

WHY SO SLOW?

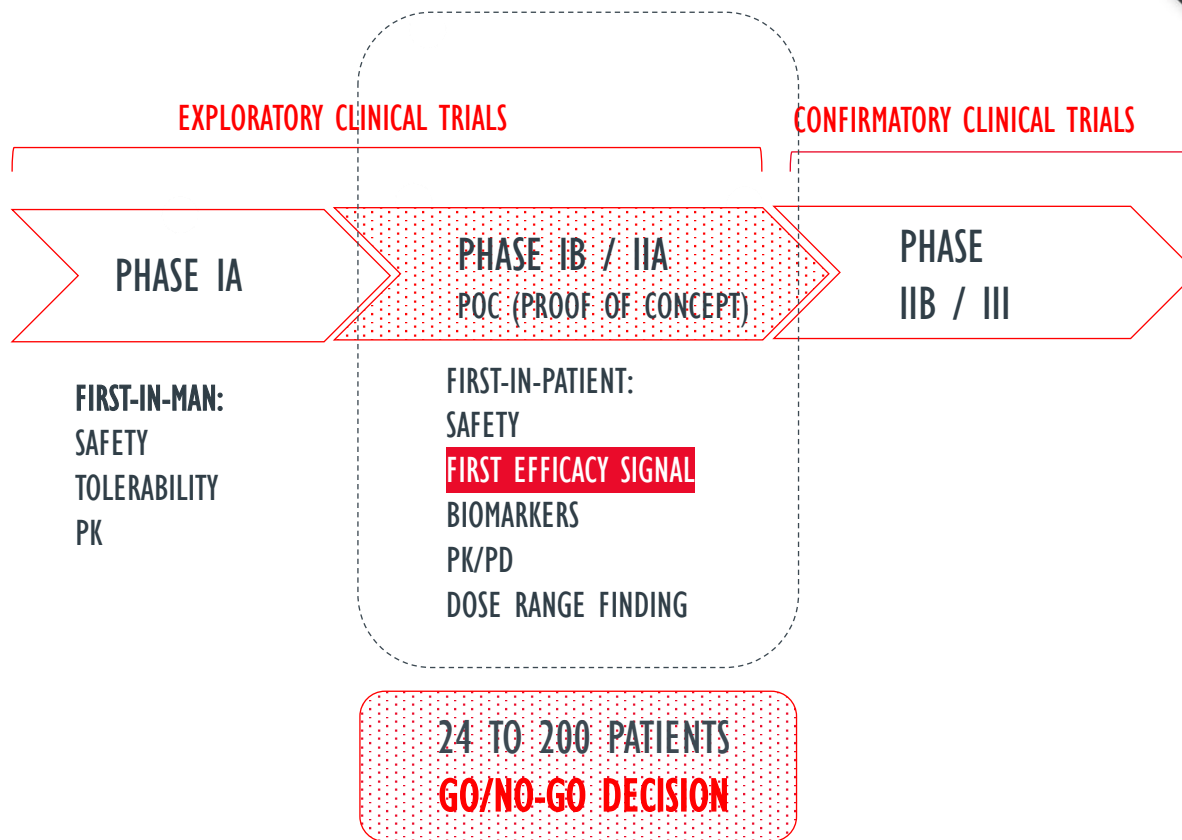
INSIDER INSIGHTS FROM THE CLINIC FLOOR TO SPEED UP THE STARTUP AND EXECUTION OF PROOF-OF-CONCEPT PATIENT TRIALS

DR. CLAUDIA HESSELMANN, PHD
FOUNDER & CEO

HOW TO:

- ▶ OBTAIN FEASIBILITY FIGURES TRUE TO DELIVERY.
- ▶ HARNESS REGULATORY DYNAMICS FOR STRATEGIC ADVANTAGES.
- ▶ CUSTOMIZE EFFICIENT PATIENT RECRUITMENT TACTICS!
- ▶ EMPLOY INNOVATIVE STUDY DESIGNS TO EXPEDITE THE DEVELOPMENT PROGRAM.

PLAYING FIELD POC TRIALS



HURDLES IN EXPLORATORY TRIALS

SHORTAGE AND HIGH TURN-OVER OF STAFF ACROSS INDUSTRY

OVER-CROWDED ACADEMIC SITES

COMPLEX REGULATORY ENVIRONMENT

LONG CONTRACTUAL TIMELINES

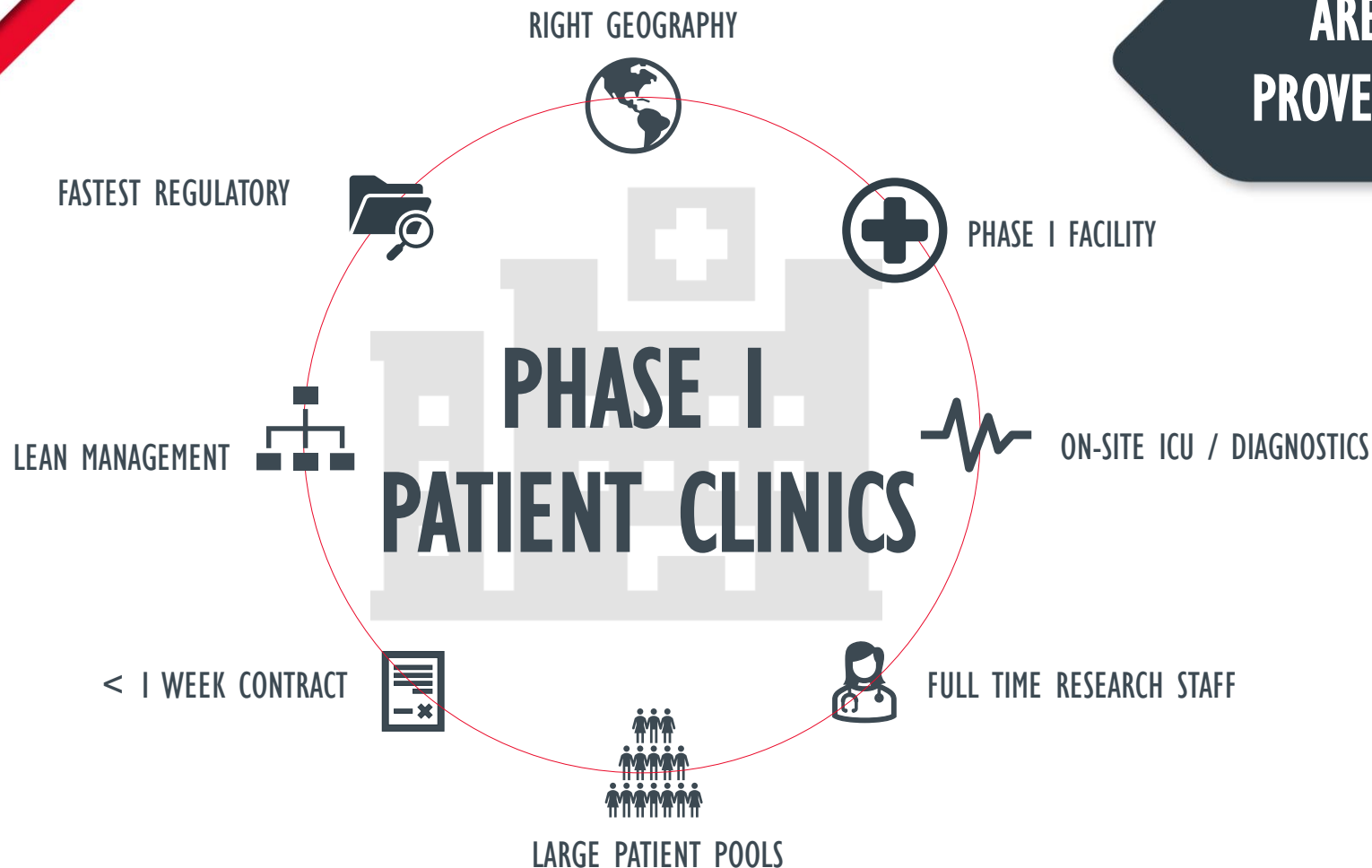
SUB-OPTIMAL SELECTION OF COUNTRIES, SITES, VENDORS

BUREAUCRACY IN LARGE ORGANIZATIONS



**SLOW PATIENT ENROLMENT
OPERATIONAL DELAYS**

ARENSIA'S PROVEN MODEL



ABOUT ARENZIA

PRIVATELY OWNED GERMAN COMPANY

14 YEARS EXPERIENCE

14 OWN RESEARCH CLINICS IN 8 COUNTRIES

SPECIALIZED TO DETECT FIRST EFFICACY SIGNAL OF NEW THERAPIES

600+ EMPLOYEES

OUR LOCATIONS

● OFFICES ● CLINICS



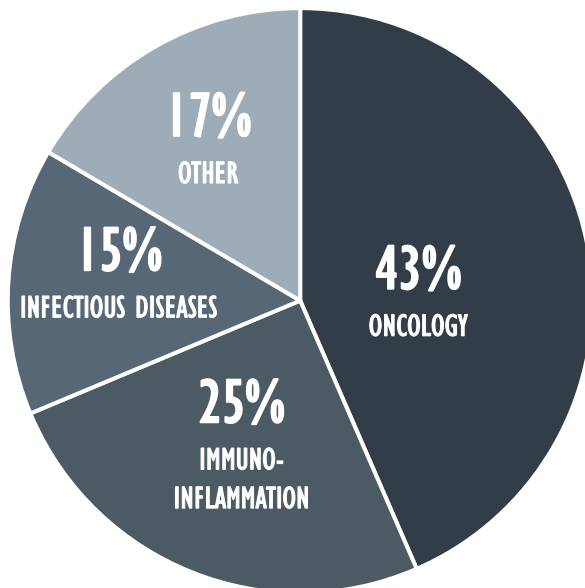
#1
PATIENT
RECRUITERS

93%
REPEAT
BUSINESS

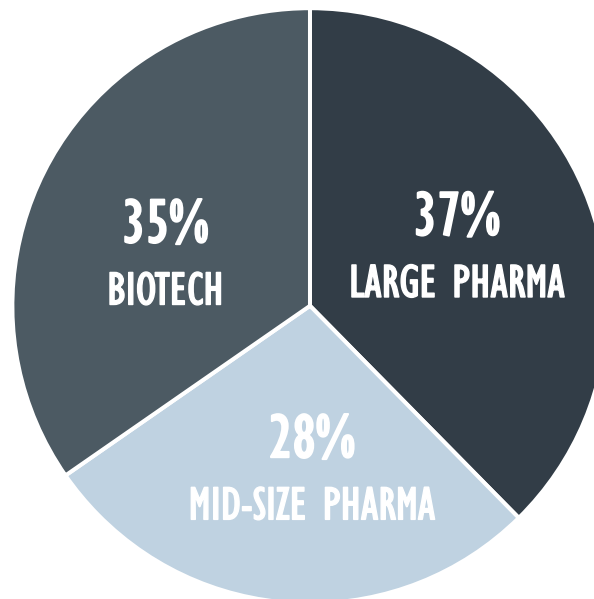
3%
STAFF
TURNOVER

230+
EARLY PHASE TRIALS

TRIALS BY THERAPEUTIC AREA



SPONSORS



**ACCESS TO OVER 70,000 PATIENTS WITH VARIOUS CANCER TYPES
IN 8 RESEARCH CLINICS**

BREAST CANCER
COLORECTAL CANCER
NSCLC
SCLC
GASTRIC CANCER
MELANOMA
OVARIAN CANCER
PANCREATIC CANCER
LIVER CANCER

RENAL CELL CARCINOMA
UROTHELIAL CANCER
PROSTATE CANCER
SCCNH
GLIOBLASTOMA
MULTIPLE MYELOMA
DLBCL
CLL
OTHER RARE CANCERS

ONCOLOGY TECHNOLOGY

GENETIC MUTATION TESTING

1,5T AND 3T CT/MRI (INCL. IRESIST)

PET

TUMOR GENOTYPING THROUGH LOCAL LABS

LEUKOPHERESIS

HIGH-ENERGY LINEAR ACCELERATORS FOR RADIATION ONCOLOGY

RADIOSURGERY

CYBERKNIFE G4

BONE MARROW BIOPSIES

INTRA-TUMOR INJECTIONS

ULTRASOUND-GUIDED FRESH BIOPSIES

ACCESS TO ARCHIVAL BIOPSIES

PBMC SAMPLES

IN-DEPTH EXPERTISE WITH SOPHISTICATED EARLY PHASE PROTOCOLS:

- ▶ FIRST-IN-PATIENT PROTOCOLS (IN-HOUSE & AMBULATORY)
 - DOSE FINDING
 - PROOF OF CONCEPT
 - UMBRELLA/BASKET/PLATFORM
- ▶ BIOEQUIVALENCE
- ▶ QTC

FEASIBILITY FIGURES TRUE TO DELIVERY

- ▶ LOOK INTO COUNTRIES WHERE THE TARGETED PATIENT POPULATION IS REALISTICALLY AVAILABLE!
- ▶ INVOLVE THE SITE AT EARLY STAGE OF PROTOCOL DEVELOPMENT
- ▶ DO NOT RELY ON FEASIBILITY DONE ON PAPER
- ▶ DO NOT RELY ON HISTORIC DATA RE SITE PERFORMANCE

“40% OF ALL OUR SITES SUPPORTING ONCOLOGY TRIALS
DO NOT DELIVER ANY SINGLE PATIENT IN THE FIRST 6 MONTHS FROM ACTIVATION”



CAST YOUR! STAR SITES

WITH DEDICATED RESEARCH RESOURCES

KEEP CONTROL OF SITE SELECTION
MEET THE SITE TEAM/PI
SHOW YOUR COMMITMENT!
FEEL SITE COMMITMENT!

WHY SO SLOW?

CONVENTIONAL MODEL (TYPICAL TRIAL SITES)

6 MONTHS

START-UP:
AWARD TO FIRST-PATIENT-IN

12 MONTHS

PHASE IB TRIAL
RECRUITMENT 48 HBV PATIENTS

12 TRIAL SITES
6 COUNTRIES

18 MONTHS

AWARD TO LAST PATIENT IN

ARENSIA MODEL (RESEARCH-ONLY CLINICS)

2 MONTHS

6 MONTHS

START-UP

PHASE IB TRIAL
RECRUITMENT 48 HBV PATIENTS

3 ARENSIA CLINICS
3 COUNTRIES

8 MONTHS

AWARD TO LAST PATIENT IN

YES!
IT IS POSSIBLE

6 TO 10 WEEKS

FROM FEASIBILITY TO FIRST PATIENT SCREENED

START-UP

**AWARD TO
SUBMISSION**

10 DAYS

RFP

5 DAYS

FEASIBILITY

5 DAYS

**SUBMISSION
TO APPROVAL**

10-60 DAYS

**APPROVAL
TO SIV**

5 DAYS

SIV TO FPS

1 DAY

BY ARENSIA

HARNESS REGULATORY DYNAMICS

EUROPE

SUBMISSION TO FIRST-PATIENT-IN

MOLDOVA



4 WEEKS

10 DAYS

GEORGIA, UKRAINE



6 WEEKS

30 DAYS

ROMANIA, BULGARIA / EU (CTIS SUBMISSION)



6 WEEKS

30 DAYS (MONO-NATIONAL)

10 WEEKS

60 DAYS (MULTI-COUNTRY)

 REVIEW BY AUTHORITIES
 DELIVERY SUPPLIES & SIV

USA

PHOENIX, AZ



6 WEEKS

30 DAYS

**WHAT MAKES THE
DIFFERENCE?**

A PROJECT LEADER WITH
WHY NOT
MENTALITY!

18-24 MONTHS
PROOF OF CONCEPT

INNOVATIVE STUDY DESIGNS DO SAVE TIME!



TRADITIONAL

DRUG I INDICATION I

▶ SINGLE TREATMENT

▶ SINGLE INDICATION



UMBRELLA

DRUG I

...

DRUG N

INDICATION I

▶ MULTIPLE TREATMENTS

FIXED # TREATMENT ARMS OR ADD/DELETE TREATMENT ARMS



BASKET

DRUG I

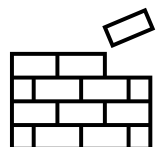
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INDICATION N

▶ SINGLE TREATMENT

▶ MULTIPLE INDICATIONS

GENOMIC INFORMATION/SEVERITY/LINES OF THERAPY/BACKGROUND CHARACTERISTICS



PLATFORM

DRUG I

...

DRUG N

INDICATION I

...

INDICATION N

▶ MULTIPLE TREATMENTS

FIXED # TREATMENT ARMS OR ADD/DELETE TREATMENT ARMS

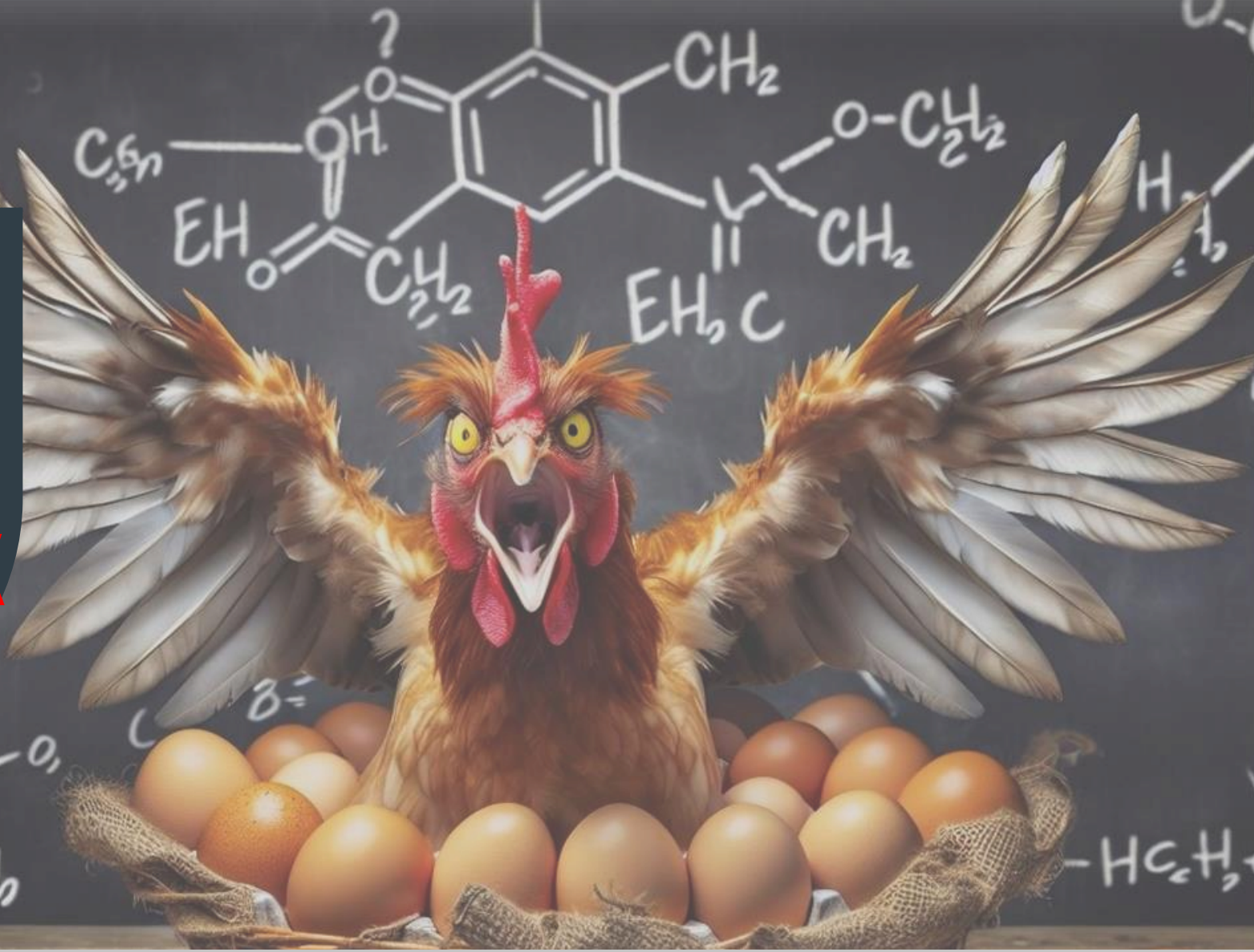
MULTIPLE INDICATIONS

▶ FIXED # INDICATIONS OR ADD/DELETE INDICATIONS

IT'S OK TO HAVE
ALL YOUR EGGS IN
ONE BASKET.

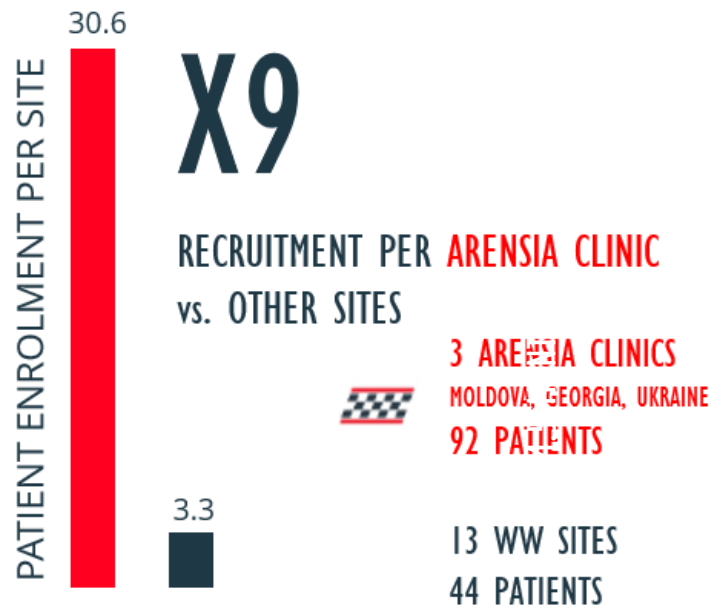
AS LONG AS YOU
CONTROL WHAT
HAPPENS TO
THAT BASKET.

ELON MUSK



**#1 PATIENT
RECRUITER**

PHASE I PROSTATE CANCER
136 PATIENTS IN 16 SITES



PATIENT IS THE VIP



ZERO! WAITING TIME



CAR TRANSPORTATION



COMFORTABLE CLINIC



COMPETENT INVESTIGATORS



HAPPY PARTNER DOCTORS

ADAPT

RECRUITMENT STRATEGY TO
PATIENT'S DISEASE &
CULTURAL PROFILE

PATIENT FIRST!



BOOTH #22



FOR ANY QUESTIONS PLEASE CONTACT:

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