

WHY SO SLOW?

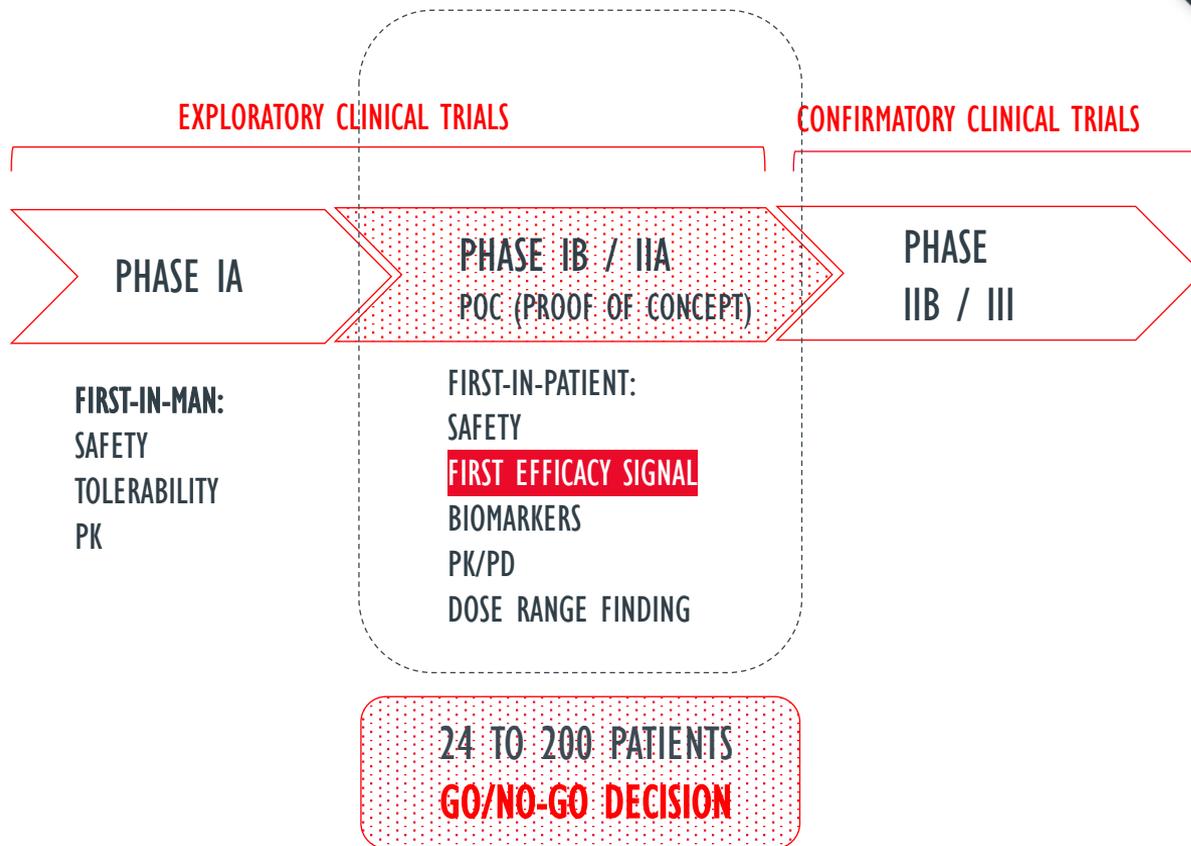
INSIDER INSIGHTS FROM THE CLINIC FLOOR TO SPEED UP THE STARTUP AND EXECUTION OF PROOF-OF-CONCEPT PATIENT TRIALS

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

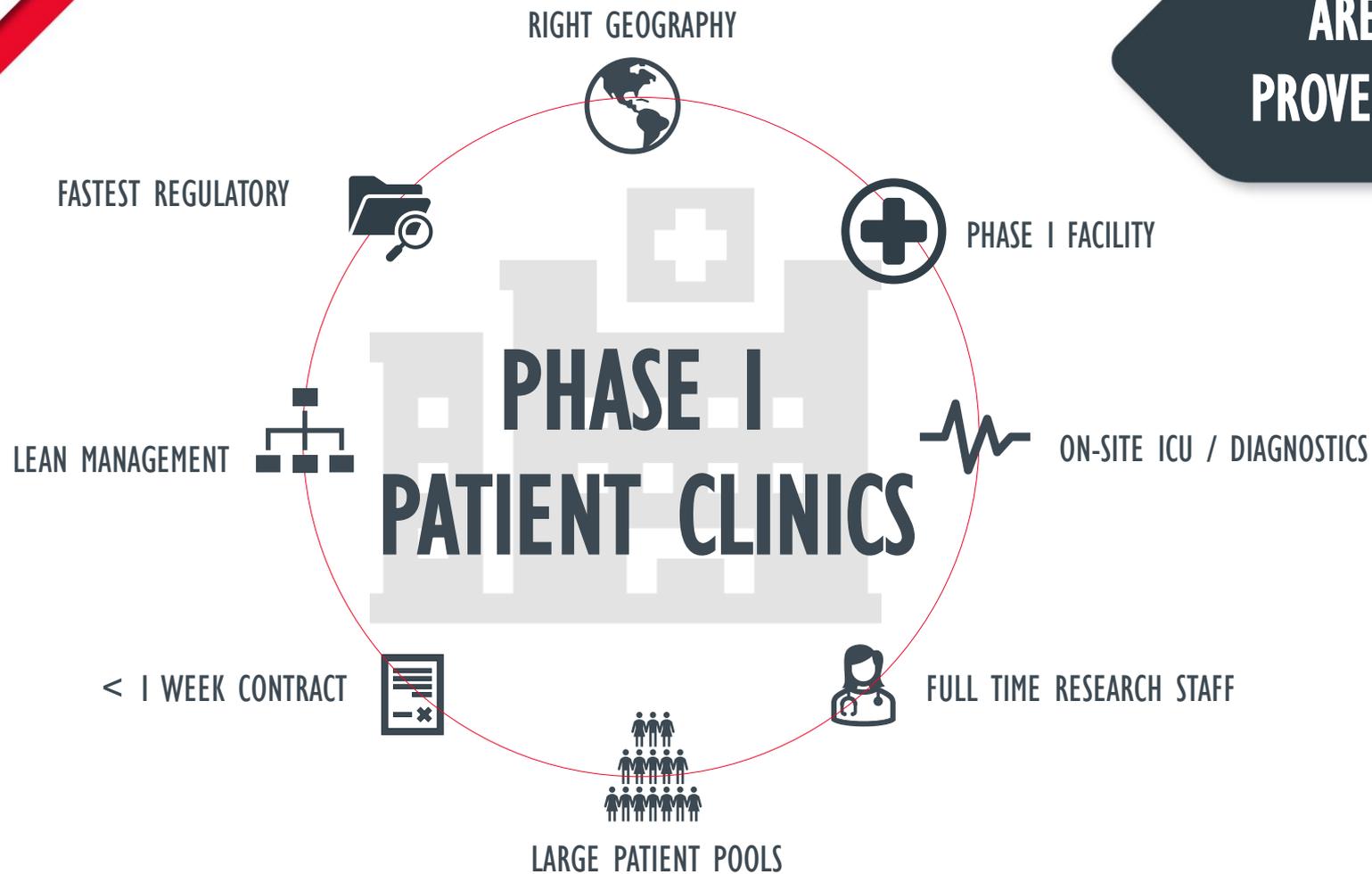
LONG CONTRACTUAL TIMELINES

SUB-OPTIMAL SELECTION OF COUNTRIES, SITES, VENDORS

BUREAUCRACY IN LARGE ORGANIZATIONS



**SLOW PATIENT ENROLMENT
OPERATIONAL DELAYS**



ABOUT ARENSIA

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



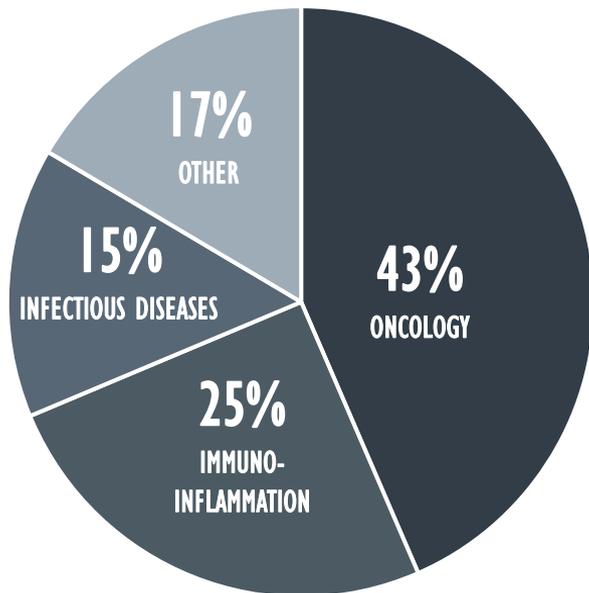
#1
PATIENT
RECRUITERS

93%
REPEAT
BUSINESS

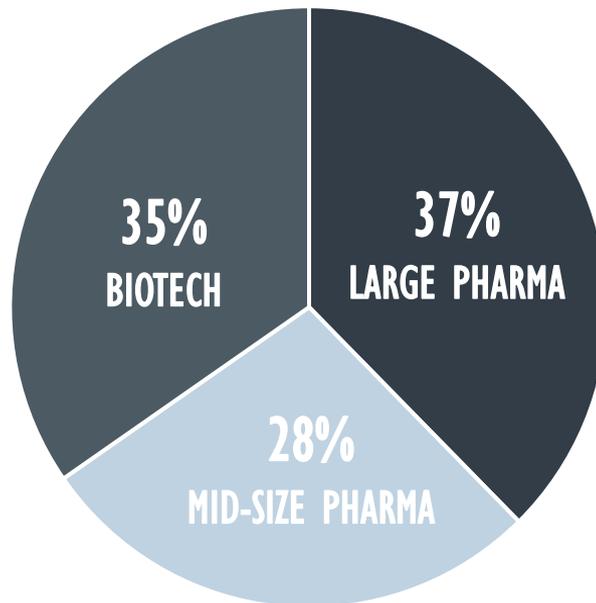
3%
STAFF
TURNOVER

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**

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

ARENZIA 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

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YES!
IT IS POSSIBLE

6 TO 10 WEEKS

FROM FEASIBILITY TO FIRST PATIENT SCREENED

START-UP

FEASIBILITY

5 DAYS

RFP

5 DAYS

**AWARD TO
SUBMISSION**

10 DAYS

**SUBMISSION
TO APPROVAL**

10-60 DAYS

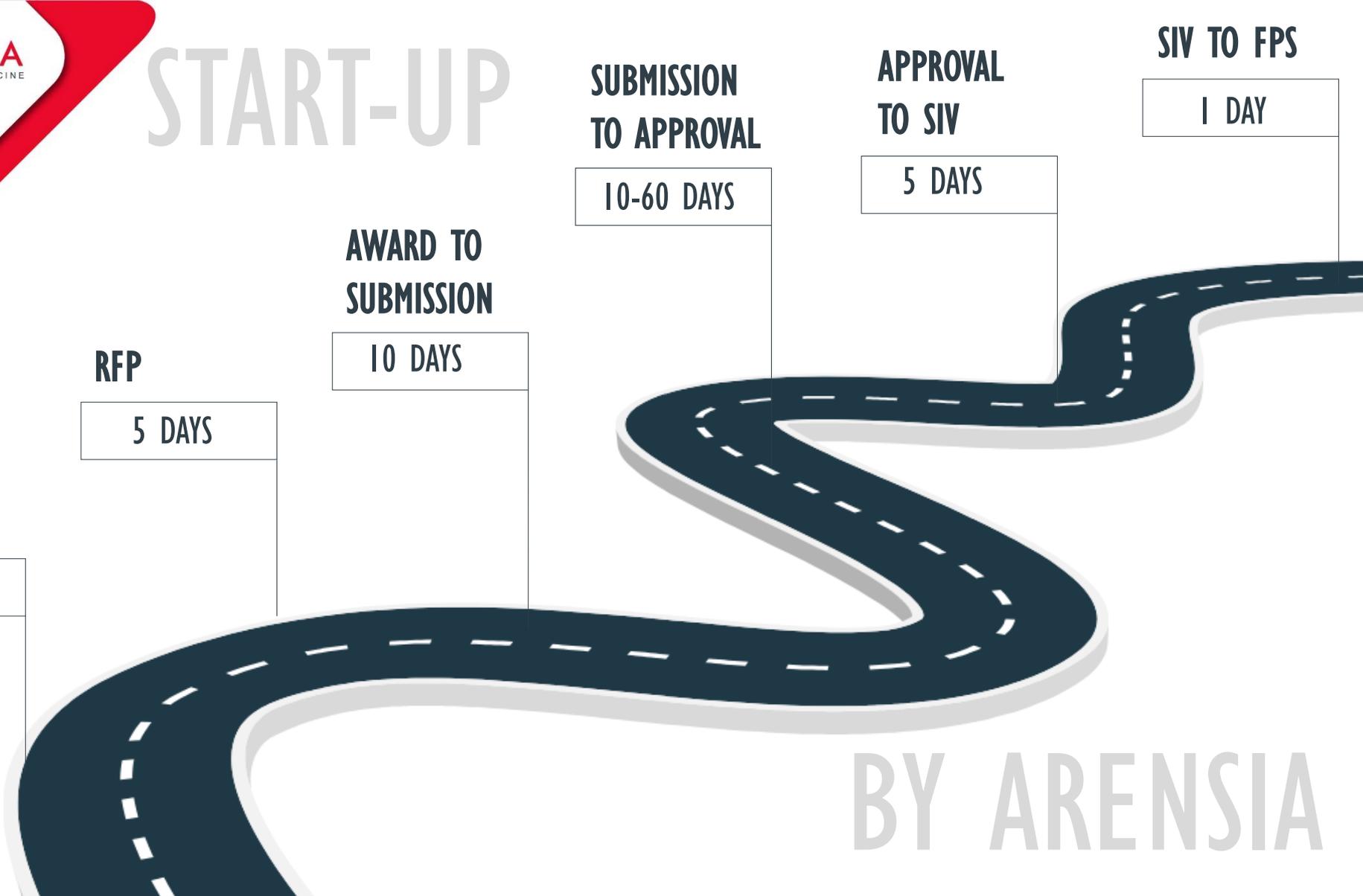
**APPROVAL
TO SIV**

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!

A dark blue arrow pointing to the left, containing the text "INNOVATIVE STUDY DESIGNS" in white, bold, uppercase letters.

**INNOVATIVE STUDY
DESIGNS**

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



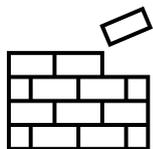
BASKET

DRUG I INDICATION I
...
INDICATION N

▶ SINGLE TREATMENT

▶ MULTIPLE INDICATIONS

GENOMIC INFORMATION/SEVERITY/LINES OF THERAPY/BACKGROUND CHARACTERISTICS



PLATFORM

DRUG I INDICATION I
... ...
DRUG N INDICATION N

▶ MULTIPLE TREATMENTS

FIXED # TREATMENT ARMS OR ADD/DELETE TREATMENT ARMS

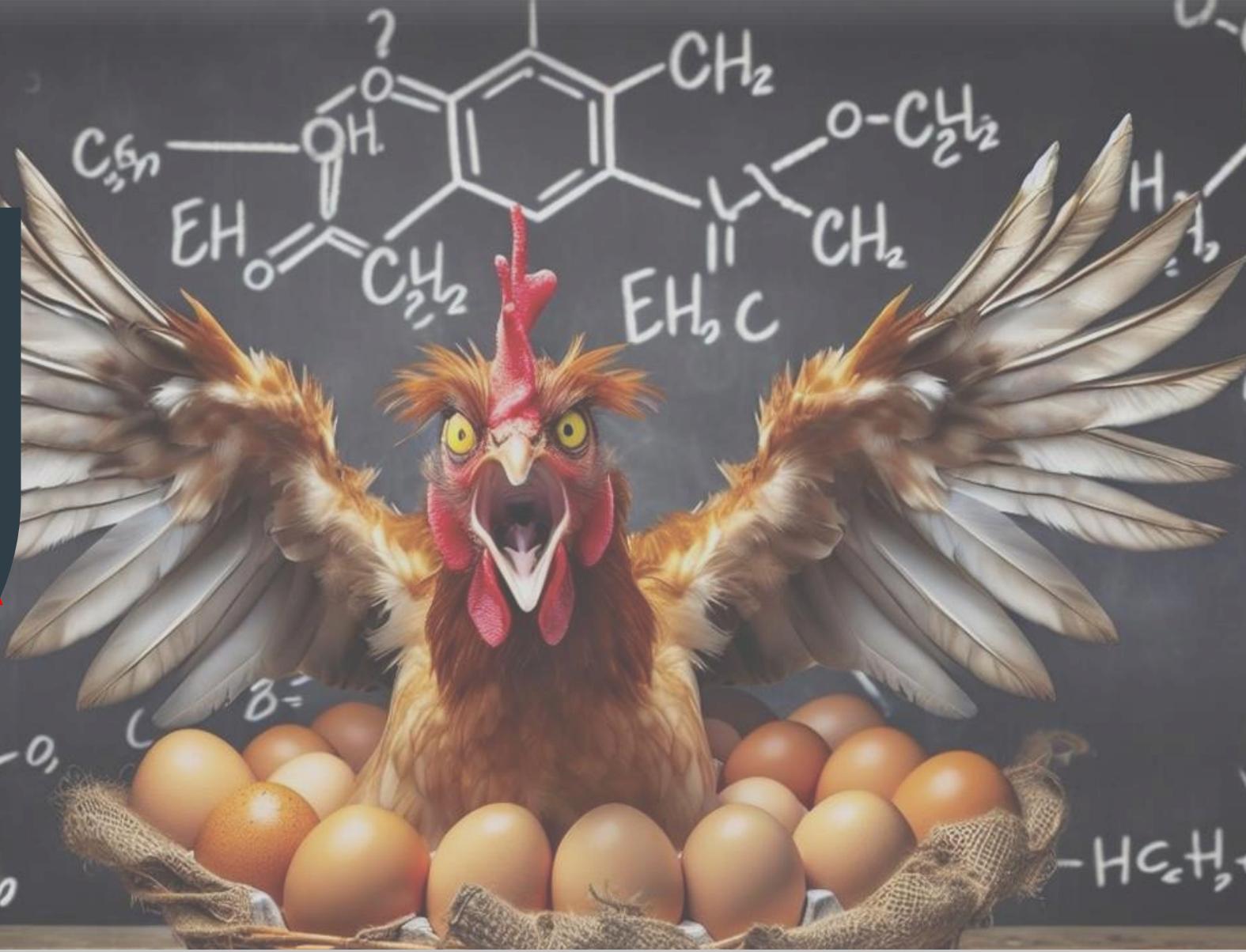
MULTIPLE INDICATIONS

▶ FIXED # INDICATIONS OR ADD/DELETE INDICATIONS

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

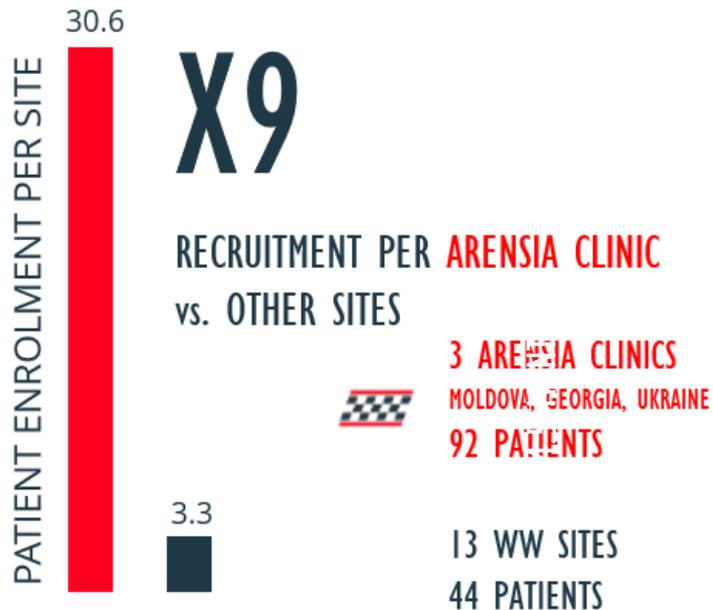
AS LONG AS YOU
CONTROL WHAT
HAPPENS TO
THAT BASKET.

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

A close-up photograph of an elderly person's face, focusing on their blue eyes and wrinkled skin. A small, reddish mole is visible on the forehead between the eyebrows. The lighting is soft, highlighting the texture of the skin.

ADAPT

RECRUITMENT STRATEGY TO
PATIENT'S DISEASE &
CULTURAL PROFILE

PATIENT FIRST!



BOOTH #22



FOR ANY QUESTIONS PLEASE CONTACT:

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