

BACKGROUND

The vast majority of clinical research documents are rarely read meticulously by the primary investigators. With typical protocols between 90 to 120 pages in length, many investigators utilize abridged, summarized versions of protocols far more often than the protocols themselves. The usage of protocol summaries often results in different interpretations of treatment interventions, procedures and appropriate patients to be enrolled on the clinical trial:

- Only 3-5% of new cancer pts participate in clinical trials
- Most trials do not meet their projected accrual timelines
- Enrollment challenges delay more than 70% of clinical trials from one to six months in the United States¹

In response, industry and government sponsors move their clinical trials to less developed countries

- The number of countries serving as trial sites outside the United States more than doubled in the past 10 years
- The number of investigators based outside the United States has grown by 15% annually, while the number of US-based investigators has declined by 5.5%²

Patient enrollment challenges in the US

- 60% of newly diagnosed cancer patients are not informed about clinical trials as a treatment option¹
 - » Increased standard treatment options available
- Patients concern about participation in research trials
 - » Fear of randomization to placebo
- Practice concerns about increased investment in time and resources to open and maintain clinical trials at the site level

Barriers to accrual^{3,4}

Site-specific barriers to accrual

- Perception of protocol unavailability
- Actual protocol unavailability
- Protocols competing for similar pt population

Protocol-specific barriers to accrual

- Perception of pt ineligibility
- Complex inclusion/exclusion criteria
- Cumbersome screening process

OBJECTIVE

Investigators (and sub-investigators) are the most important driver for patient accrual to oncology clinical trials. DAVA created and implemented investigator-focused Accrual Workshops to increase protocol awareness and accelerate patient accrual through case-based learning.

ANALYSIS, RECRUITMENT, EXECUTION



METHODS

Analysis

- Detailed site analysis to identify the research personnel to include PIs, Sub-Is, Research Coordinators & Nurses
- DAVA uncovers the accrual potential at each site and identifies the most involved investigators

Recruitment

- A DAVA Medical Oncologist personally invites each identified member of the research staff to the Accrual Workshops
- A DAVA Medical Oncologist discusses the trial protocol & asks each site to bring two relevant case studies to be shared at the workshop as well as a detailed site overview

Execution

- Accrual Workshop content is created to include a treatment landscape, unmet clinical needs, protocol outline, inclusion/exclusion criteria, management of adverse events, case studies, & accrual goals
- A DAVA Medical Oncologist moderates each workshop and engages the research staff to uncover accrual challenges & develop solutions designed to identify the appropriate patient and increase enrollment

Figure 1. Case-Based Learning - Case Study Example

RESULTS

We evaluated the impact of 15 Accrual Workshops designed to increase enrollment to four different clinical trials:

- Impact was evaluated by comparing the patients enrolled 120 days before and after the workshop by investigators who attended the meeting
- Overall accrual increased 112% from 91 patients to 193 patients
- Accrual Workshops had a positive impact on each of the four clinical trials

Table 1. Tumor Specific Accrual Workshops

	Tumor Type	Number of Workshops
TRIAL #1	Sarcoma	6
TRIAL #2	Non-Hodgkins Lymphoma	4
TRIAL #3	Melanoma	1
TRIAL #4	Colorectal	4
Total		15

Figure 2. Overall Impact of Fifteen Accrual Workshops

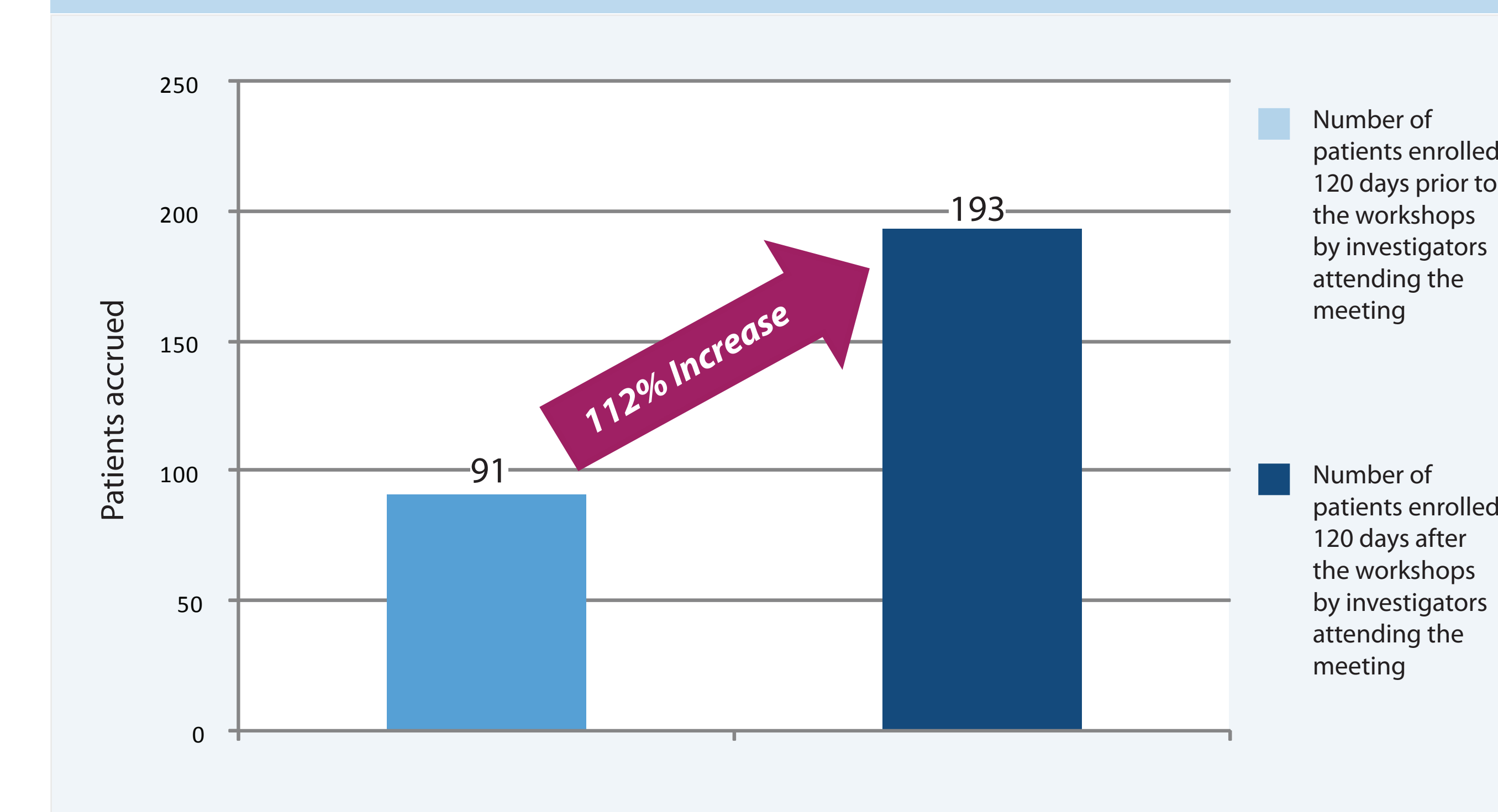
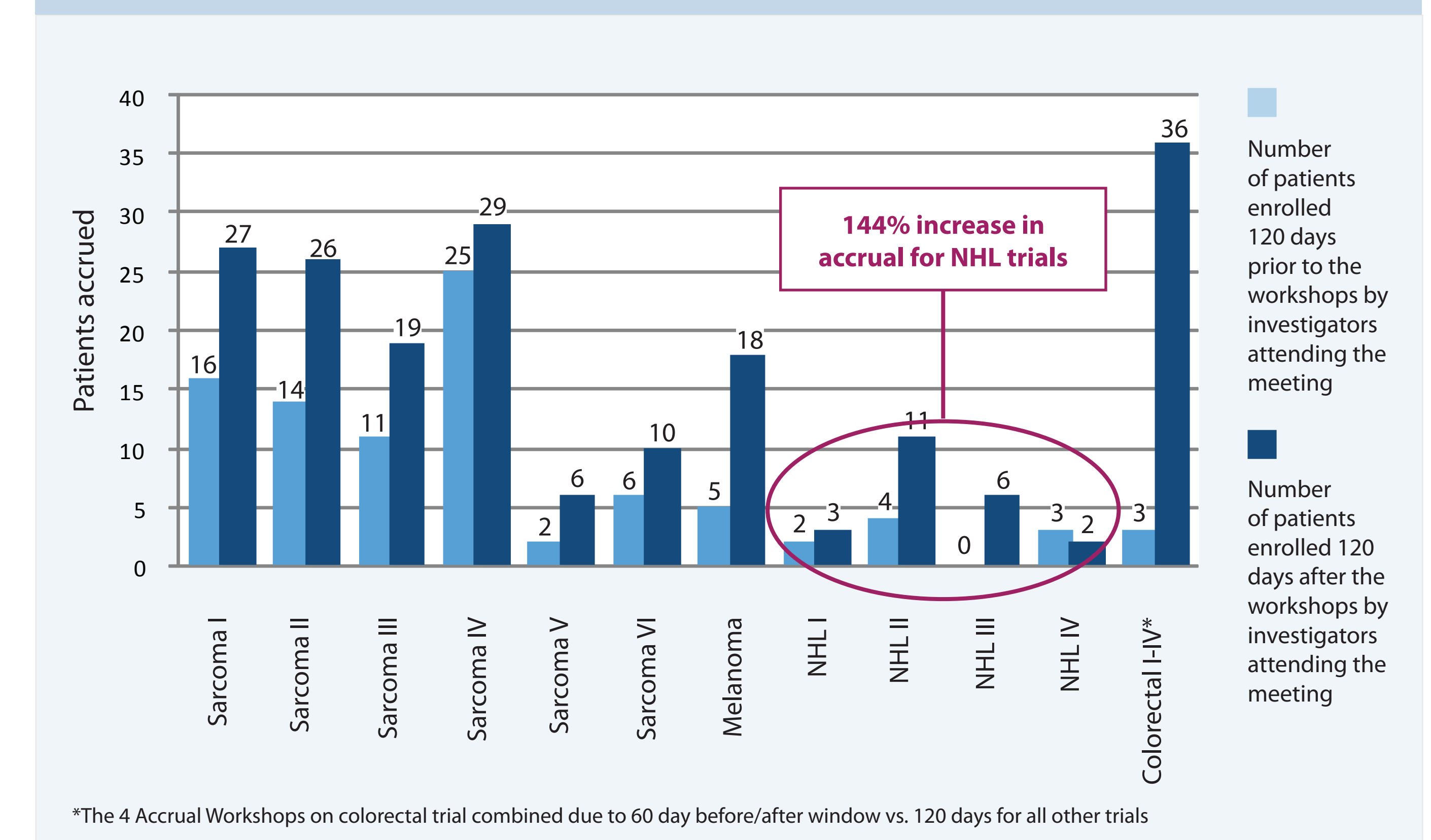


Figure 3. Individual Impact of Accrual Workshops



- 14 out of 15 Accrual Workshops (93%) had a significant impact on accrual ranging from 16% to 1100%
- Overall accrual to the Non-Hodgkin's Lymphoma Accrual Workshops increased by 144% from 9 patients to 22 patients

CONCLUSIONS

- Accrual workshops have a significant impact on accelerating enrollment to oncology clinical trials
- Physician to physician case based learning reinforces the inclusion & exclusion criteria for each clinical trial and is an effective patient identification strategy to increase accrual

SUMMARY

- Oncology clinical trial protocols are complicated and rarely read meticulously by the investigator and research staff
- US accrual to oncology clinical trials lags behind the rest of the world
- Accrual Workshops are a successful tool designed to simplify the protocol, identify eligible patients, and accelerate enrollment

References

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