Operational metrics for the ELAINE 2 study combining a traditional approach with a just-in-TIME model

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Medical Director, Northwest Medical Specialties

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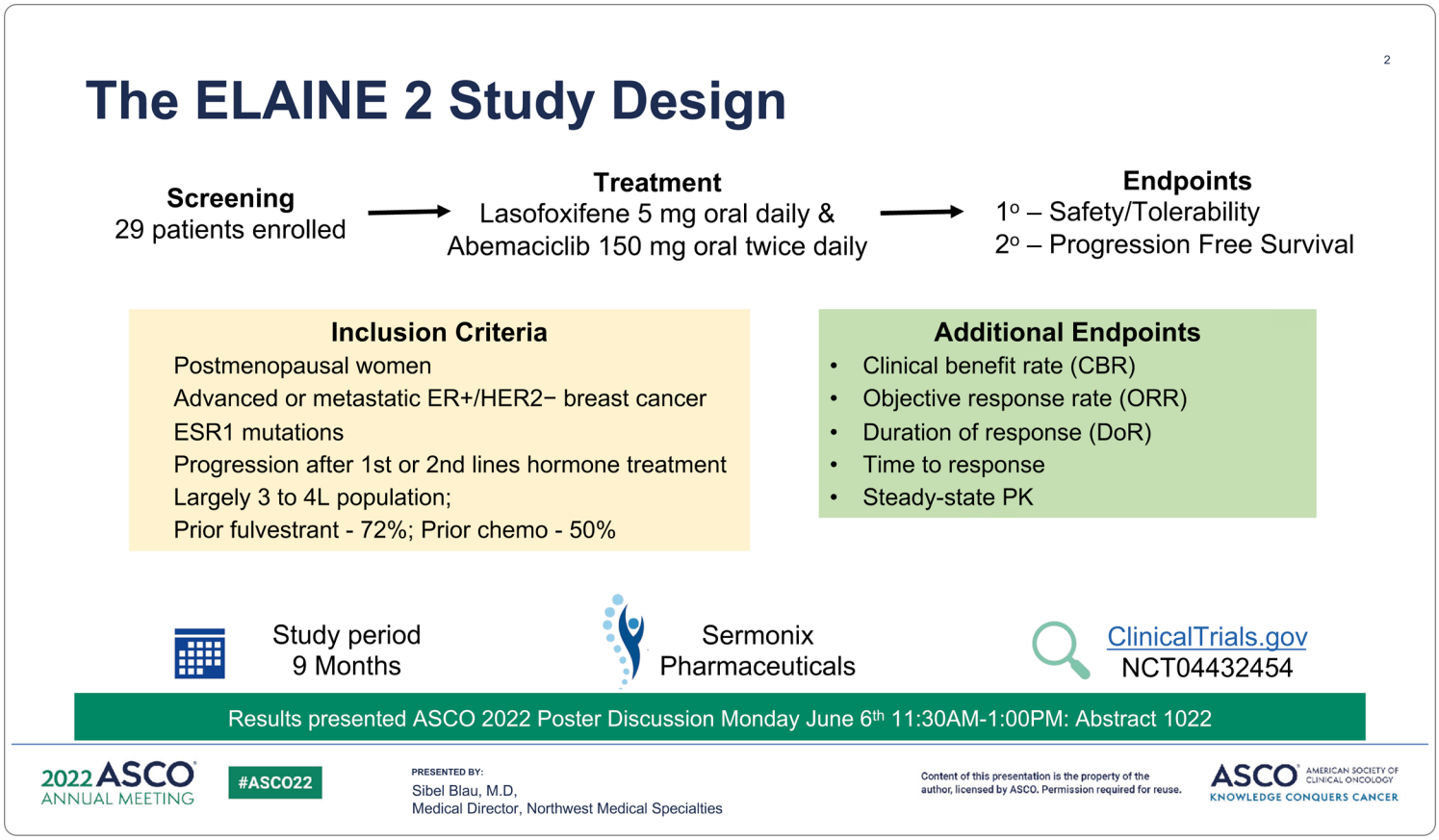
VP, Therapeutic Development, Tempus

In the spring 2022, Sibel Blau, MD, President and CEO of the Quality Cancer Care Alliance Network and medical Director of Northwest Medical Specialties, worked with Matthew Cooney, MD, Vice President of Therapeutic Development at Tempus, to share how Sermonix Pharmaceuticals used a traditional patient recruitment approach with Tempus' clinical research network, called the Tempus TIME Trial Program®, to meet Sermonix's accrual goal for a phase 2 interventional study faster than anticipated.

ELAINE 2 (NCT04432454) included 29 patients with previously treated metastatic breast cancer with ER+/HER2- with acquired ESR1 mutation who were treated with Lasofoxifene 5 mg daily and Abemaciclib 150 mg twice daily.

Dr. Blau presented this work at the 2022 ASCO Annual Meeting. In case you missed it, we are summarizing what you need to know below.



Twenty-nine participants enrolled in the ELAINE 2 study. The study's inclusion criteria were:

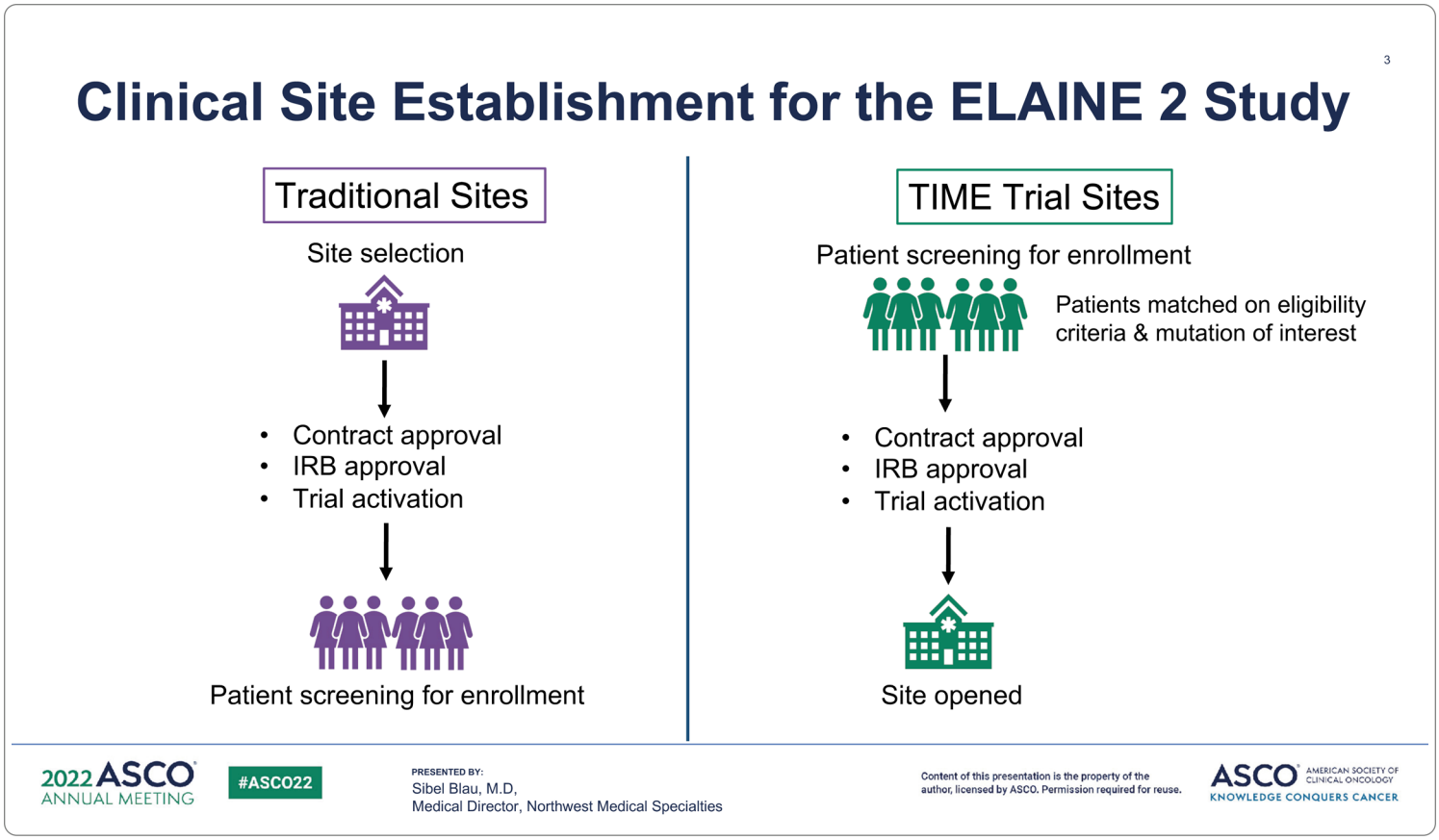
- Postmenopausal women with advanced or metastatic ER+/HER2- breast cancer
- ESR1 mutation and progression after first- or 2nd-line hormonal treatment
- Primarily third- to fourth-line patient populations

The patients' prior treatment:

- > 70% received a hormone therapy (fulvestrant)
- 50% of patients had prior chemotherapy before fulvestrant

The study's primary endpoints were safety and tolerability. Its secondary endpoint included progression-free survival.

We invite you to review the full clinical trial data.



There were two different operational models for the ELAINE 2 study.

The first is the traditional academic medical center model. In this paradigm:

- A hospital or physician is first selected to participate in the study.
- Then, the prospective clinical trials team must successfully complete an extensive process of contractual approval, IRB approval, and trial activation.
- Patients are then screened for enrollment, generally only after the trial is open.

The second model is the Tempus TIME Trial Program. Tempus identifies patients across hundreds of U.S. hospitals for clinical trials. As a result, Tempus can activate a new site for a patient in less than 14 days.

Participating Sites – TIME Trial & Traditional

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Mayo Clinic Jacksonville, FL
Mayo Clinic Rochester, MN
Ohio State University, OH
MD Anderson Cancer Center, TX
Cleveland Clinic, OH
University of Alabama Birmingham, AL
Northwest Medical Specialties, WA
Oncology Consultants, TX
St. Joseph Health Medical Group, CA
Mary Crowley Cancer Research, TX
Illinois Cancer Care, IL
Yuma Regional Medical Center, AZ
Beacon Medical Group, IN
Compassionate Cancer Care Medical Group, CA
New Jersey Cancer Care and Blood Disorders, NJ
Hematology Oncology Associates of Fredericksburg, MD

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In ELAINE 2, TIME Trial sites were community-based oncology practices and the traditional approach was academic medical centers.

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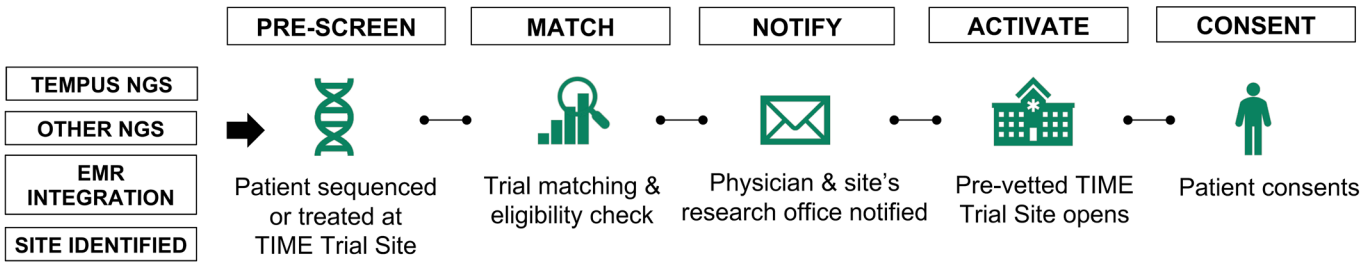
TIME Trial Operational Model



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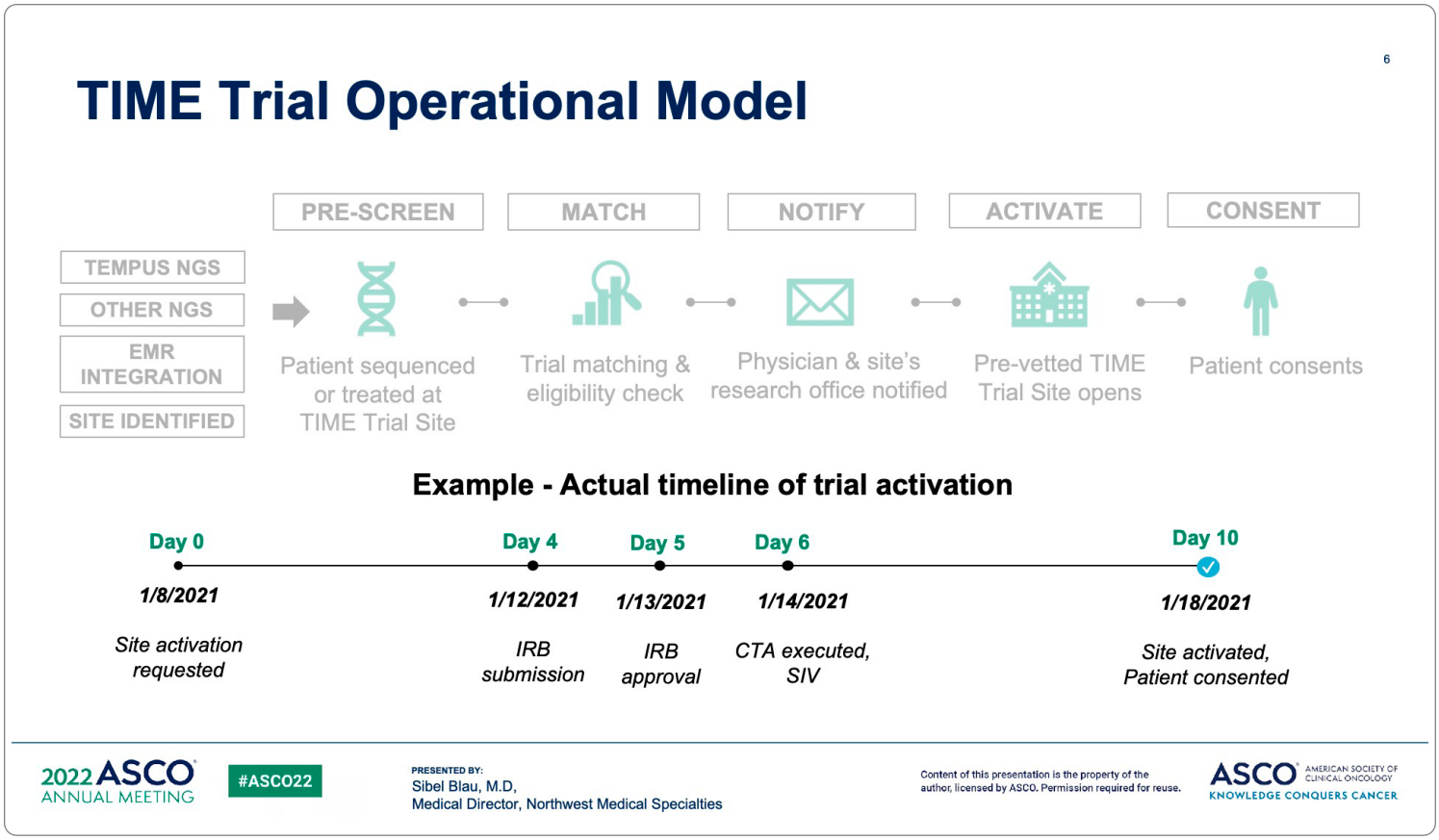
The TIME Trial Program is designed to achieve appropriate patient matching and rapid site activation. The program has four key components:

- Cancer patients are sequenced by Tempus or other labs and clinical data is abstracted.
- Tempus initially matches patients' clinical and molecular data to a trial's I/E criteria.
- Tempus notifies a TIME Trial site of a patient's match to a trial, so the patient can be further evaluated.
- After eligibility is confirmed, the patient is enrolled into trial at a TIME Trial site.



One example of ELAINE 2 trial activation, included a TIME Trial site opening within 10 business days:

- **Day 0:** Tempus requested a practice to activate its site.
- **Day 4:** Tempus submitted the IRB.
- **Day 5:** The IRB was approved.
- **Day 6:** The site initiation visit occurred.
- **Day 10:** Tempus activated the site, and the site enrolled the first patient.

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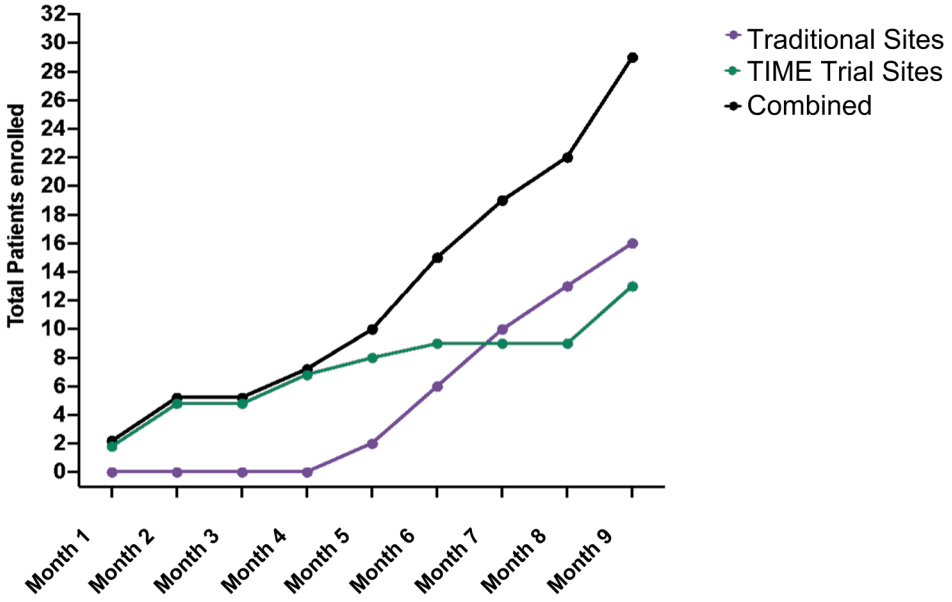
The ELAINE 2 Study Total Patient Enrollment



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TIME Trial sites opened four months earlier and enrolled the first seven patients prior to any Traditional sites.

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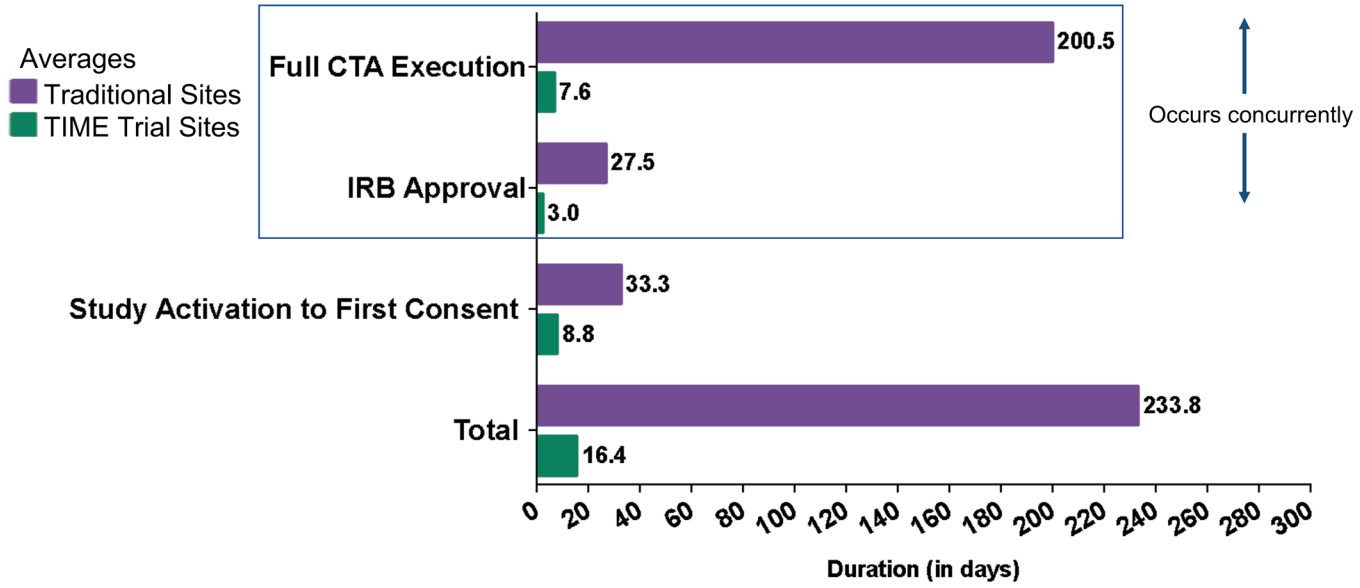
The ELAINE 2 Site Activation Timeline to First Consent



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The site activation timeline through the first patient consent was 16 days for the TIME Trial Program, compared to 234 days for the traditional approach.

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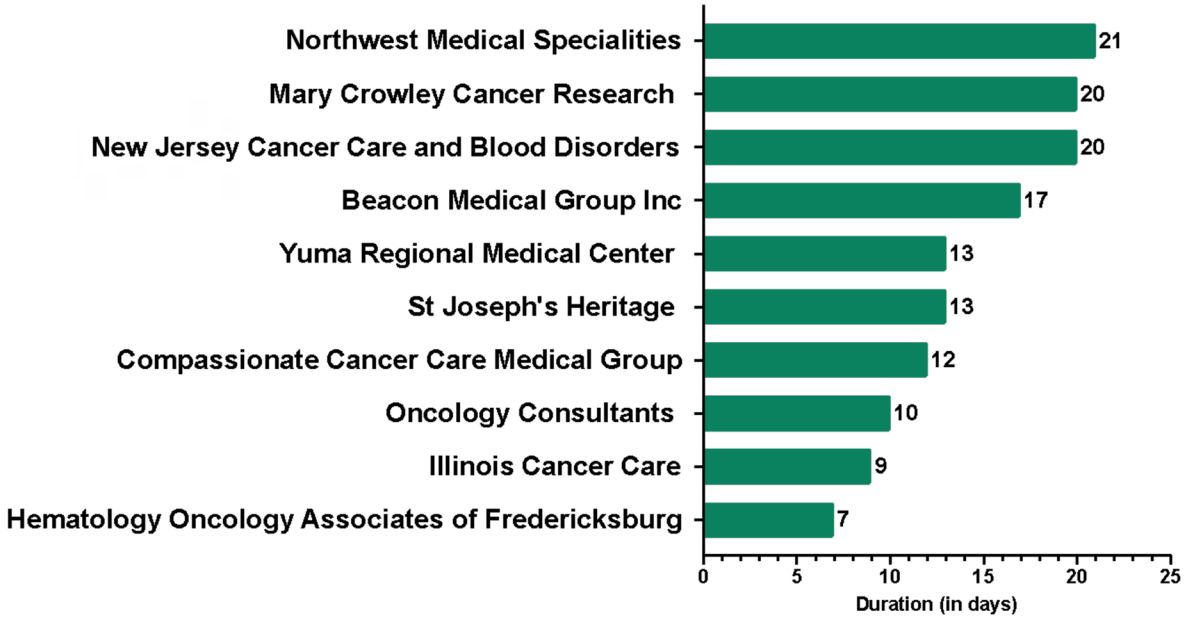
Activation Duration For The TIME Trial Sites



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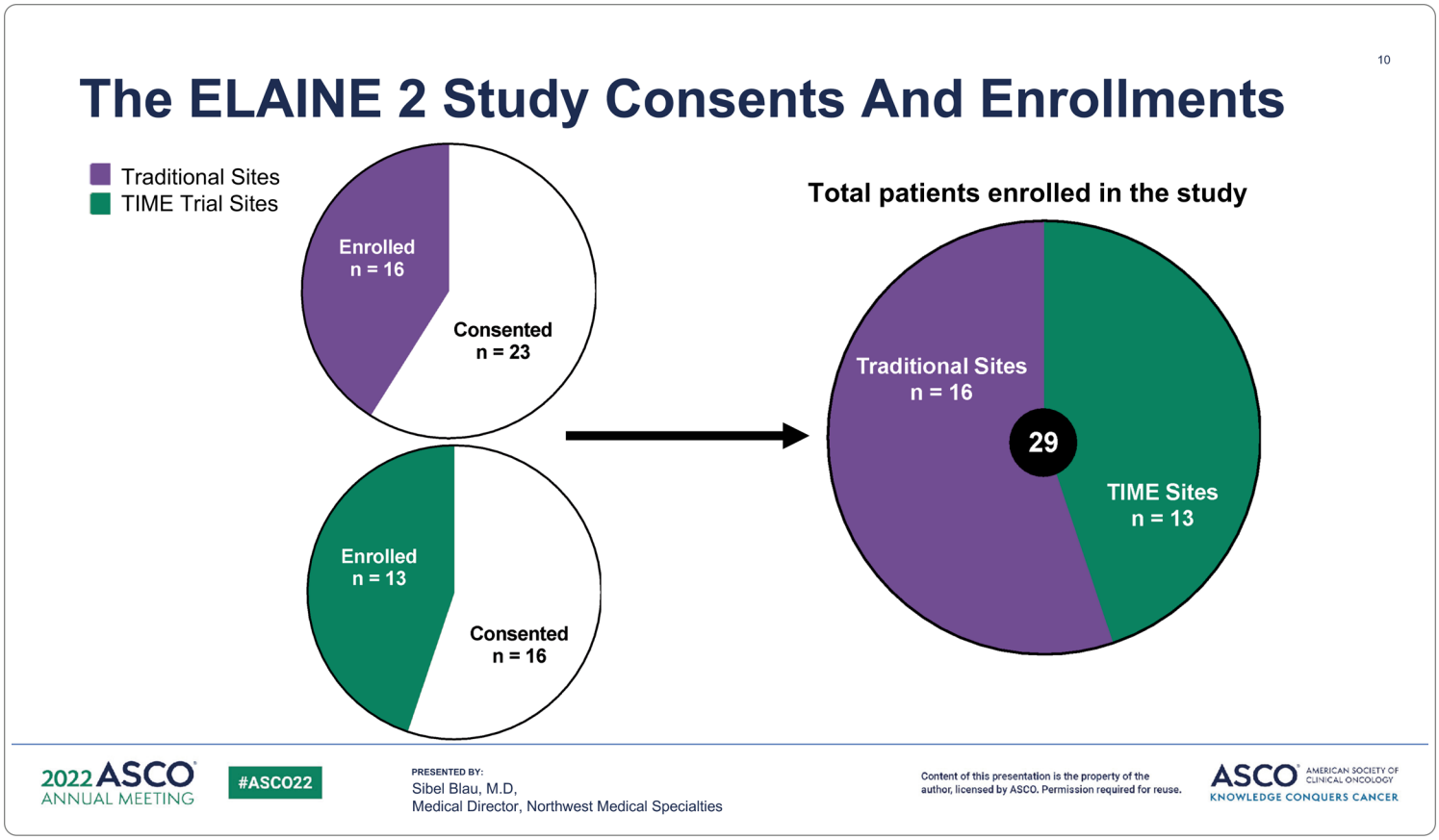
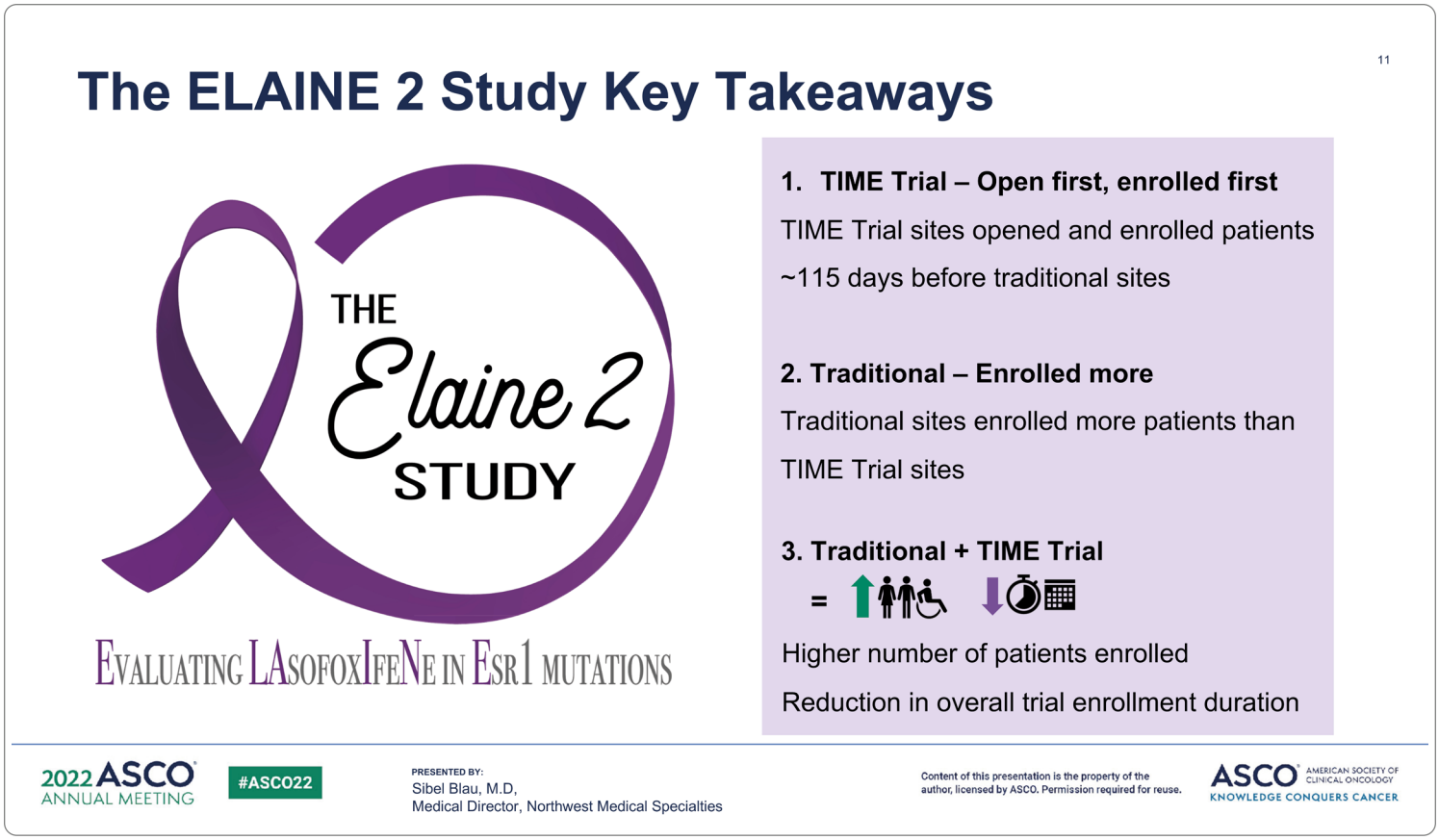
It took 7 to 21 days to activate each TIME Trial site.



The number of patient consents were similar between the traditional academic medical center approach and the TIME Trial Program (23 vs.16 patients consented; 16 vs.13 patients enrolled).



Key takeaways from this ELAINE 2 study:

- TIME Trial sites opened and enrolled patients earlier.
- Both recruitment approaches enabled the clinical research sponsor to meet its accrual goal faster than anticipated.

Contact Tempus to discuss this important approach to patient recruitment with one of our clinical research experts.

Tempus is grateful to the team that led and contributed to this important clinical research.

Acknowledgements

Traditional Sites

- Halle Moore, MD (Cleveland Clinic)
- Mathew Cherian, MD (Ohio State University)
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- Senthil Damodaran, MD (MDACC)

TIME Trial Sites

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Acknowledgements – TIME Trial & Traditional Sites

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MD Anderson Cancer Center, TX
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Northwest Medical Specialties, WA
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