
link2trials

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

e-Consent

- Enhanced patient s' understanding of your clinical study
- Lessens the burden on your sites
- Improved patient experience
- Lessens the burden on your sites

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

Patient Feasibility

Patient Feasibility

Documentation review by recruitment experts

- Recruitment and adherence expert review of the protocol and patient-facing documentation
- Risk assessment for the protocol recruitment potential
- Risk assessment for the protocol adherence profile
- Recommendations for adaptations of the protocol and/or patient-facing materials

Patient feasibility

- Outreach to a small portion of the target population
- Online questionnaire
- In-depth interviews and focus groups
    - Protocol design
    - Patient-facing materials
    - Other study information and specifics

Outcomes

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

E-Consent

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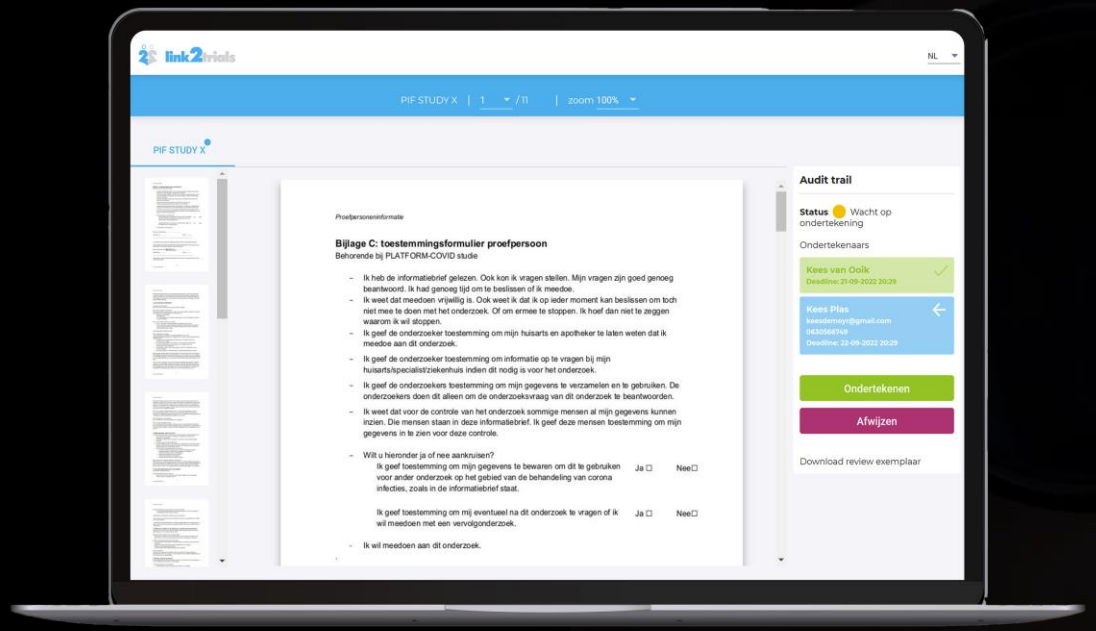
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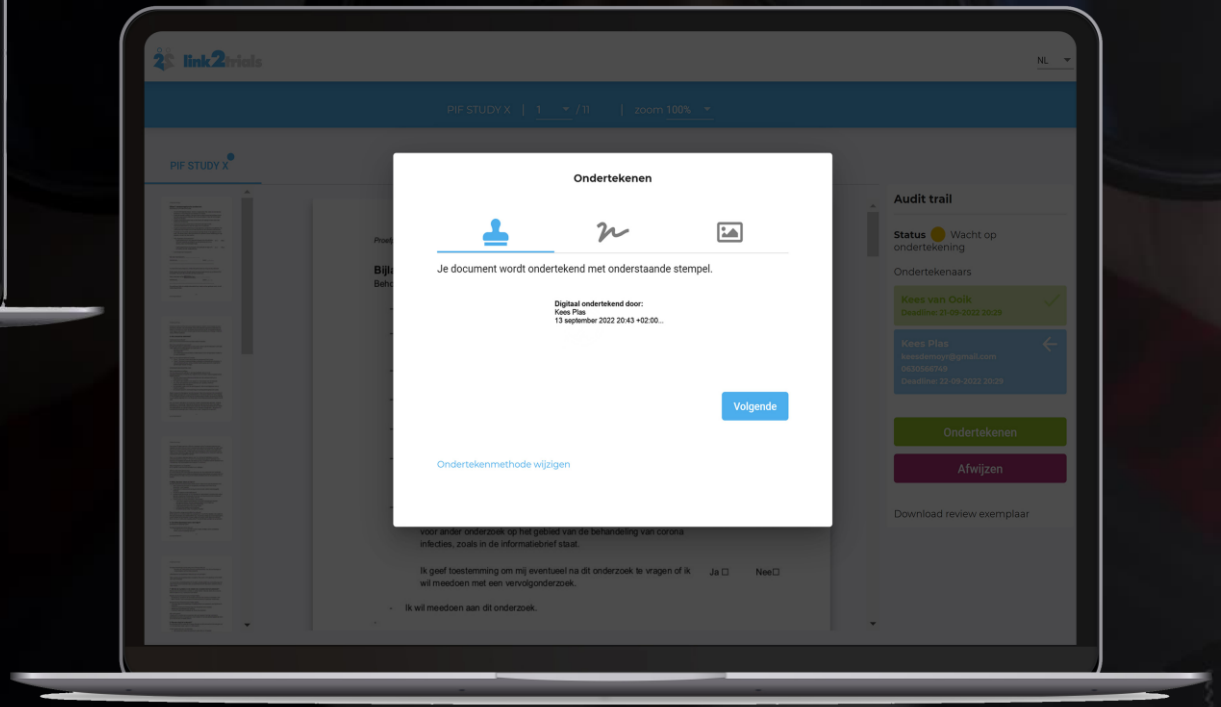
Proefpersoneninformatie
Bijlage C: toestemmingsformulier proefpersoon
Behorende bij PLATFORM-COVID studie
Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn goed genoeg beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen om toch niet mee te doen met het onderzoek. Of om ermee te stoppen. Ik hoef dan niet te zeggen waarom ik wil stoppen.
Ik geef de onderzoeker toestemming om mijn huisarts en apotheker te laten weten dat ik meedoe aan dit onderzoek.
Ik geef de onderzoeker toestemming om informatie op te vragen bij mijn huisarts/specialist/ziekenhuis indien dit nodig is voor het onderzoek.
Ik geef de onderzoekers toestemming om mijn gegevens te verzamelen en te gebruiken. De onderzoekers doen dit alleen om de onderzoeksvraag van dit onderzoek te beantwoorden.
Ik weet dat voor de controle van het onderzoek sommige mensen al mijn gegevens kunnen inzien. Die mensen staan in deze informatiebrief. Ik geef deze mensen toestemming om mijn gegevens in te zien voor deze controle.
Wilt u hieronder ja of nee aankruisen?
Ik geef toestemming om mijn gegevens te bewaren om dit te gebruiken voor ander onderzoek op het gebied van de behandeling van corona infecties, zoals in de informatiebrief staat. Ja ☐ Nee ☐
Ik geef toestemming om mij eventueel na dit onderzoek te vragen of ik wil meedoen met een vervolgonderzoek. Ja ☐ Nee ☐
Ik wil meedoen aan dit onderzoek.
Audit trail
Status Wacht op ondertekening
Ondertekenaars
Kees van Ooik
Deadline: 21-09-2022 20:29
Kees Plas
keesdemooy@gmail.com
0630566749
Deadline: 22-09-2022 20:29
Ondertekenen
Afwijzen
Download review exemplaar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Ondertekenen
Je document wordt ondertekend met onderstaande stempel.
Digitaal ondertekend door:
Kees Plas
13 september 2022 20:43 +02:00...
Volgende
Ondertekenmethode wijzigen
Audit trail
Status Wacht op ondertekening
Ondertekenaars
Kees van Ooik
Deadline: 21-09-2022 20:29
Kees Plas
keesdemooy@gmail.com
0630566749
Deadline: 22-09-2022 20:29
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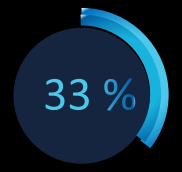
Patient Recruitment & Pre-qualification

Why online recruitment?

90% of trial fail to complete on time and within budget

Almost 50% of sites under-enroll

85% of days lost in clinical trials are due to delays in site recruitment



33% of the investigators find patient recruitment very to extremely burdensome

Traditional v.s. New Strategies

Traditional

- Increase # sites
- Posters
- Newspapers
- GP referrals

New Strategies

Search engine marketing

- Google AdWords
- YouTube

Social media advertising

- Facebook
- Instagram
- X (Twitter)
- TikTok

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Just in Time
Presents study opportunity when people are actively searching for information

Targeted and Flexible
Based on relevant keywords/searches

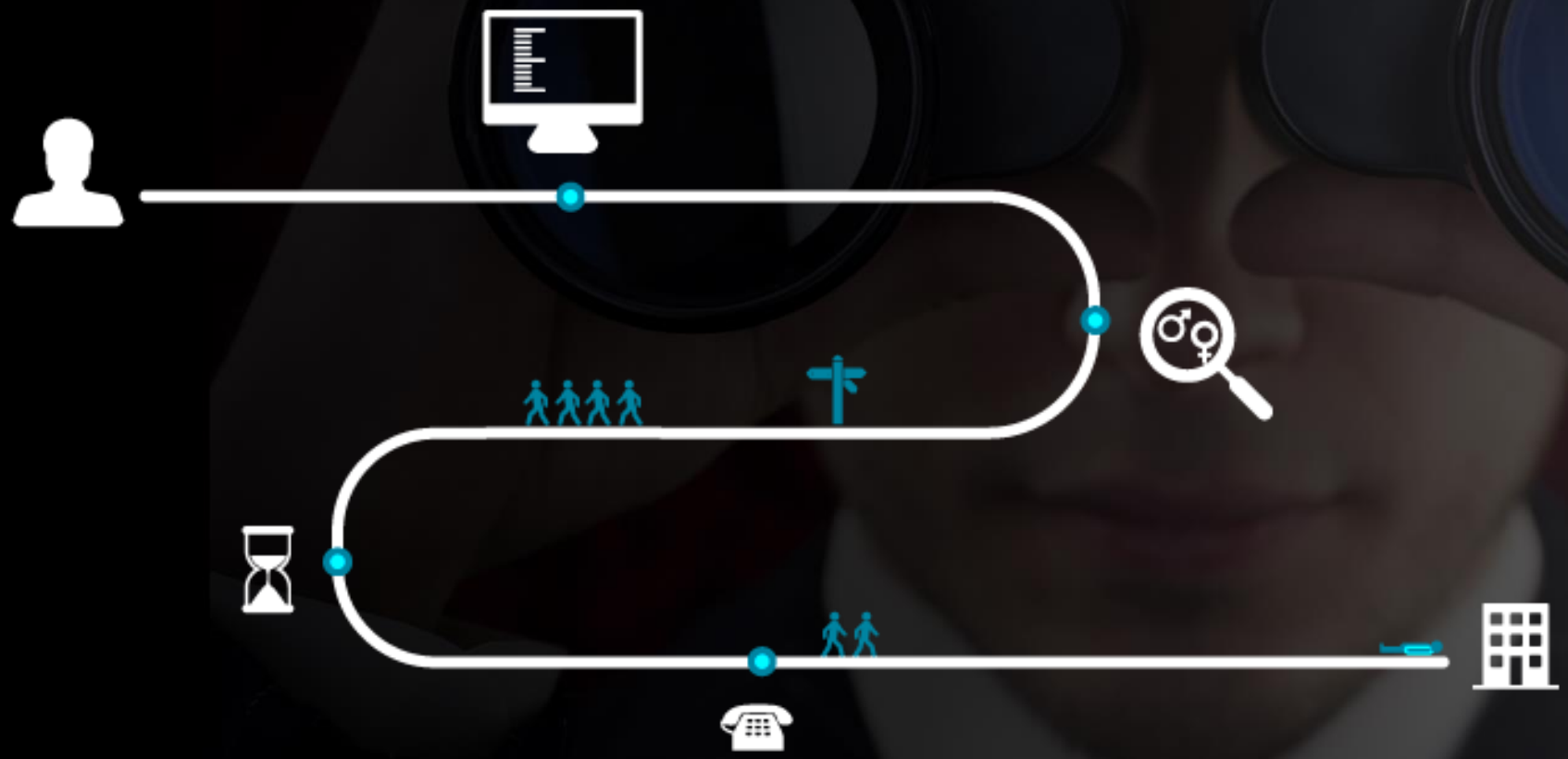
Optimized
High level of control through real-time performance analysis

Highly Targeted
Based on demographic and behavioral parameters related to the indication

Real-time Data
Cost-per-click model allows for an agile and precise deployment

How we work

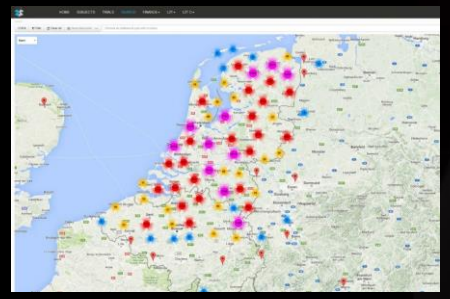
4 steps to success



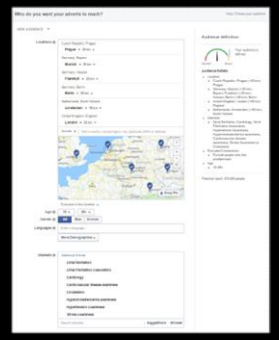
Strategy & Market Research

1 Online recruitment potential

Database search



Searchability / Targetability

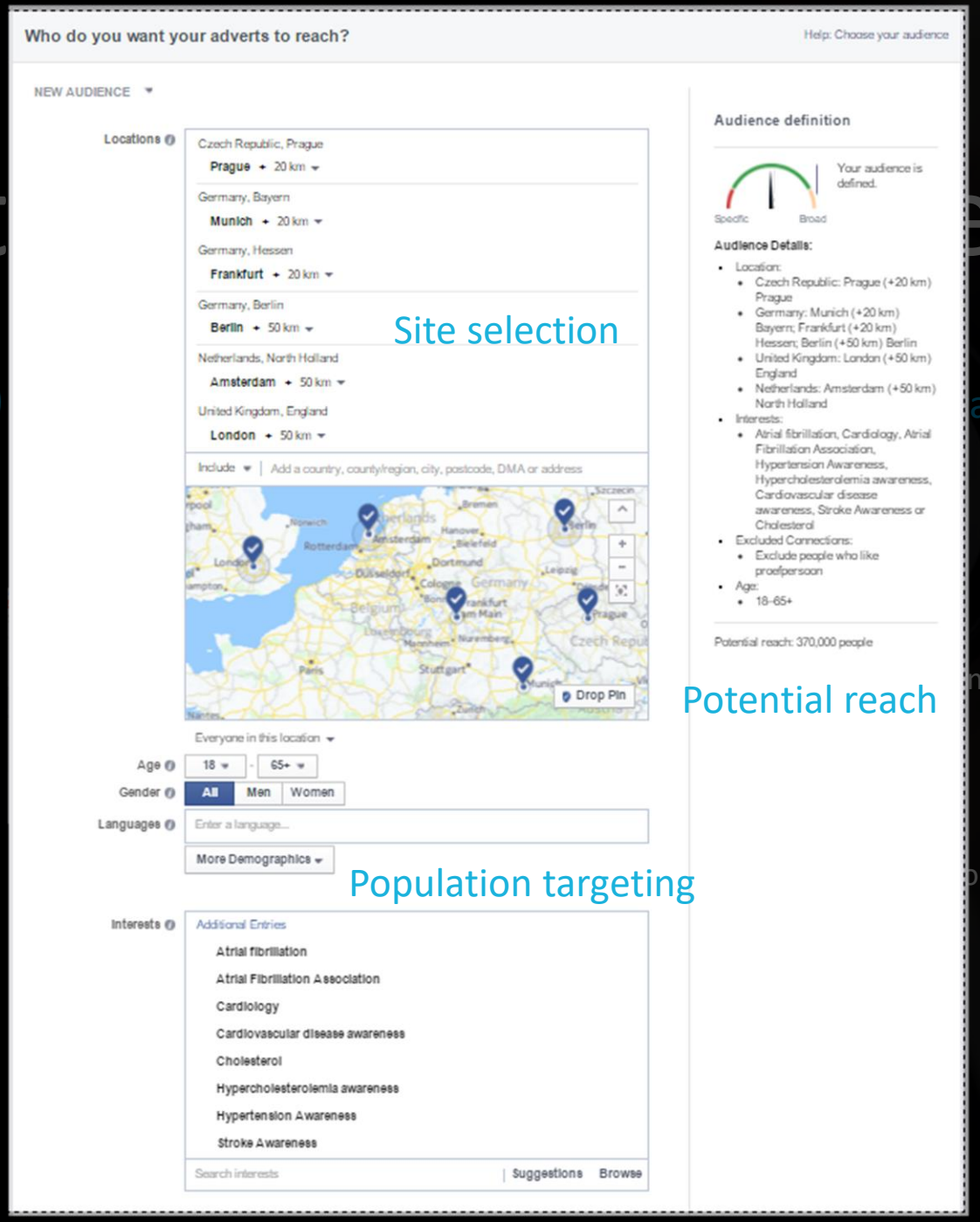


2 Patient motivation

- Protocol
- Current treatment option
- What's in it for the patient?

3 Pre-screening

- Online Questionnaire
- Medical phone team



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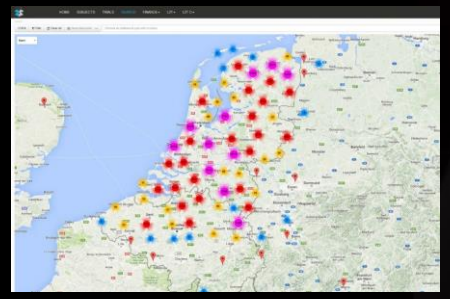

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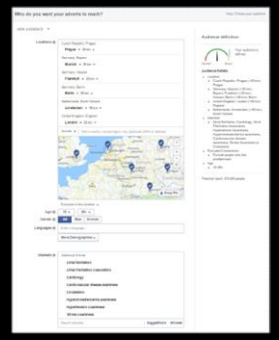

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A Patient’s perspective

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Chronic Low Back Pain

Trial location

England (2)

Preston, Oxford

Wales (1)

Cardiff / Caerphilly

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

Research has shown that **Chronic Low Back Pain** may be caused by low grade bacterial infection and may be treated with antibiotics. Persica Pharmaceuticals is researching a new treatment for this painful condition.

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.
- You will be reimbursed for reasonable expenses (meals and transport) for attending the study visits. However, there will not be any payment for participating in the clinical trial.
- You will be monitored throughout the study.

How to apply

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- 2-4 times per week
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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.

Full privacy statement

Send

A Patient's perspective

1

selection

4 Medical phone screening

A Patient’s perspective

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Chronic Low Back Pain

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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

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

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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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

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Full privacy statement

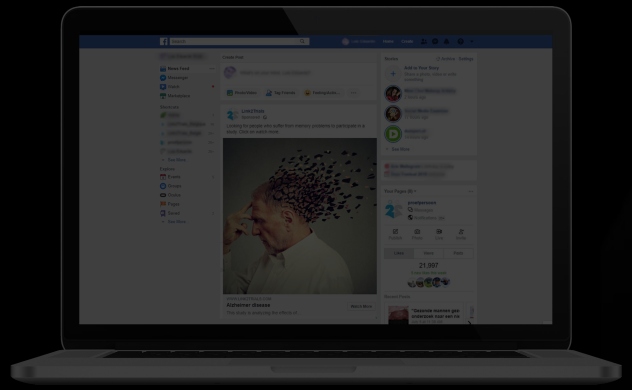
Send

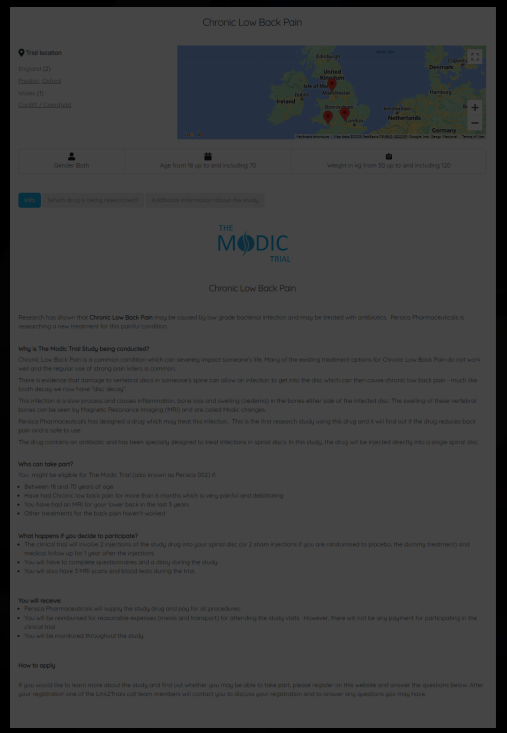
A Patient's perspective

1 Online advertisements

2 Study landing page

3





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?

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A Patient’s perspective

1. Online advertisements
2. Study landing page
3. Online pre-selection questionnaire
4. Medical phone screening

Chronic Low Back Pain

Trial location

England (2)

Preston, Oxford

Wales (1)

Cardiff / Caerphilly

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

Research has shown that **Chronic Low Back Pain** may be caused by low grade bacterial infection and may be treated with antibiotics. Persica Pharmaceuticals is researching a new treatment for this painful condition.

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.
- You will be reimbursed for reasonable expenses (meals and transport) for attending the study visits. However, there will not be any payment for participating in the clinical trial.
- You will be monitored throughout the study.

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.

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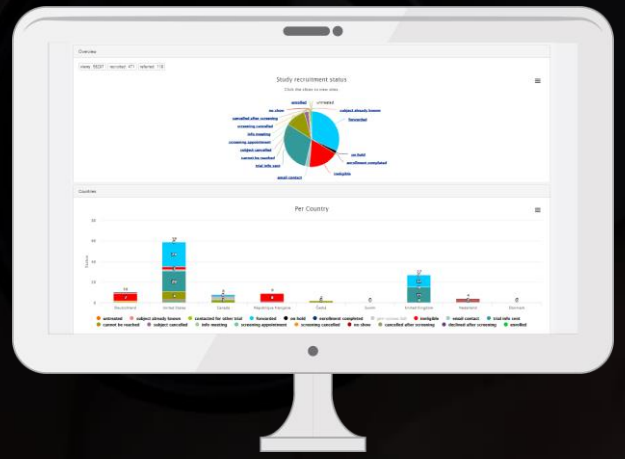
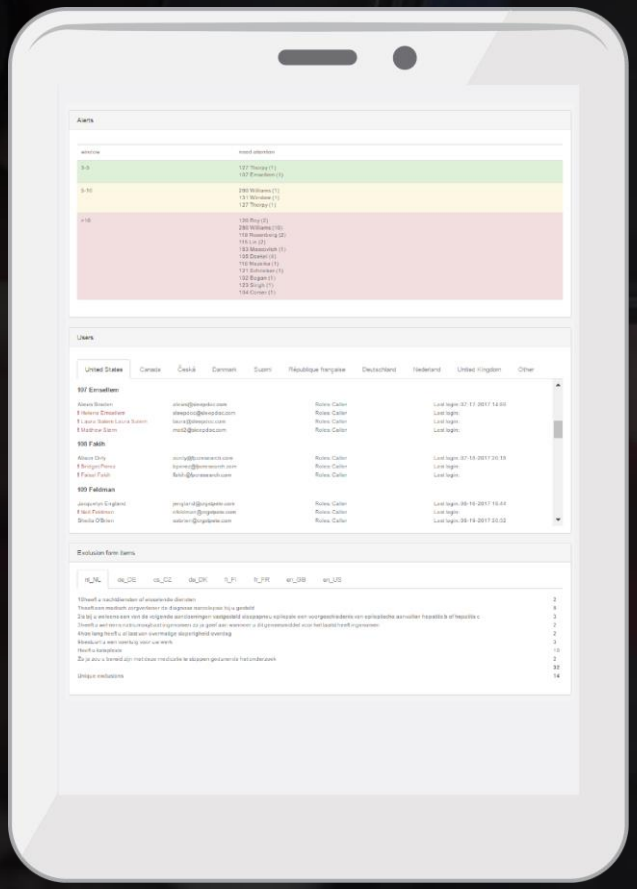
Statistics & Reporting

Risk Indicators

Study management statistics on a:
- Study level
- Country level
- Site level

Study access levels and log-in statistics





Why Link2Trials?

Link2Trials helped us enormously. They delivered on both speed and efficiency from inception to launch

GEORGINA LINES
DIRECTOR CLINICAL AFFAIRS / AQLANE MEDICAL

For me, it's a pleasure to follow up on these referred subjects because of the high standards of the Link2Trials recruitment process. I met this company first in the recruitment strategy of one of my first studies, and we were impressed.

WESLEY PULINX
CLINICAL STUDY LEAD / ANIMA RESEARCH CENTER

Link2Trials helped us enormously to realize a study mainly remotely during the COVID-19 pandemic and therefore to achieve very good results under special circumstances. Hence, they supported us from idea brainstorming until the most efficient recruitment of subjects on speed and efficiency.

SANDRA TOBISCH
SENIOR CLINICAL TRIAL MANAGER / ESSITY

NOVARTIS
GEDEA Biotech
BAYER
castor
Boehringer Ingelheim
Unilever
Amsterdam UMC Universitair Medische Centra
GH Research

Global Reach v.s. Local Focus

Offices: Amsterdam, The Netherlands, and Lund (Sweden)

Team: 30+

900+ supported studies

24 countries: Including the US, EU, Oceania, South America

Country-specific webpages in local languages

Extensive experience in the EU, with a solid local presence.

Global Reach v.s. Local Focus

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Team: 30+

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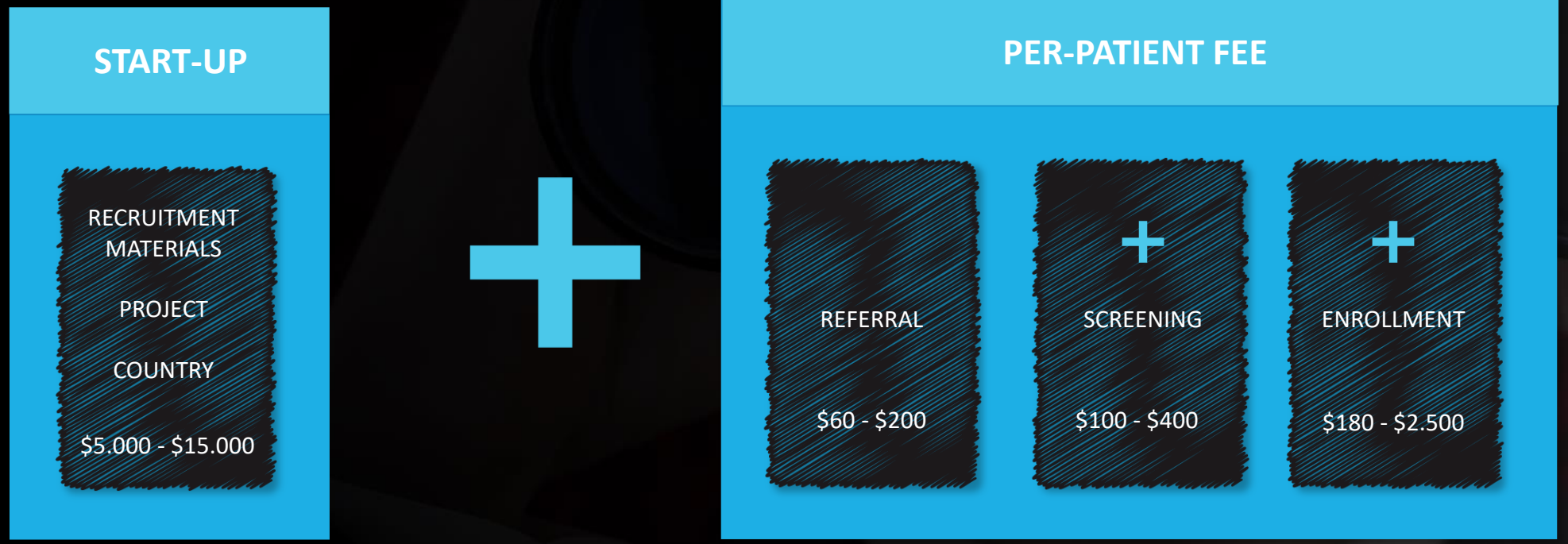
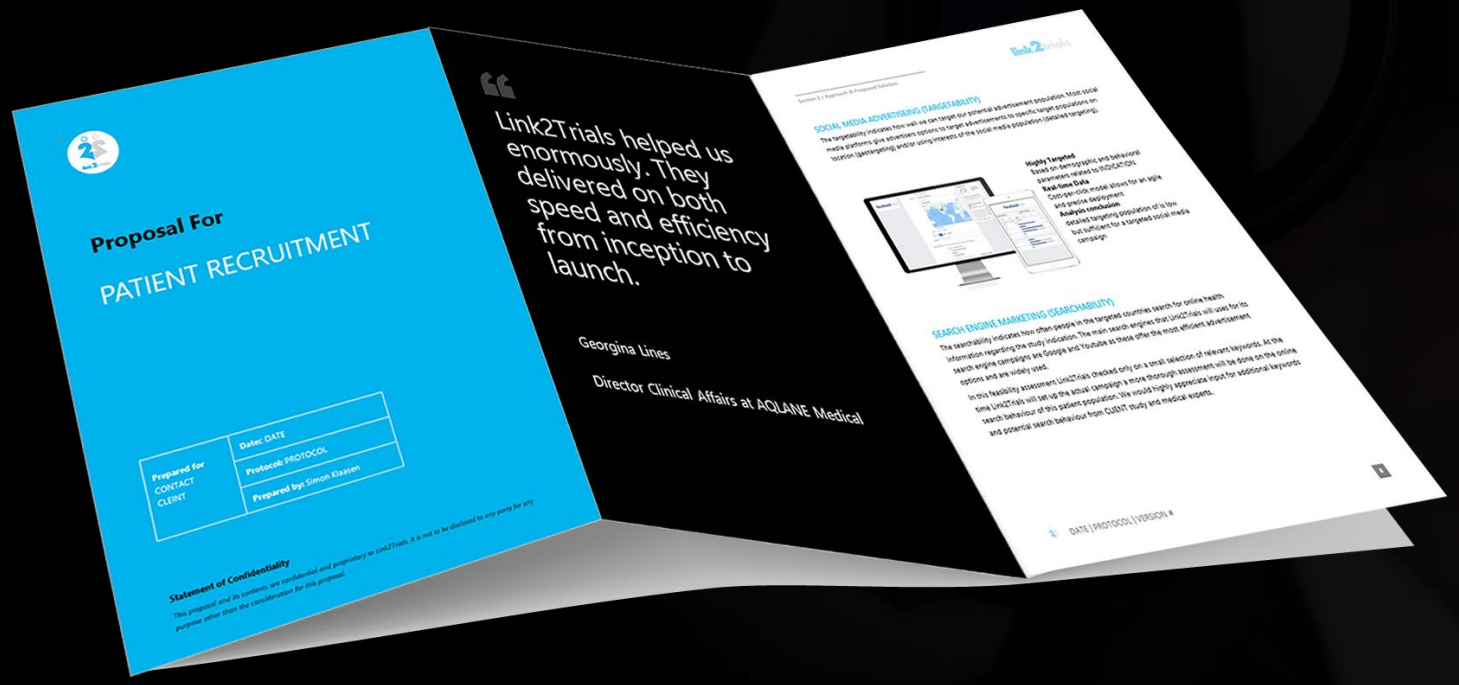
Pricing


START-UP
RECRUITMENT MATERIALS
PROJECT
COUNTRY
$5.000 - $15.000
PER-PATIENT FEE
REFERRAL
$60 - $200
SCREENING
$100 - $400
ENROLLMENT
$180 - $2.500

Next steps



We are happy to provide you with a proposal including the following:

Strategy and market research for your study

Pricing information, including the trial-specific per-patient fee

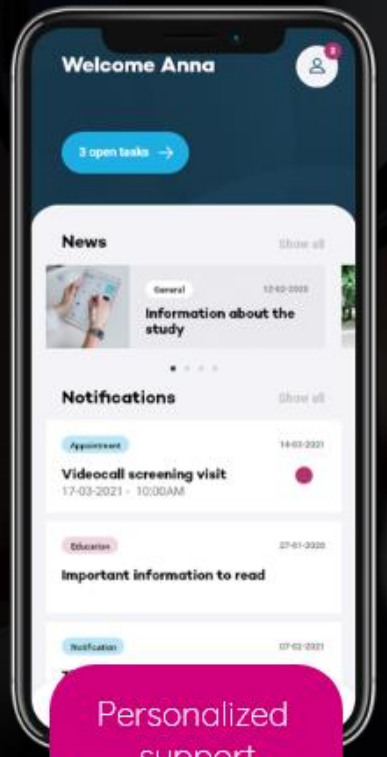
Capabilities and relevant case studies

Adherence Risk Management (ARM) Services

Adherence Risk Management (ARM)

a significant challenge in both clinical research and clinical care

ARM profile questionnaire



Personalized support

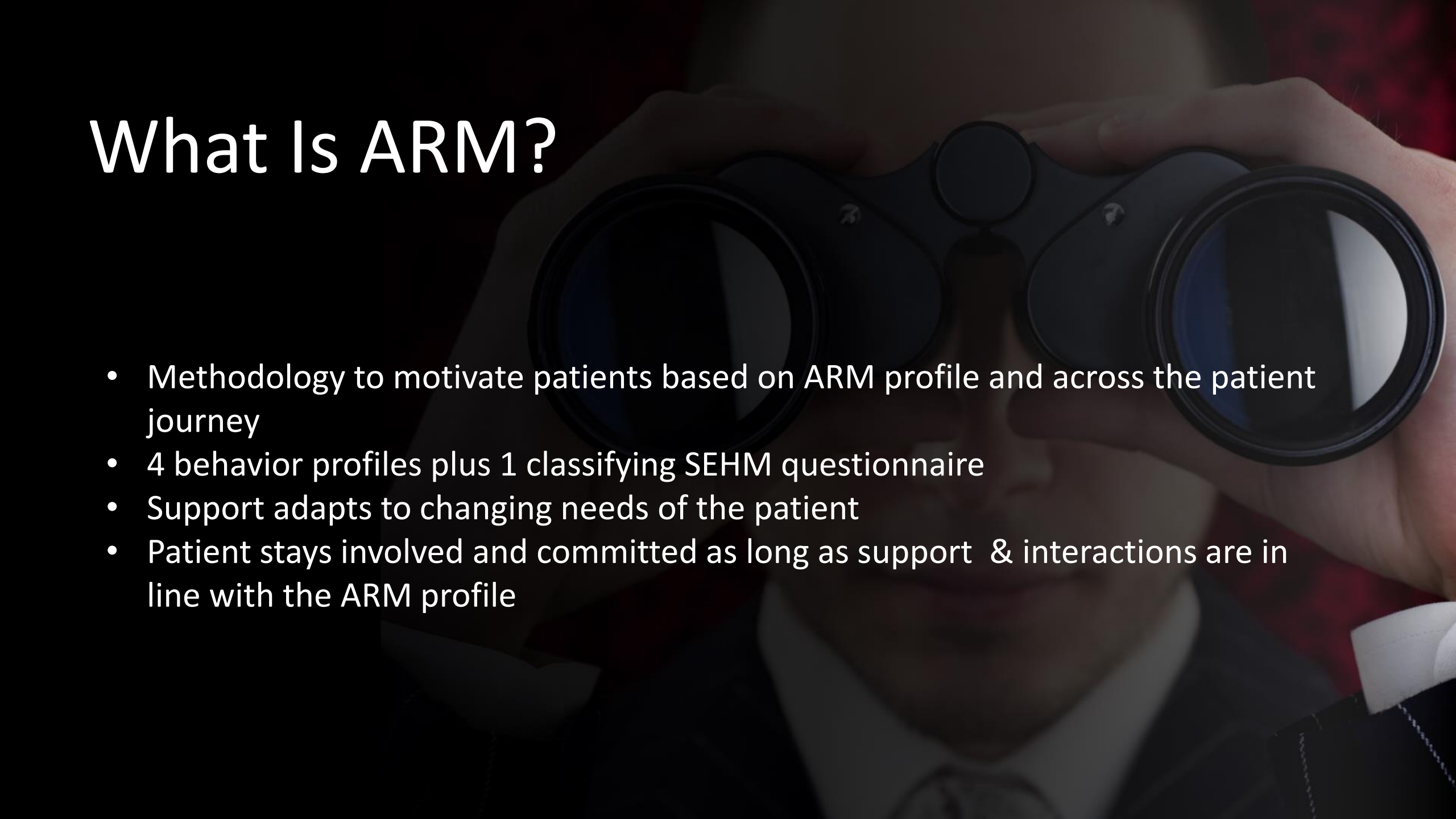
Study team ARM dashboard and notifications

The Challenge Today

- Patient non-adherence is a significant issue across all therapeutic areas
  (200,000 annual EU premature deaths[1], EUR 125 billion annual costs in Europe[2], similar figures for other regions)
- Adherence rates in clinical care are 50% on average
- Early Drop-Out rates are still 30% on average
- Over 60% of protocol deviations can be linked to non-adherence[3]

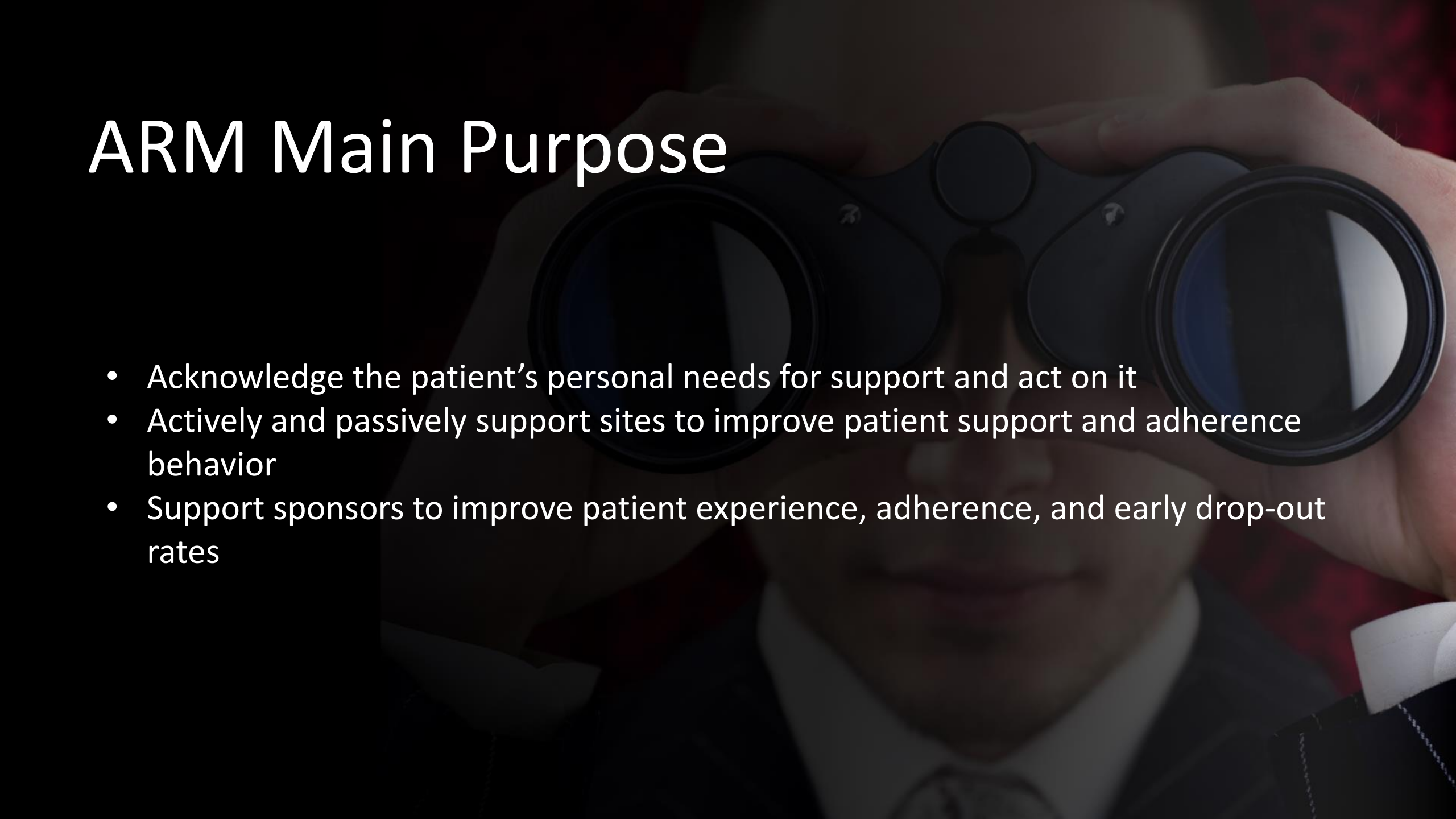
1. https://www.oecd-ilibrary.org/docserver/health_glance_eur-2018-en.pdf
2. A.O. Iuga, M.J. McGuire. Adherence and Healthcare Costs. Risk Management
3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4703381/

What Is ARM?



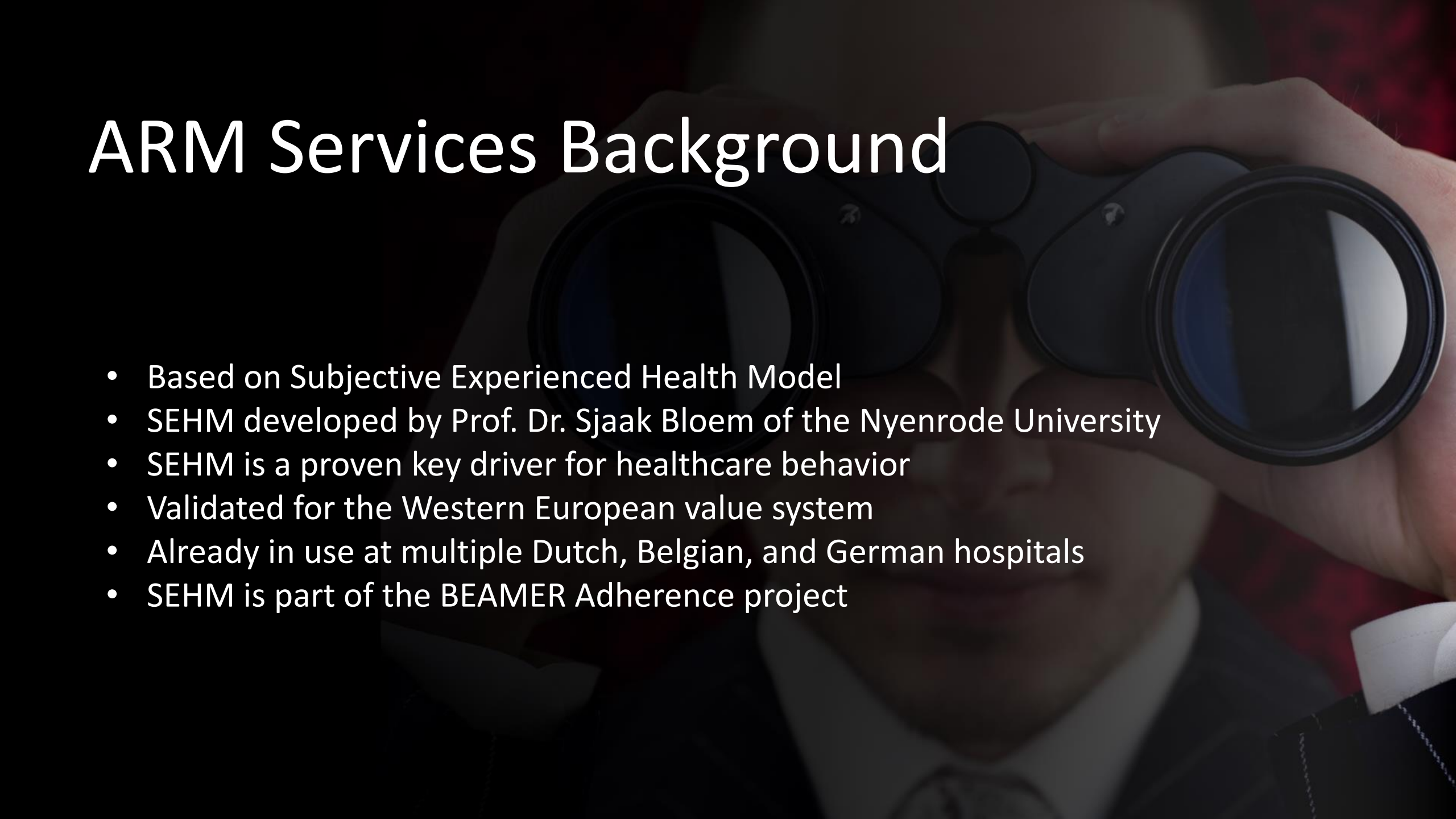
- Methodology to motivate patients based on ARM profile and across the patient journey
- 4 behavior profiles plus 1 classifying SEHM questionnaire
- Support adapts to changing needs of the patient
- Patient stays involved and committed as long as support & interactions are in line with the ARM profile

ARM Main Purpose



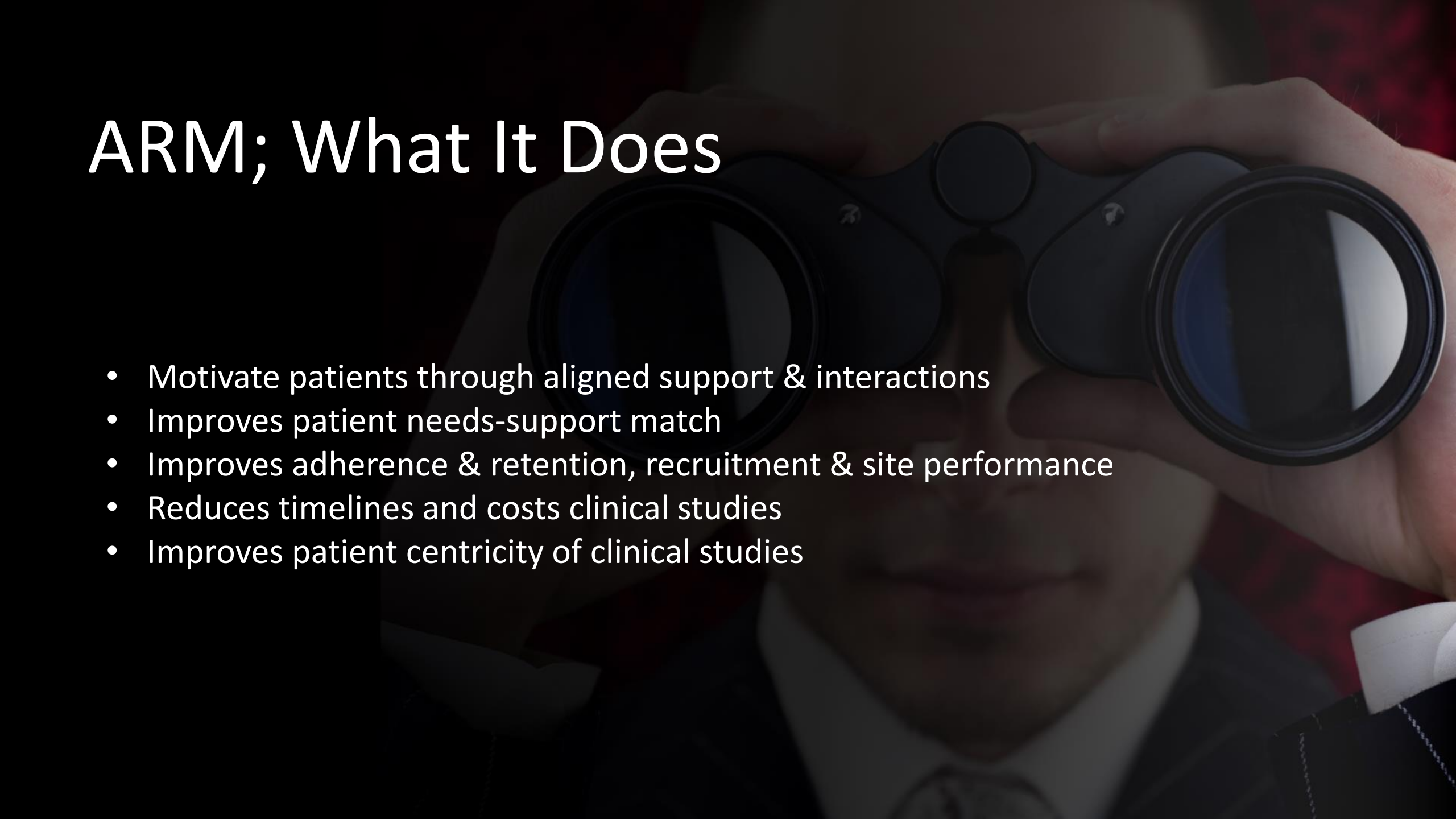
- Acknowledge the patient's personal needs for support and act on it
- Actively and passively support sites to improve patient support and adherence behavior
- Support sponsors to improve patient experience, adherence, and early drop-out rates

ARM Services Background



- Based on Subjective Experienced Health Model
- SEHM developed by Prof. Dr. Sjaak Bloem of the Nyenrode University
- SEHM is a proven key driver for healthcare behavior
- Validated for the Western European value system
- Already in use at multiple Dutch, Belgian, and German hospitals
- SEHM is part of the BEAMER Adherence project

ARM; What It Does



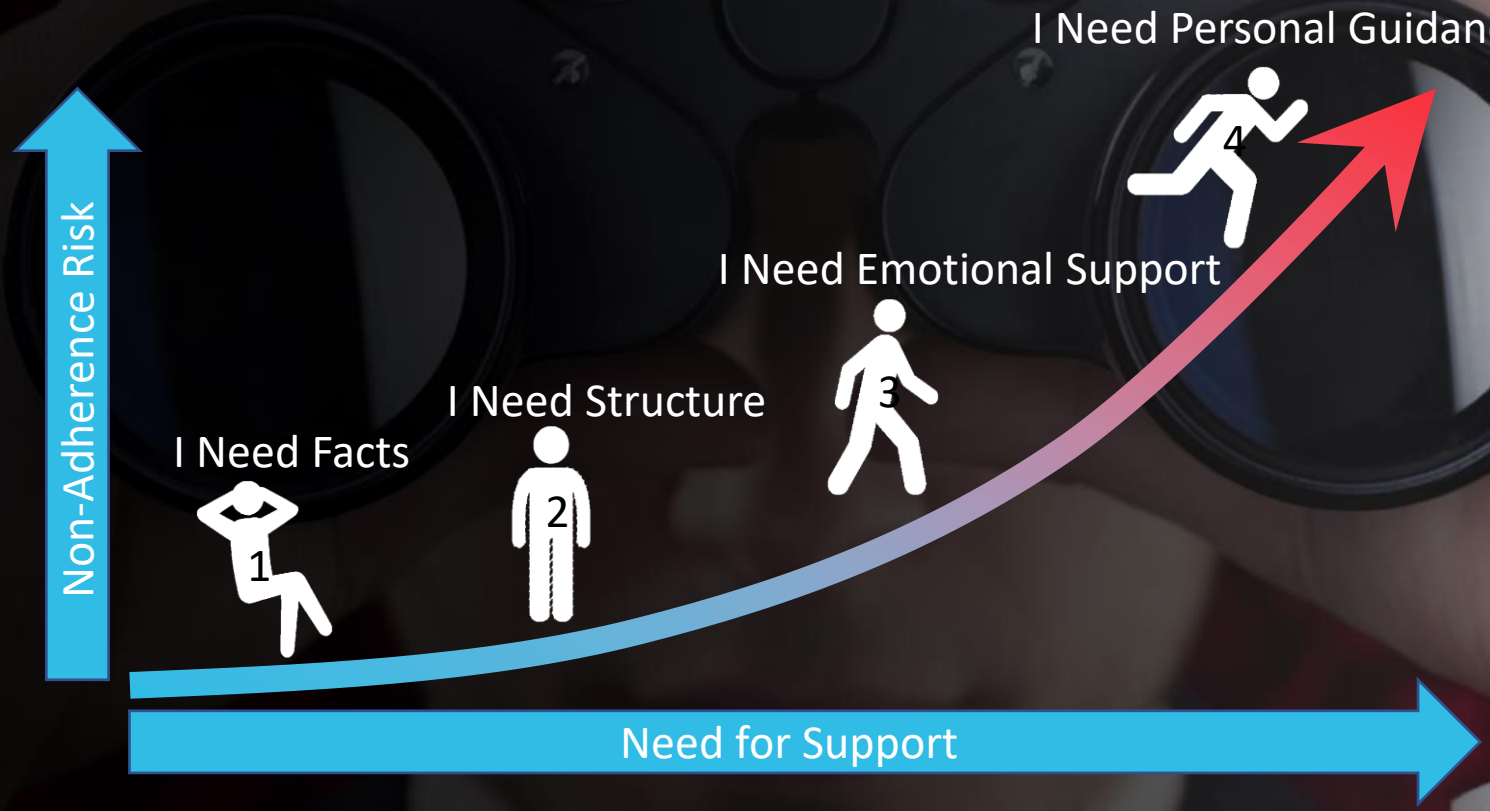
- Motivate patients through aligned support & interactions
- Improves patient needs-support match
- Improves adherence & retention, recruitment & site performance
- Reduces timelines and costs clinical studies
- Improves patient centricity of clinical studies

ARM Profiles & Non-adherence

ARM preparation

1. Identify the top risk factors of non-adherence for your clinical study

2. Develop communications and support packages for each ARM profile targeting trial events and risk factors. These packages are designed to motivate and improve adherent behavior.



ARM Execution Cycle

1. Identify the ARM profile of each patient

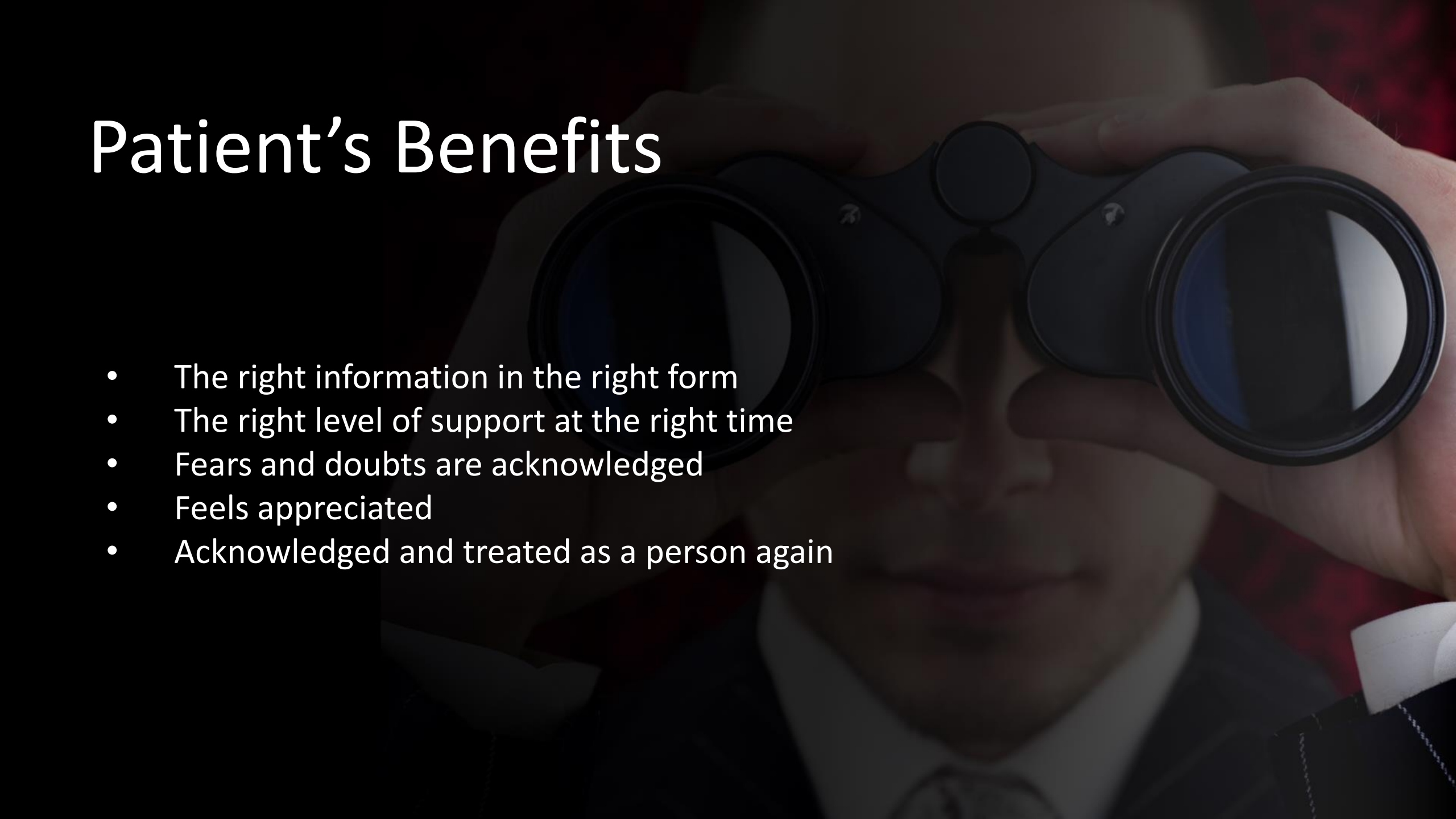
2. Push the right information and support to each patient, based on their up-to-date ARM profile. Each patient will:
    a. Get the right information in the right form
    b. Get the right level of support at the right time
    c. Feel acknowledged, appreciated, and treated as an individual again

3. Send alerts to the clinical trial team if and when a patient's ARM profile moves into the high-risk zone.

4. Adjust and fine tune interactions

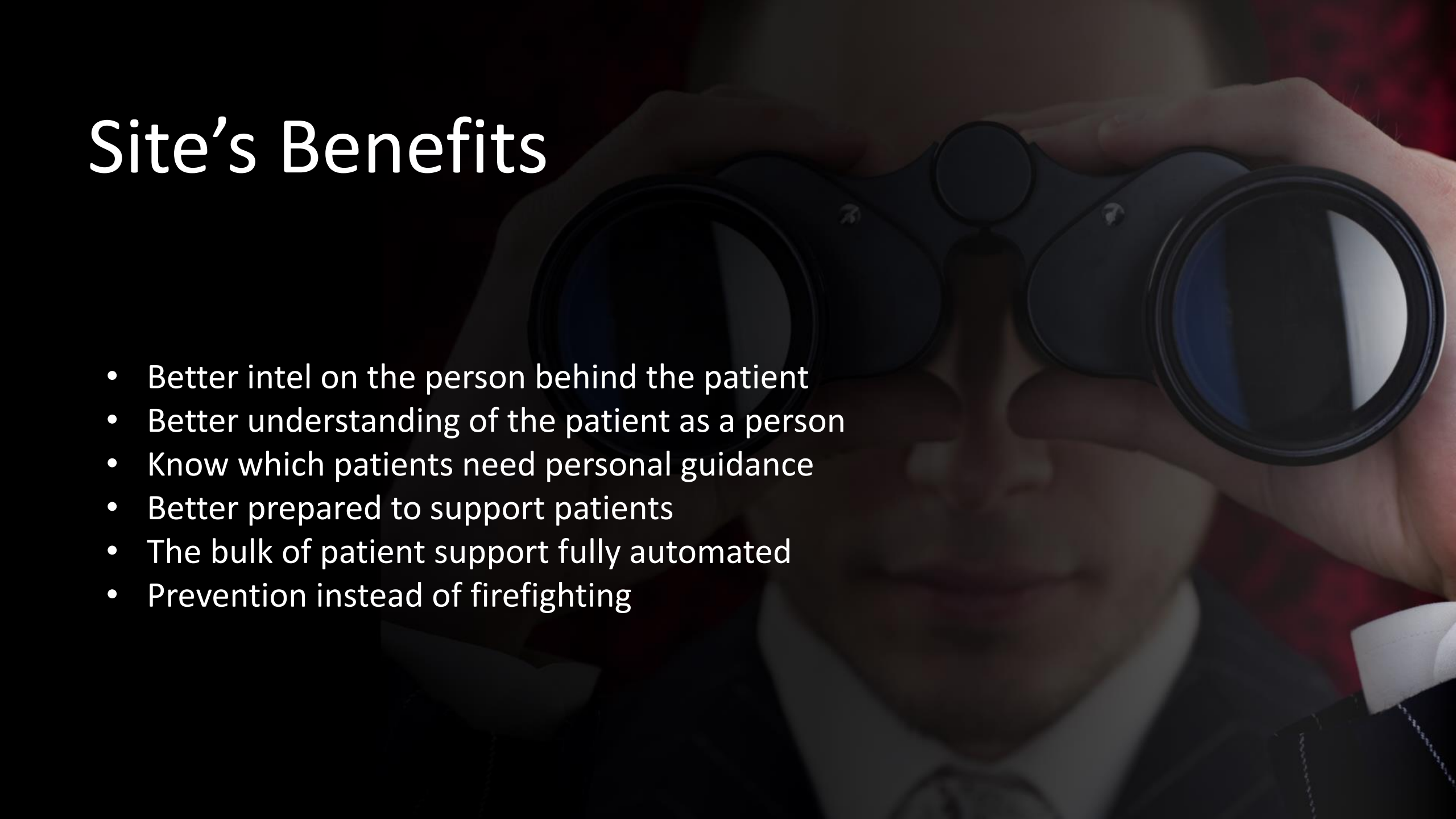
Benefits

Patient’s Benefits



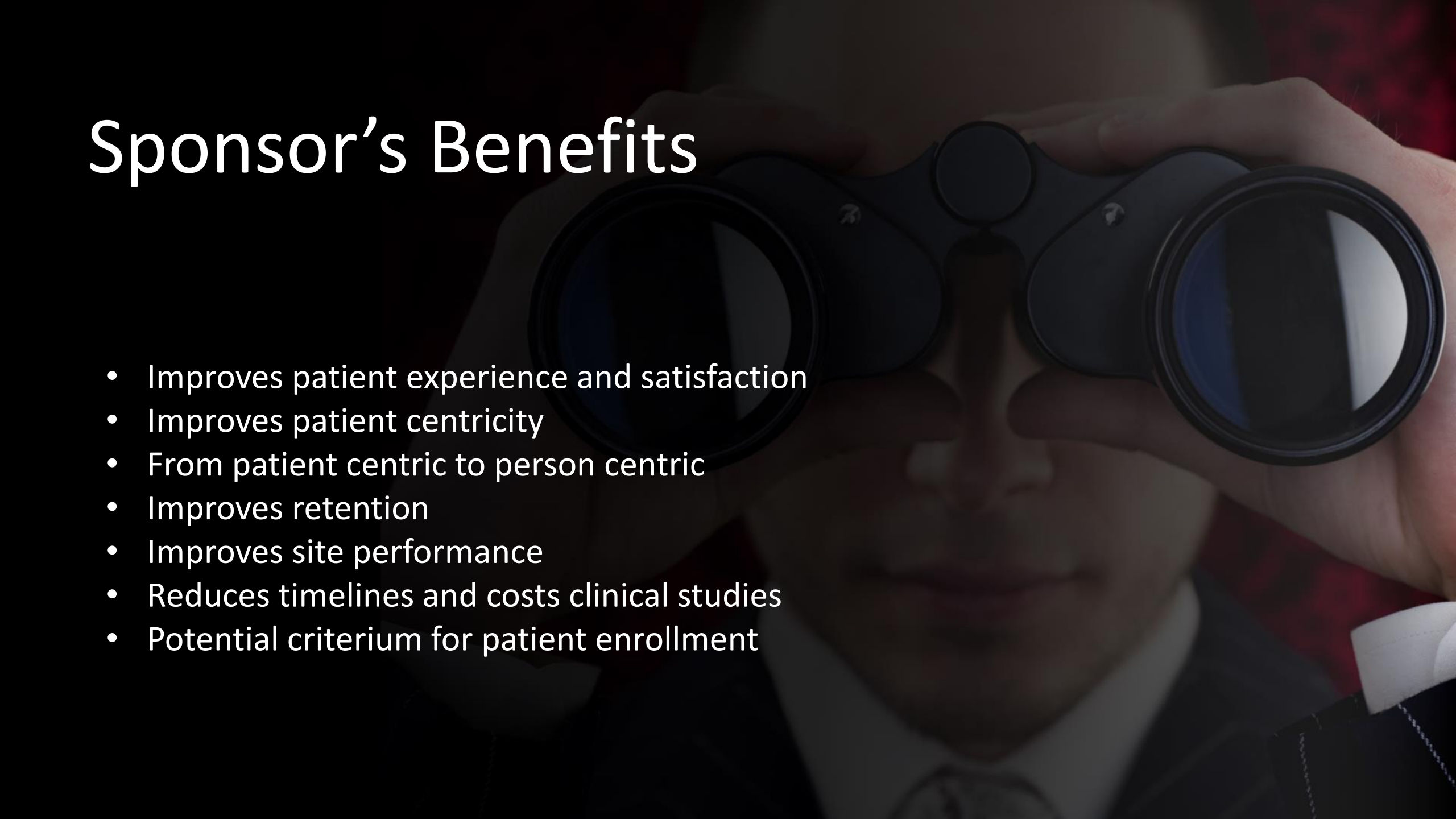
- The right information in the right form
- The right level of support at the right time
- Fears and doubts are acknowledged
- Feels appreciated
- Acknowledged and treated as a person again

Site’s Benefits



- Better intel on the person behind the patient
- Better understanding of the patient as a person
- Know which patients need personal guidance
- Better prepared to support patients
- The bulk of patient support fully automated
- Prevention instead of firefighting

Sponsor’s Benefits

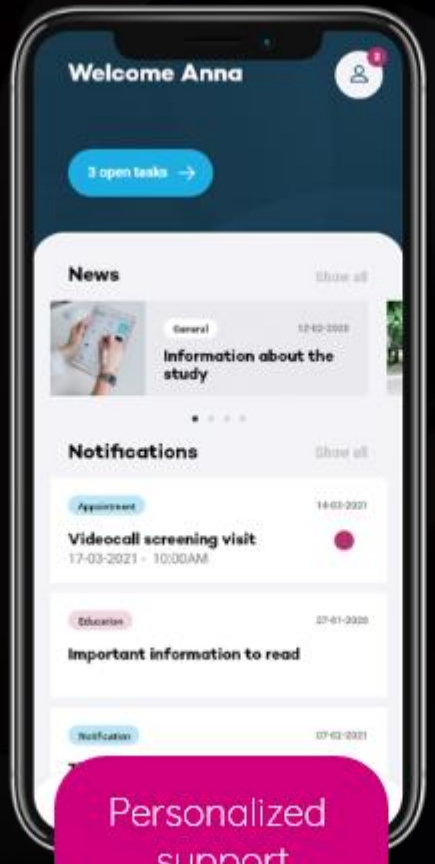


- Improves patient experience and satisfaction
- Improves patient centricity
- From patient centric to person centric
- Improves retention
- Improves site performance
- Reduces timelines and costs clinical studies
- Potential criterium for patient enrollment

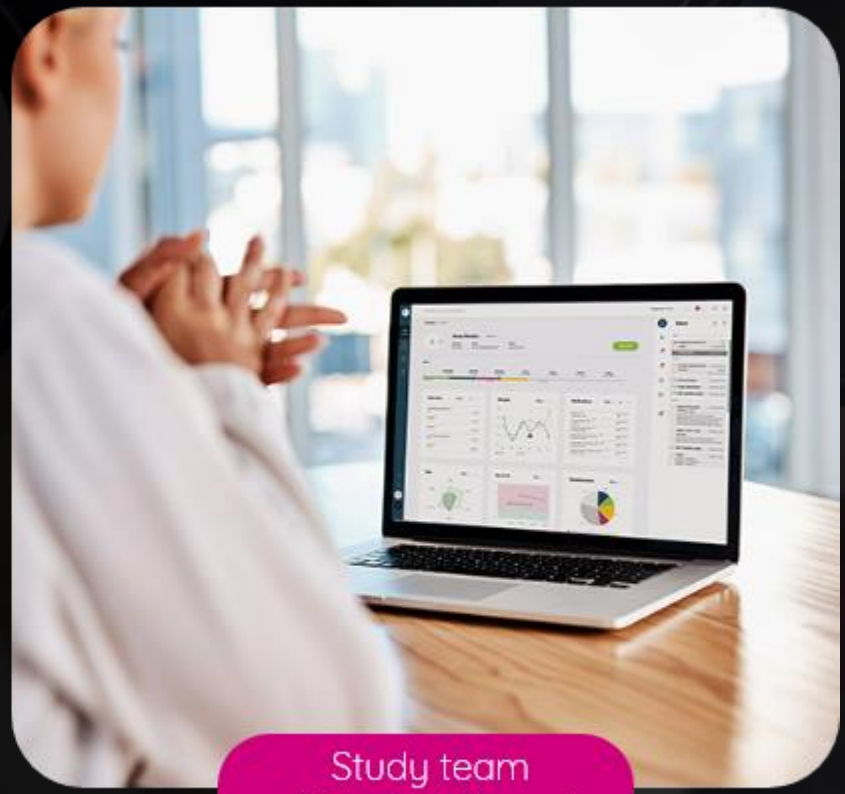
What Does It Look Like?

ARM TrialCoach Platform

ARM profile questionnaire



Personalized support



Study team ARM dashboard and notifications

Technology Background

- Based on existing and proven platform
- Seamless partnership
- ARM adherence support integrated
- Other modules available
- Over 125,000 patients supported by platform

Supported studies sponsored by

Proven and Compliant

- Certified ISO 27001 / NEN 7510
- GDPR, HIPPAA compliant
- GCP ISO-14155 (Good Clinical Practice)
- Software development according to ISO-62304
- Quarterly vulnerability scan and yearly penetration test
- Medical Device and ISO 13485 compliant

Questions?

Contact Link2Trials for more information:

info@link2trials.com