend too much time thinking about your answers, as your first thoughts are likely to be the most accurate. If you do not wish to answer any of these questions, please leave it blank, or leave details of the reason(s) why it was not answered.

**Part 1: Your symptoms**

On average, over the last 4-6 weeks:

1) How often have you experienced pain or discomfort from your fistula?

a) Never	100	<input type="checkbox"/>
b) Occasionally	75	<input type="checkbox"/>
c) A few times a week	50	<input type="checkbox"/>
d) Daily	25	<input type="checkbox"/>
e) Several times a day	0	<input type="checkbox"/>

2) How severe has the pain from your fistula been?


a) No pain at all	100	<input type="checkbox"/>
b) Mild pain	75	<input type="checkbox"/>
c) Moderate pain	50	<input type="checkbox"/>
d) Severe pain	25	<input type="checkbox"/>
e) The worst pain imaginable	0	<input type="checkbox"/>

3) How often have you experienced discharge of fluid, pus or blood from your fistula?

a) Never	100	<input type="checkbox"/>
b) Occasionally	75	<input type="checkbox"/>
c) A few times a week	50	<input type="checkbox"/>
d) Daily	25	<input type="checkbox"/>
e) Several times a day/ constantly	0	<input type="checkbox"/>

4) How often have you been worried about not being able to control the passage of wind or leaking stool from your back passage or fistula?

a) Never	100	<input type="checkbox"/>
b) Occasionally	75	<input type="checkbox"/>
c) A few times a week	50	<input type="checkbox"/>
d) Daily	25	<input type="checkbox"/>
e) Several times a day	0	<input type="checkbox"/>



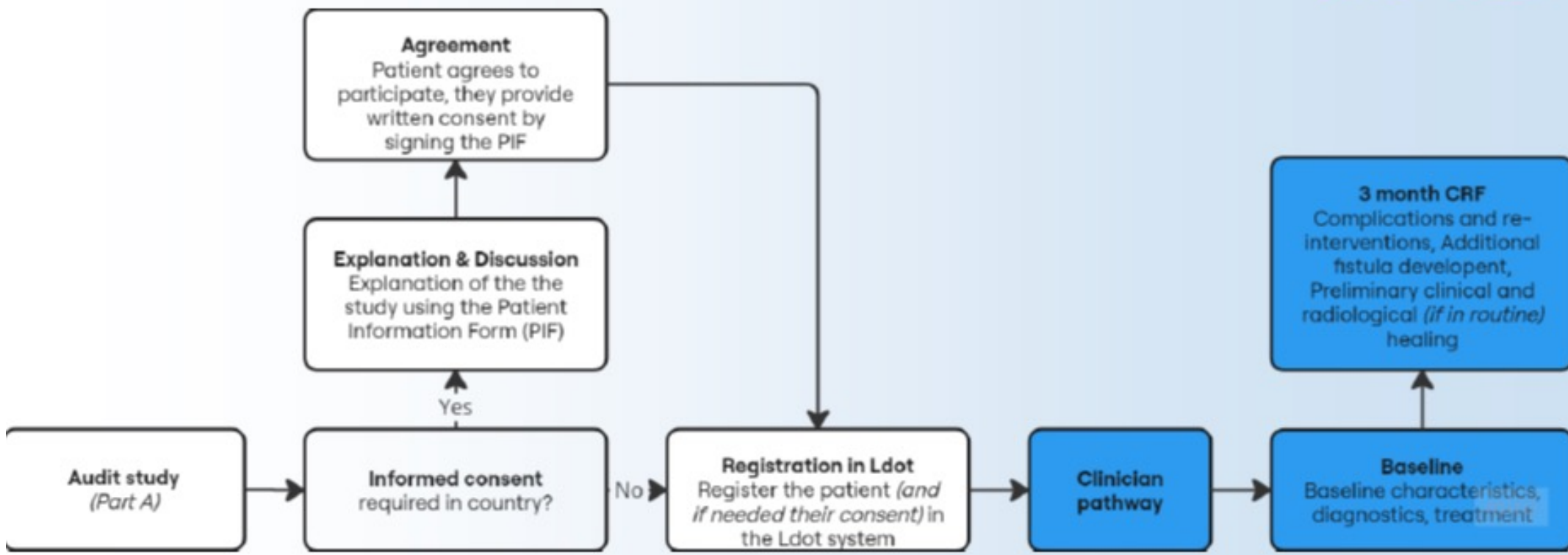


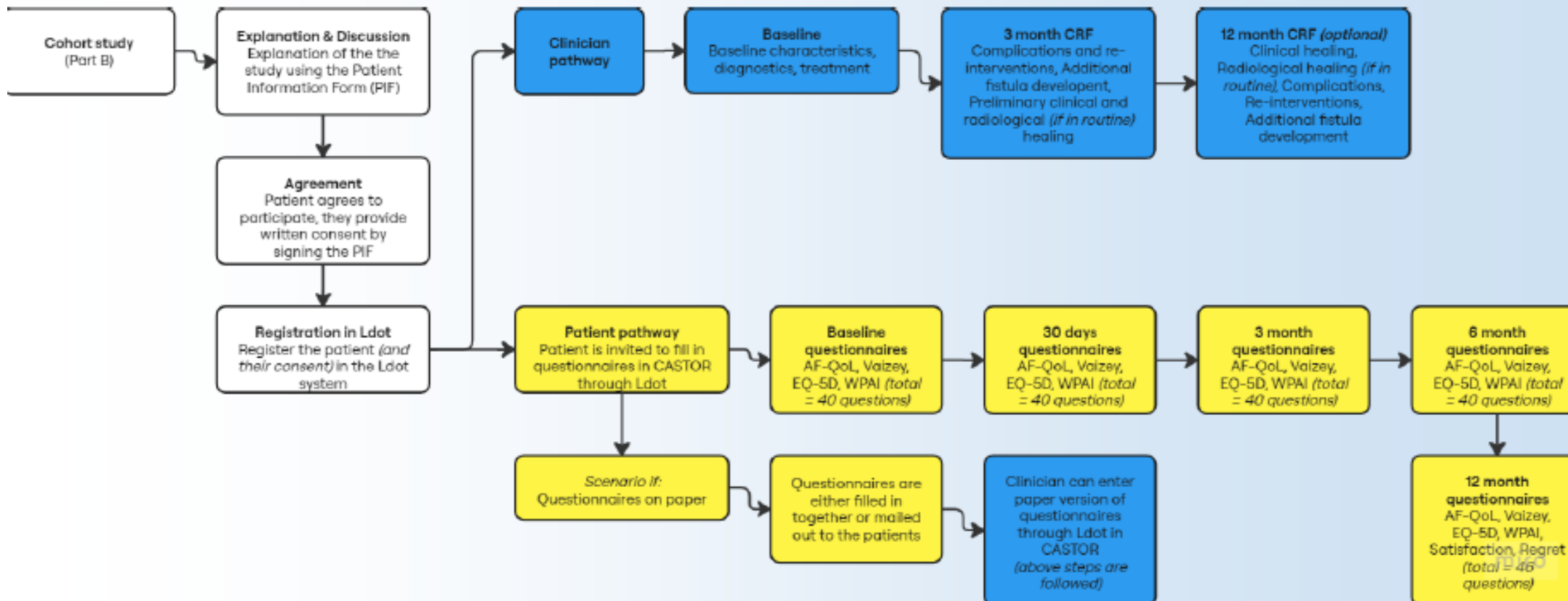
# Audit study

Phase	Start Date	End Date	Duration
Centre Accrual	September 26 <sup>th</sup> , 2024	January 1 <sup>st</sup> , 2025	3 months
Patient Recruitment	January 6 <sup>th</sup> , 2025	March 31 <sup>st</sup> , 2025	3 months per centre
Patient Follow-up	Varies per patient	July 1 <sup>st</sup> , 2025	3 months per patient

# Cohort study

Phase	Start Date	End Date	Duration
Centre Accrual	September 26 <sup>th</sup> , 2024	March 31 <sup>st</sup> , 2025	6 months
Patient Recruitment	<b>April 1<sup>st</sup>, 2025</b>	<b>July 1<sup>st</sup>, 2025</b>	3 months per centre
Patient Follow-up	Varies per patient	July 1 <sup>st</sup> , 2026	12 months per patient





# Collaborative authorship

- Study Management Group
- National Coordinator



- Local Coordinator
- Collaborator



- MINIMUM of **10** patients per center
- 95% data-completeness



- Up to **5** per center

Share the QR-code!

