Modernized patient recruitment

The perspective of the patient

Link2Trials services

Patient Feasibility / Patient insight assessment

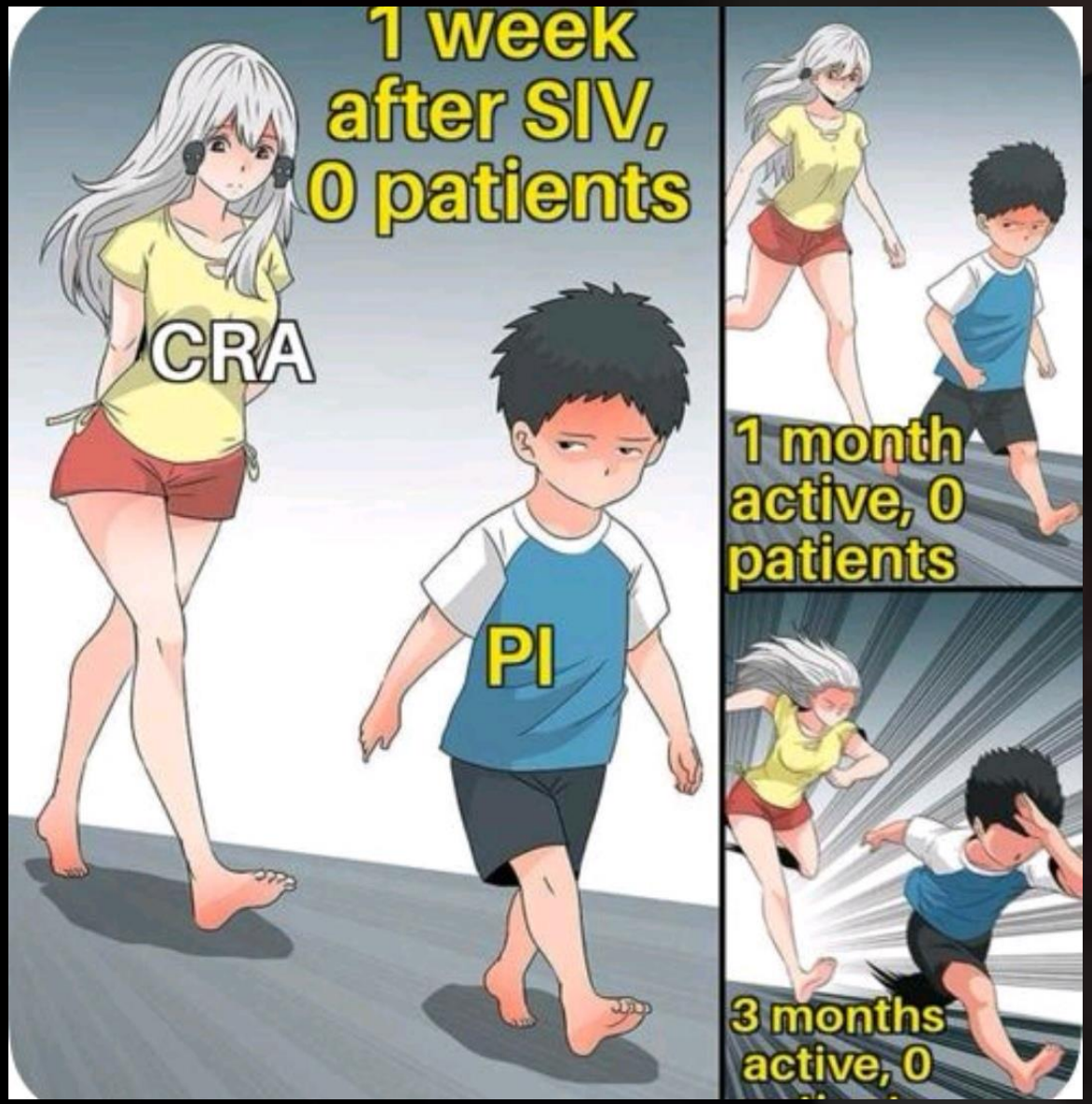
- Improved protocol and study feasibility
- Improved patient experience
- Faster and smoother recruitment
- Improved adherence potential
- Cost reduction through optimized site and country selection

Patient Recruitment & Pre-qualification

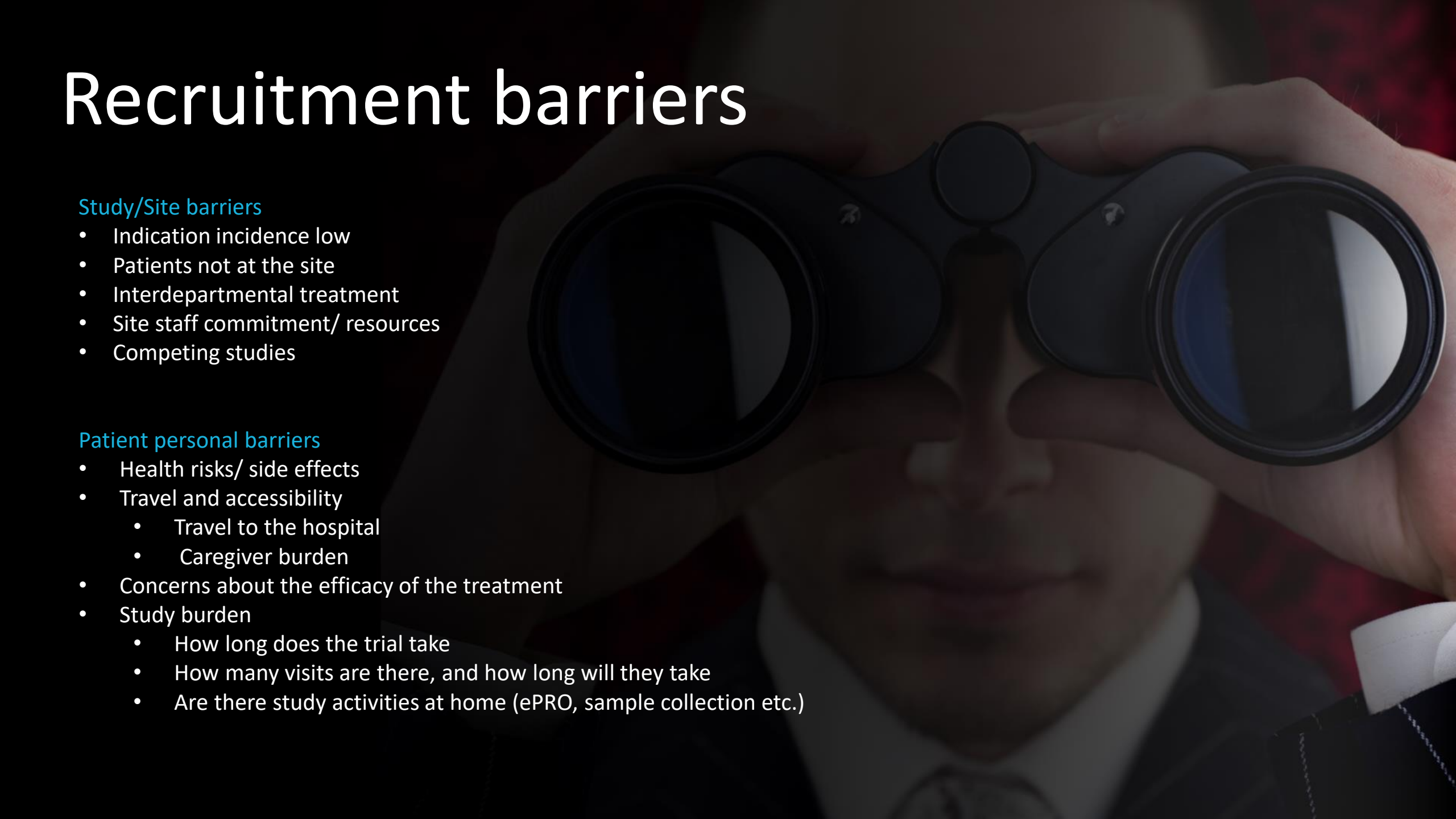
- Faster and more effective recruitment
- Faster study start-up
- Improved patient experience
- Lessens the burden on your sites
- High-quality patient referrals

Adherence Risk Management Services

- Dynamic, personalized patient support
- Patient support at the right time and the right level
- Improved patient experience
- Improved site support through up-to-date intelligence on patient support needs
- Digital support takes care of the bulk of patient support
- Prevention instead of firefighting


1 week after SIV, 0 patients
CRA
PI
1 month active, 0 patients
3 months active, 0

Recruitment barriers



Study/Site barriers

- Indication incidence low
- Patients not at the site
- Interdepartmental treatment
- Site staff commitment/ resources
- Competing studies

Patient personal barriers

- Health risks/ side effects
- Travel and accessibility
  - Travel to the hospital
  - Caregiver burden
- Concerns about the efficacy of the treatment
- Study burden
  - How long does the trial take
  - How many visits are there, and how long will they take
  - Are there study activities at home (ePRO, sample collection etc.)

Strategy shift

Traditional strategy

The emphasis on logistical arrangements sometimes overshadows the centrality of patients in clinical trials.

- Planning for recruitment during the site qualification and activation stage
- Recruiting from established clinics
- Responding to failed recruitment efforts with new sites and one-off campaigns

Modern strategy

Modern patient recruitment is an approach that prioritizes patient needs over logistical considerations. It proactively incorporates recruitment into the trial planning process from its inception.

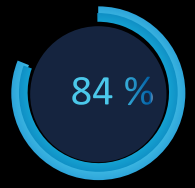
- Proactive: Patient recruitment is meticulously planned from the initial stages of trial design and remains a top priority throughout the trial duration.

- Patient-centered: Patient needs and preferences are paramount throughout the development process. Patient insights are incorporated into all aspects of solution creation.

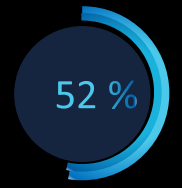
Why focus on patient recruitment?

Costs associated with site startup and operational costs. [1]

Total monthly costs associated with extending trial timeline due to a lower-than-planned accrual rate [2]



84% of patients aren't educated about trials by their primary care provider [3]



52% of patients independently conduct their research online for clinical trials [3]

1. Funakoshi J, Tate W. Strategies for Successful Site Selection in Clinical Trials. Advarra. Published October 4, 2022.
2. Ledesma P. How Much Does a Clinical Trial Cost? Sofpromed. Published January 2, 2020
3. Center for Information and Study on Clinical Research Participation. 2019 Perceptions and Insights Study.; 2019.

Patient recruitment strategy

1 Trial set-up

- Know your patients
- Make your trial patient centric
  - DCT components
  - Protocol assessments
  - #Visits
  - Clinical visits v.s. home visits
  - Econsent vs paper
  - ePro v.s. on site
- Patient diversity

2 Awareness and Consideration

- Write trial information that patients can understand (patient reviewed)
- Make sure patients learn about your trial (study website, mailing, socials etc.)
- Ensure access for under-represented groups
- Provide the patient access on information about the top 5 barriers for the trial
- Provide answers on the top 5 questions patients have about the study

3 Decision

- Facilitate contact between patients and site teams
- Provide clear study information e.g. via eConsent

Trial set-up

What do we want to know?

- **Are patients knowledgeable about their diagnosis (NASH, PCOS)**
- Are patients in this indication engaged in researching CTs (Diabetes, Asthma)
- What is the standard of care
- Will this patient population be motivated to try your new therapy
- **Is your treatment/therapy more or less convenient than the standard of care (BV v.s. VC study)**
- Where do these patients present themselves, and is that your study site?
- **What will the patients find burdensome about your trial**
- What are the top 5 questions patients will ask about your trial

Trial set-up

What do we want to know?

- Are patients knowledgeable about their diagnosis (NASH, PCOS)
- Are patients in this indication engaged in researching CTs (Diabetes, Asthma)
- What is the standard of care
- Will this patient population be motivated to try your new therapy
- Is your treatment/therapy more or less convenient than the standard of care (BV study)
- Where do these patients present themselves, and is that your study site?
- What will the patients find burdensome about your trial
- What are the top 5 questions patients will ask about your trial

How to find this information?

- Online research
- Social listening
- Discussions with HCPs also RNs/RCs
- Discussions with Patient associations
- Patient feasibility studies/ patient insight assessments
    - Patient questionnaires
    - Interviews
    - Focus groups

Aletta feasibility case study

Objectives and Scope

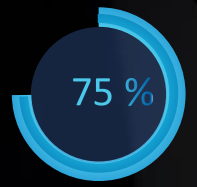
Feasibility Objective:
Refinement of the study protocol and patient materials for the ALETTA study, focusing on patient-centric perspectives.

Scope:
Evaluation of **inclusion criteria**, **study setup**, **participation willingness**, and **comprehensibility of study documents**.

Data Collection:
Online questionnaire and in-depth interviews to gather patient insights.

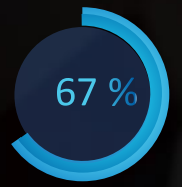
Participant Demographics:
139 questionnaires from NL and DE
14 in-depth interviews

96% of respondents showed interest in participating in the trial.

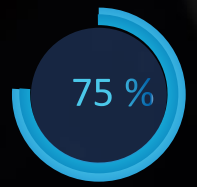


75% believed women with Female Sexual Interest & Arousal Disorder (FSIAD) would welcome treatment opportunities.

45% of participants were motivated by the prospect of receiving professional support and the additional checks and examinations.



67% of participants preferred remote visits



75% showing substantial interest in trying potential treatments for low sexual desire, 71% wanted to contribute to research for better FSIAD therapies

Aletta feasibility case study

Landing page recommendations

Enhanced Medication Information: Augment the medication tab with detailed, comprehensive information on safety and expected outcomes.

Clear Exclusion Criteria: Integrate a distinct section outlining the main exclusion criteria for quick eligibility assessment.

Screening Period Clarity: Clarify this section by removing the 8-week reference or providing a detailed explanation to avoid confusion.

Visit Scheduling Flexibility: Highlight the collaborative approach in scheduling visits on the landing page, emphasizing flexibility to accommodate participant schedules.

ICF recommendations

Simplifying Patient Information: Revise to simplify complex language and introduce visual aids or summaries for better understanding.

Mammography Procedure Explanation: Provide detailed information about the method, rationale, benefits, and safety measures related to mammography in the study.

Post-Study Guidance: Clearly outline post-study options, including discussions with the clinical team about future steps.

Emotional and Psychological Support: Include information on the availability of such support within the study and how the study team can assist in these areas.

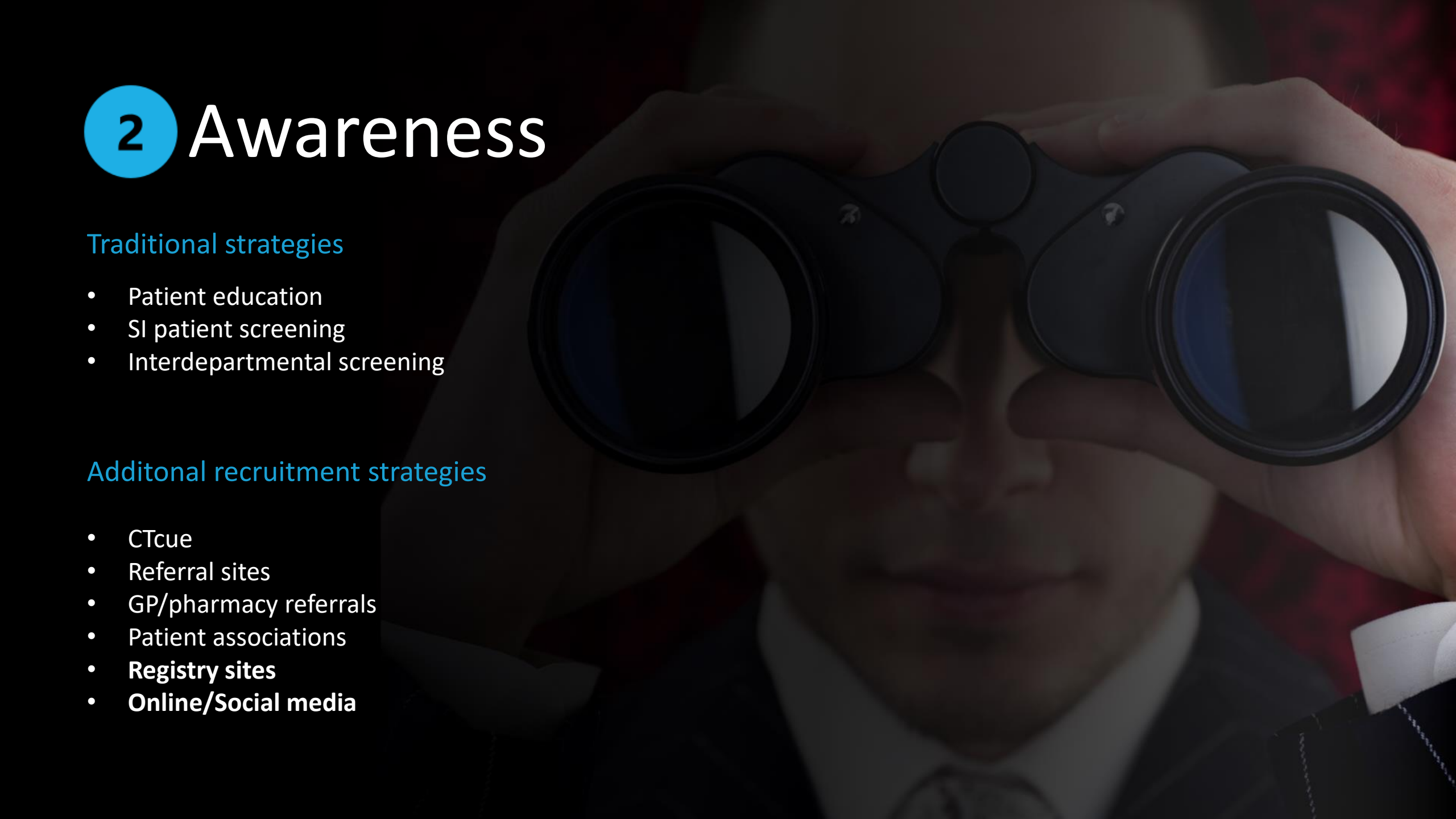
2 Awareness

Traditional strategies

- Patient education
- SI patient screening
- Interdepartmental screening

Additonal recruitment strategies

- CTcue
- Referral sites
- GP/pharmacy referrals
- Patient associations
- **Registry sites**
- **Online/Social media**



Overview of different (online) tools

Registries:
- Curewiki
- FindMeCure
- Kanker.nl
- Patientenverenigingen

Recruitment strategy:
- Clariness
- Trials24
- Link2Trials
- Trialbee
- AntidoteTechnology

Other:
- MediPaCe (patient engagement)
- MyTomorrows (early access programs)
- Everyone.org (pre-registration access)

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Chronic Low Back Pain

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Preston, Oxford

Wales (1)

Cardiff / Caerdydd

Gender Both

Age from 18 up to and including 70

Weight in kg from 50 up to and including 120

Info | which drug is being researched? | Additional information about the study

THE MODIC TRIAL

Chronic Low Back Pain

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Why is The Modic Trial Study being conducted?

Chronic Low Back Pain is a common condition which can severely impact someone's life. Many of the existing treatment options for Chronic Low Back Pain do not work well and the regular use of strong pain killers is common.

There is evidence that damage to vertebral discs in someone's spine can allow an infection to get into the disc which can then cause chronic low back pain - much like tooth decay, we now have "disc decay".

This infection is a slow process and causes inflammation, bone loss and swelling (oedema) in the bones either side of the infected disc. The swelling of these vertebral bones can be seen by Magnetic Resonance Imaging (MRI) and are called Modic changes.

Persica Pharmaceuticals has designed a drug which may treat this infection. This is the first research study using this drug and it will find out if the drug reduces back pain and is safe to use.

The drug contains an antibiotic and has been specially designed to treat infections in spinal discs. In this study, the drug will be injected directly into a single spinal disc.

Who can take part?

You might be eligible for The Modic Trial (also known as Persica 002) if:

- Between 18 and 70 years of age
- Have had Chronic low back pain for more than 6 months which is very painful and debilitating
- You have had an MRI for your lower back in the last 3 years
- Other treatments for the back pain haven't worked

What happens if you decide to participate?

- The clinical trial will involve 2 injections of the study drug into your spinal disc (or 2 sham injections if you are randomised to placebo, the dummy treatment) and medical follow up for 1 year after the injections
- You will have to complete questionnaires and a diary during the study.
- You will also have 3 MRI scans and blood tests during the trial.

You will receive:

- Persica Pharmaceuticals will supply the study drug and pay for all procedures.
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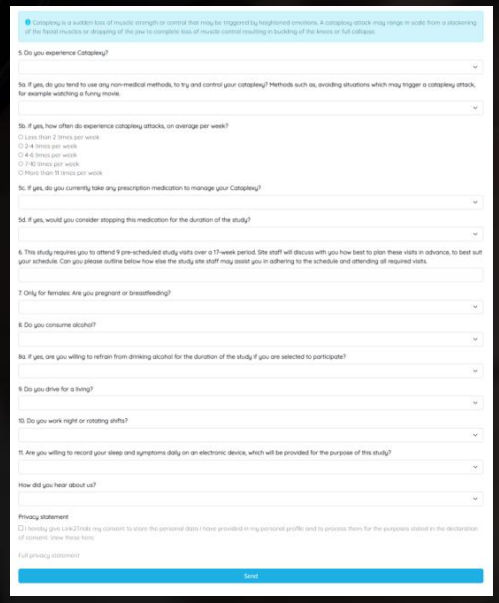

Cataplexy is a sudden loss of muscle strength or control that may be triggered by heightened emotions. A cataplexy attack may range in scale from a slackening of the facial muscles or dropping of the jaw to complete loss of muscle control resulting in buckling of the knees or full collapse.

5. Do you experience Cataplexy?

5a. If yes, do you tend to use any non-medical methods, to try and control your cataplexy? Methods such as, avoiding situations which may trigger a cataplexy attack, for example watching a funny movie.

5b. If yes, how often do experience cataplexy attacks, on average per week?

- Less than 2 times per week
- 2-4 times per week
- 4-6 times per week
- 7-10 times per week
- More than 11 times per week

5c. If yes, do you currently take any prescription medication to manage your Cataplexy?

5d. If yes, would you consider stopping this medication for the duration of the study?

6. This study requires you to attend 9 pre-scheduled study visits over a 17-week period. Site staff will discuss with you how best to plan these visits in advance, to best suit your schedule. Can you please outline below how else the study site staff may assist you in adhering to the schedule and attending all required visits.

7. Only for females: Are you pregnant or breastfeeding?

8. Do you consume alcohol?

8a. If yes, are you willing to refrain from drinking alcohol for the duration of the study if you are selected to participate?

9. Do you drive for a living?

10. Do you work night or rotating shifts?

11. Are you willing to record your sleep and symptoms daily on an electronic device, which will be provided for the purpose of this study?

How did you hear about us?

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Send

A Patient's perspective

1

selection

4 Medical phone screening

A Patient’s perspective

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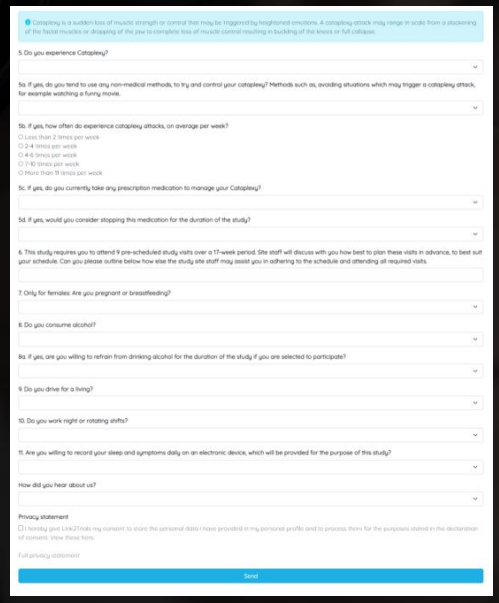

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Info | Which drug is being researched? | Additional information about the study

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Info | **Which drug is being researched?** | Additional information about the study

THE MODIC TRIAL

Persica Pharmaceuticals has designed a drug called PP353 to treat Chronic Low Back Pain. This is the first research study using PP353 and it will check the safety of PP353, how PP353 moves through the body (pharmacokinetics) and find out if PP353 reduces back pain.

PP353 contains an antibiotic and has been specially designed to treat infections in spinal discs. In this study, PP353 will be injected directly into a single spinal disc.

40 patients will be randomised (like 'flipping a coin') to receive one of two treatments, PP353 or placebo (dummy treatment). Neither you nor your study doctor will know which treatment has been assigned to you.

All patients will receive 2 injections, approximately 5 days apart (e.g., Monday and Friday). Half of the patients will be randomised to receive 2 injections of PP353 into the disc. The other half will receive 2 placebo injections. During a placebo injection a needle will be inserted into your muscle, close to (but not into the disc) and nothing will be injected.

You will receive anesthetic – in most cases local anesthetic - before each injection.

You can continue to use your normal pain medication during the study. You will be followed up in the study for one year (12 months). PP353 will only stay in your body for a short time but it may take several months before your body responds and we know if it helps your back pain.

At the end of the study, you have the right to be informed of the overall results of this research. The outcome of the trial will be shared by the Persica Pharmaceuticals with your study doctor who can pass this information on to you.

↓ Apply for this trial

At which research center do you want to participate?

Your location and distance to the research centre could not be determined. Retrieve your location .

- Royal Preston Hospital - Lancashire Teaching Hospitals - NSH Foundation Trust (Preston / England) 5986.61 km
- John Radcliffe Hospital (JR) - Oxford University Hospitals - NHS (Oxford / England) 5756.92 km
- University Hospital of Wales (Cardiff / Caerdydd / Wales) 5735.18 km

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THE MODIC TRIAL

What is a clinical study?

- A clinical study is a scientific study on how a new or existing medicine, product, procedure or treatment works in people.
- Through clinical studies, doctors can find new and better ways to prevent, detect, diagnose, control and treat illnesses.
- All clinical studies are carefully monitored and regulated to ensure participant well-being.
- Participating in a clinical study is completely voluntary

What happens if you decide to participate?

In summary, The Modic Trial will need a significant commitment from you:

- Several checks will be done to make sure you are suitable for the trial and not everybody will be able to enter the clinical trial;
- 2 injections will be given over 5 days;
- You would be on the trial for up to 14 months requiring regular visits to the hospital, especially in the first 3 months;
- After the first 3 months the visits to the hospital are approximately every 3 months;
- You have to be available for phone calls at specified times during the study;
- You will need to complete the electronic diary regularly during the study;
- Tell your study team about any other medicines that you take, even if it is a medicine you buy without a prescription. You are asked not to take any other medication without speaking to your study doctor first;
- Report all experienced side effects and changes in your health;
- You cannot take long term antibiotic therapy for any reason for the duration of the study.
  - Should you need to take long term antibiotics you will need to stop taking part in this study;
  - Short courses of antibiotics are allowed after discussion with your study doctor;
- If you are a woman, you must not be currently breastfeeding or plan to get pregnant while in the study and for 1 month after you finish the study.
- If you are a man, you must not cause your partner to become pregnant in the 100 days following the injection. You must agree not to donate sperm until 100 days after the injection.

How can bacteria get into a spinal disc?

It may seem strange to think that bacteria can get into a spinal disc and that antibiotics might be able to reduce that pain. However, in patients with a slipped disc (known as disc herniation) the outer tough rings of the disc split open, and some of the soft gel in the centre of the disc-the nucleus-breaks through the outer rings. Bacteria are then able to enter the disc via the bloodstream.

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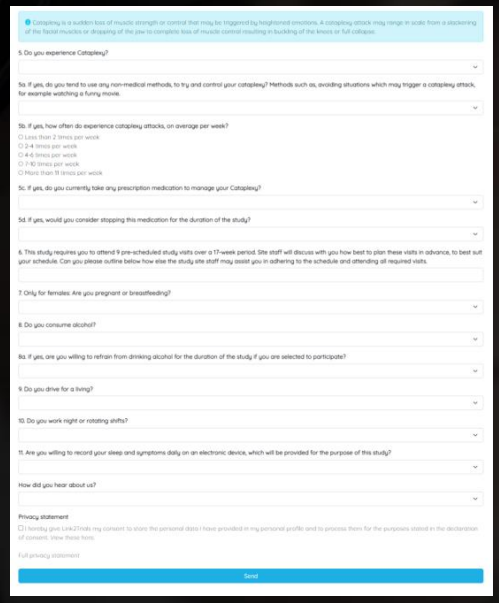
How to apply

If you would like to learn more about the study and find out whether you may be able to take part, please register on this website and answer the questions below. After your registration one of the Link2Trials call team members will contact you to discuss your registration and to answer any questions you may have.



Cataplexy is a sudden loss of muscle strength or control that may be triggered by heightened emotions. A cataplexy attack may range in scale from a slackening of the facial muscles or dropping of the jaw to complete loss of muscle control resulting in buckling of the knees or full collapse.

5. Do you experience Cataplexy?

5a. If yes, do you tend to use any non-medical methods, to try and control your cataplexy? Methods such as, avoiding situations which may trigger a cataplexy attack, for example watching a funny movie.

5b. If yes, how often do experience cataplexy attacks, on average per week?

- Less than 2 times per week
- 2-4 times per week
- 4-6 times per week
- 7-10 times per week
- More than 11 times per week

5c. If yes, do you currently take any prescription medication to manage your Cataplexy?

5d. If yes, would you consider stopping this medication for the duration of the study?

6. This study requires you to attend 9 pre-scheduled study visits over a 17-week period. Site staff will discuss with you how best to plan these visits in advance, to best suit your schedule. Can you please outline below how else the study site staff may assist you in adhering to the schedule and attending all required visits.

7. Only for females: Are you pregnant or breastfeeding?

8. Do you consume alcohol?

8a. If yes, are you willing to refrain from drinking alcohol for the duration of the study if you are selected to participate?

9. Do you drive for a living?

10. Do you work night or rotating shifts?

11. Are you willing to record your sleep and symptoms daily on an electronic device, which will be provided for the purpose of this study?

How did you hear about us?

Privacy statement

I hereby give Link2Trials my consent to store the personal data I have provided in my personal profile and to process them for the purposes stated in the declaration of consent. View these here.

I will privacy statement

Send

Case study online recruitment

Bayer Netherlands
Postmenopausal women moderate to severe hot flashes
Treatment with non-hormonal medication

4 sites in NL
L2T to recruit 14-18 subjects
Recruitment timelines 10 months

In the first 5 months of recruitment the sites were able to enroll 3 patients

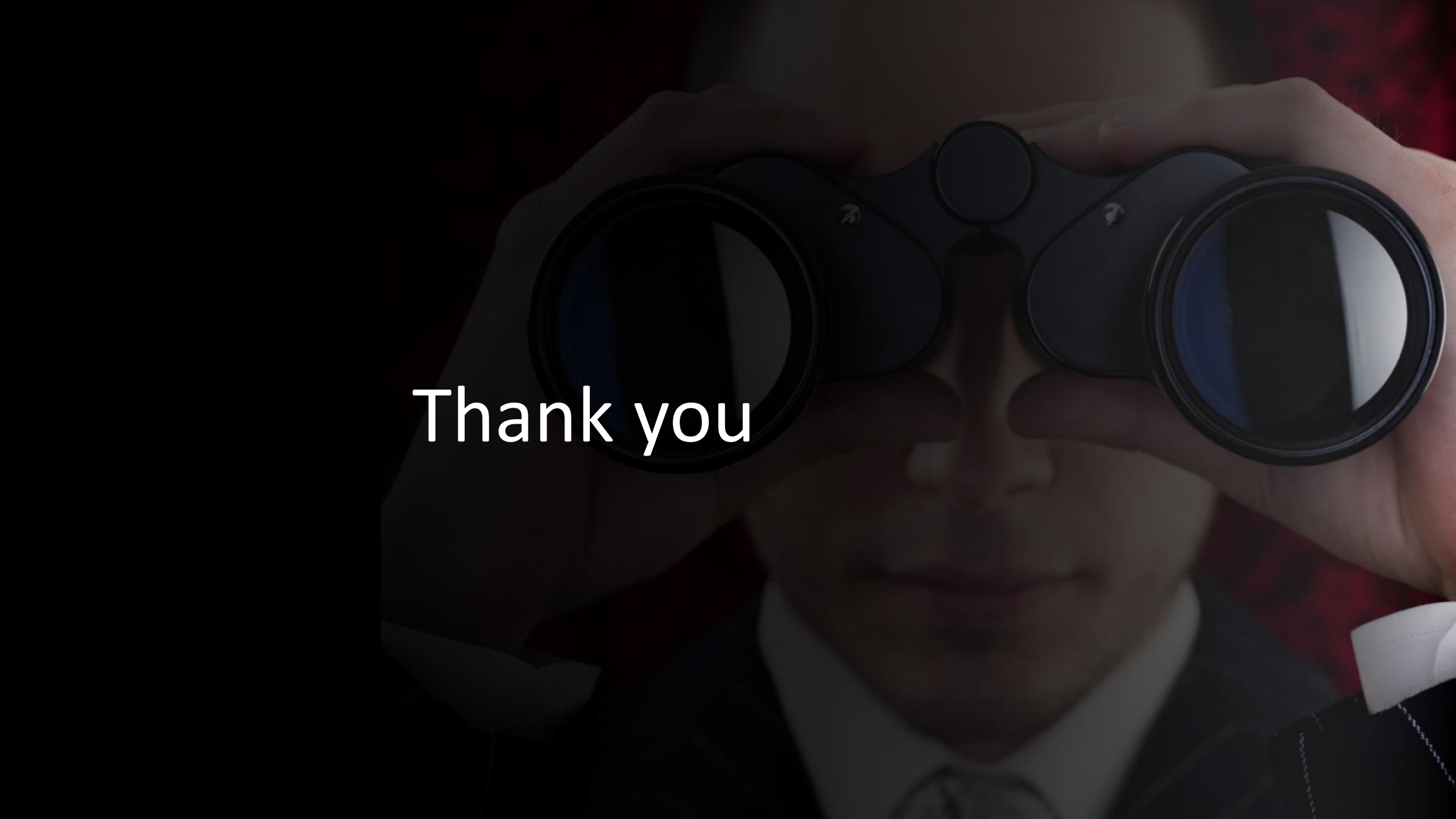
Major hurdles:
Patients did not come to trial sites on regular basis

688 subjects completed online questionnaire

508 subjects called by medical call team

188 referred to the 4 sites

15 enrolled in the study


Thank you