



Driving Trial Success

The Growing Need for Optimal Site Support

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Clinical Trial Liaison



Outline

- **Trends**
- **Site Support Philosophy**
- **Site Support Model**
 - **Goals**
 - **The People**
 - **Strategy & Implementation**
 - **Impact**
- **Summary**



As we start...

Keep things in perspective:

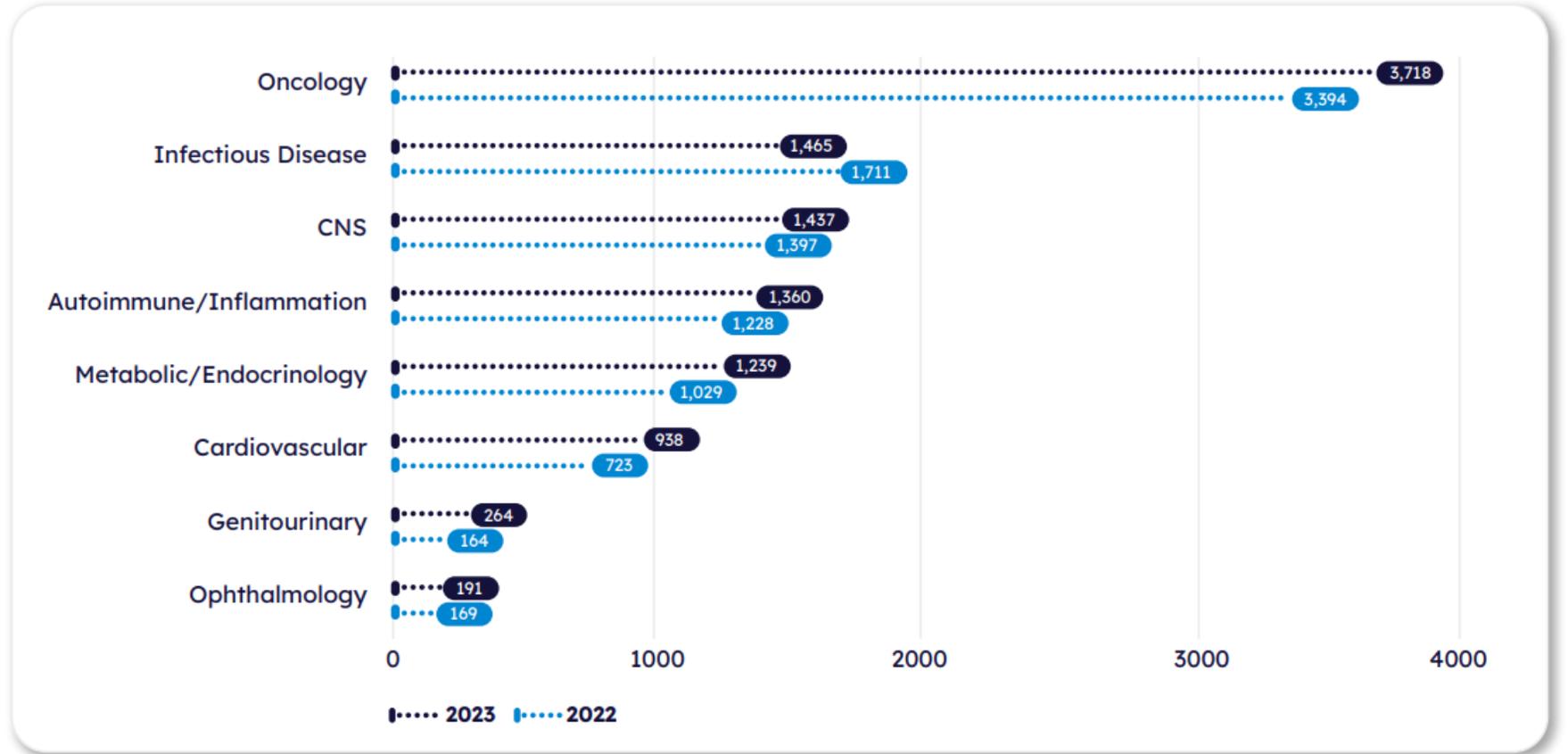
- ❖ **On the patient/family**
- ❖ **On the staff delivering care**



Clinical Trial Landscape

Phase I-III clinical trial initiations by therapeutic area¹

In 2023, oncology remained the lead therapeutic area by far, posting an increase of 9.5% from 2022. All therapeutic areas showed growth except for infectious disease, which declined 14%.



¹Trials that include multiple indications across different TAs will be counted for each targeted TA. As such, the sum of trial counts for the eight TAs will be higher than the total number of Phase I-III trials started in 2023. Trial counts for ID include activity from vaccines (infectious diseases), which is a separate TA module within Trialtrove. For the purposes of this analysis, all ID activity has been combined into a single TA.

Recognizing the need for site support....

Barriers to clinical trials:

- Site infrastructure
- Staffing/turnover
- Time
- Structural
- Clinical
- Clinician attitudes
- Patient attitudes

The New Site Management: PSI's Philosophy

Site Support

- Positive site relationships
- Unified approach with CRA and Site Support Team
- A true site tailored approach is key
- Tool and guidance development
- Leverage local grassroots opportunities
- Priority on understanding each sites needs

Patient Support

- Leveraging relationships with patient advocates
- Focused and meaningful patient education materials
- An emphasis on optimized study operations to ease patient burden
- Patient facing materials
- Patient liaisons for payments, accommodations, etc.
- Every patient counts

A Strategic Focus

- PSI's next gen site management model
- Abandon the "one size fits all" approach
- Dedication to understanding site and patient needs
- Tailored service development
- Understanding population nuances



What Are Our Goals?

Idea is to remain focused on small scale actions that serve a large purpose and create an impact

- **Improve/shorten site activation**
 - Early engagement with clinical and technical teams during startup
 - Address knowledge gaps for technology qualifications
- **Additional support for sites and project team**
 - Provide SME's to our project teams to guide them in indication/drug specific considerations
 - Increase support to improve project team retention so your team isn't a revolving door
- **Improve data quality, query turnaround times, technology upload compliance**

What Are Our Goals?

- **Boost enrollment**
 - Site tailored enrollment planning to optimize patients to study
 - Better understanding of patient populations and clinical pathway
- **Improve relationships with investigators and site staff**
 - Providing a means for more peer-to-peer interactions between our team and key site stakeholders
 - Especially in highly technical areas (nucmed/imaging, lab, etc.)
- **Laser focus on key study drivers that are often not addressed proportionally**
 - Important not to duplicate tasks or communications
- **Cultivate a more proactive anticipation of site needs**

Relationships with Sites – CRA as Trusted Advisor

Excellent oncology and soft skills training = fully qualified CRAs

One CRA as key contact for site = full support with all questions throughout the lifecycle of the study

Study specific support network for CRAs = Lead CRA, Regional Lead and Site Support Team

Knowledgeable CRA = appropriate support to sites with materials and customized tips

CRAs advocate for sites = building site trust

Our CRAs are Site Managers



Our CRAs are Study Ambassadors

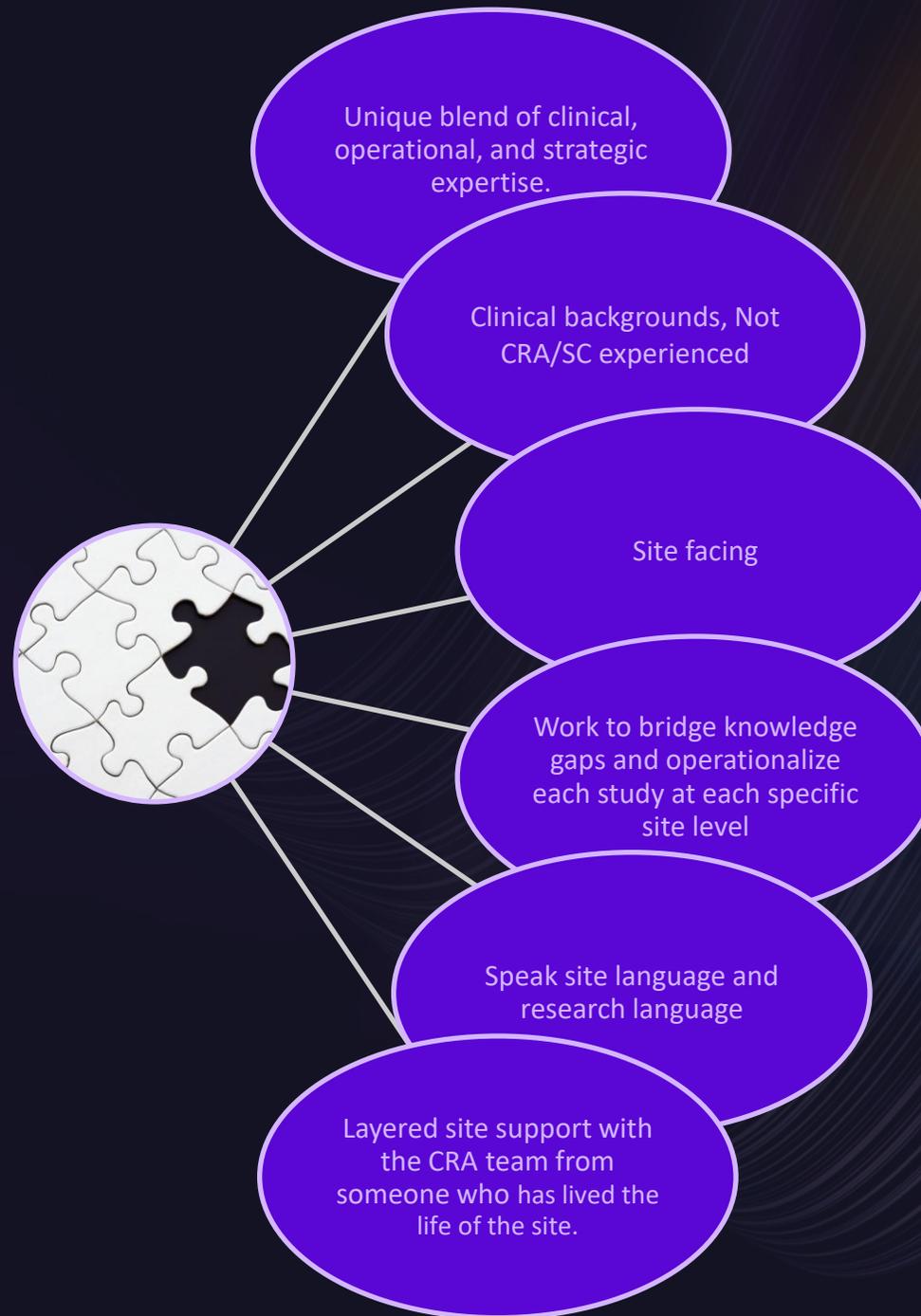
Manageable workload = regular remote follow-up in between visits

One PA per country = admin support with site file and timely eTMF filing

Deep working knowledge of protocol

Happy CRAs = high retention rate

CTL Team





Tailored Clinical Trial Liaison Support

Site ID/Selection

- Join regional start up calls
- Identify sites nearing SSV*
- Meet with PM team to define the needs of the CTL role (broad vs. QTL triggered approach) – this may vary by study and even by site*

Site Start-Up: After SSV

- Role is introduced to the site – work with site to understand site enrollment process, site needs, anticipated study issues – via site email/meeting or work with CRA at SSV*
- Draft site-specific enrollment plan and file in CTMS - Coordinate with the CRA*

Site Activation & Enrollment

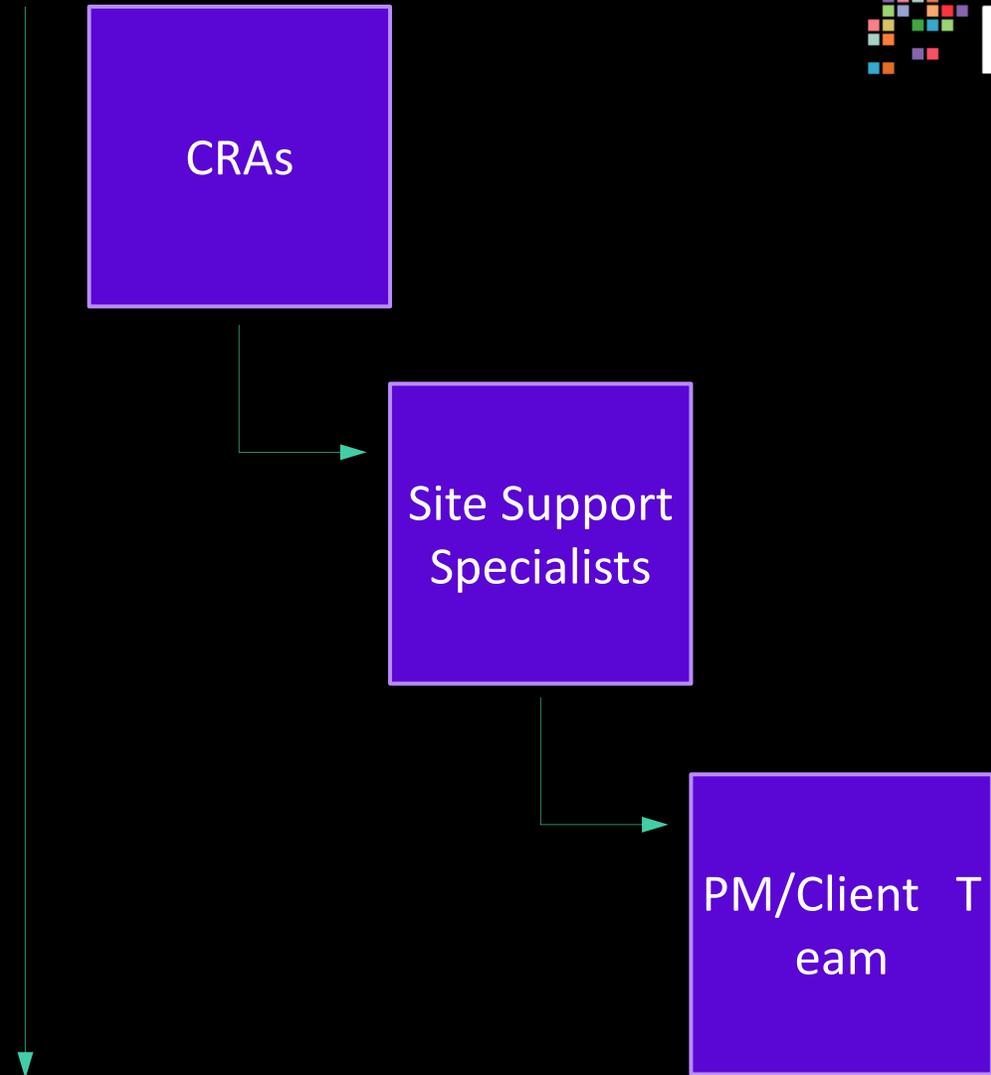
- Meet with CRA/site
- Transition enrollment support to a broad approach or triggered approach
- Follow along with enrollment and milestones

Other Common CTL Activities

- I/E criteria questions
- Deep dive site assessments
- Attend IM/SC meetings
- Present for internal/Sponsor calls as needed
- Development of pathway, worksheets, pocket cards, any materials needed by the site to support enrollment
- Technical help: camera qualification, labs, dosimetry, imaging, etc.
- Therapeutic education/refresh for CRA's, PM Team
- IP Administration Training

Communication is Key

- Increase site engagement around patient enrollment
- Encourage and streamline CRA, SSS, PSI MM and client communication
- Decrease duplicate efforts around site outreach
- Standardize documentation of site outreach
- Maintain consistency with existing plans; study monitoring plan





Case Studies

Phase 3 Breast Study

- **Challenges:**

- Slow recruitment
- Nuanced and many I/E criteria
- High screen fail rate

- **Solutions:**

- Tool development
- Re-education
- Increased CRA collaboration/training

- **Outcomes:**

- SF rate coming down
- Increased recruitment
- Increased site knowledge



Case Studies

Phase 3 Ovarian Study

- **Challenges:**

- Slow initial recruitment
- Complicated I/E criteria
- Complex IP administration

- **Solutions:**

- Deep dive calls
- Tool development
- IP training

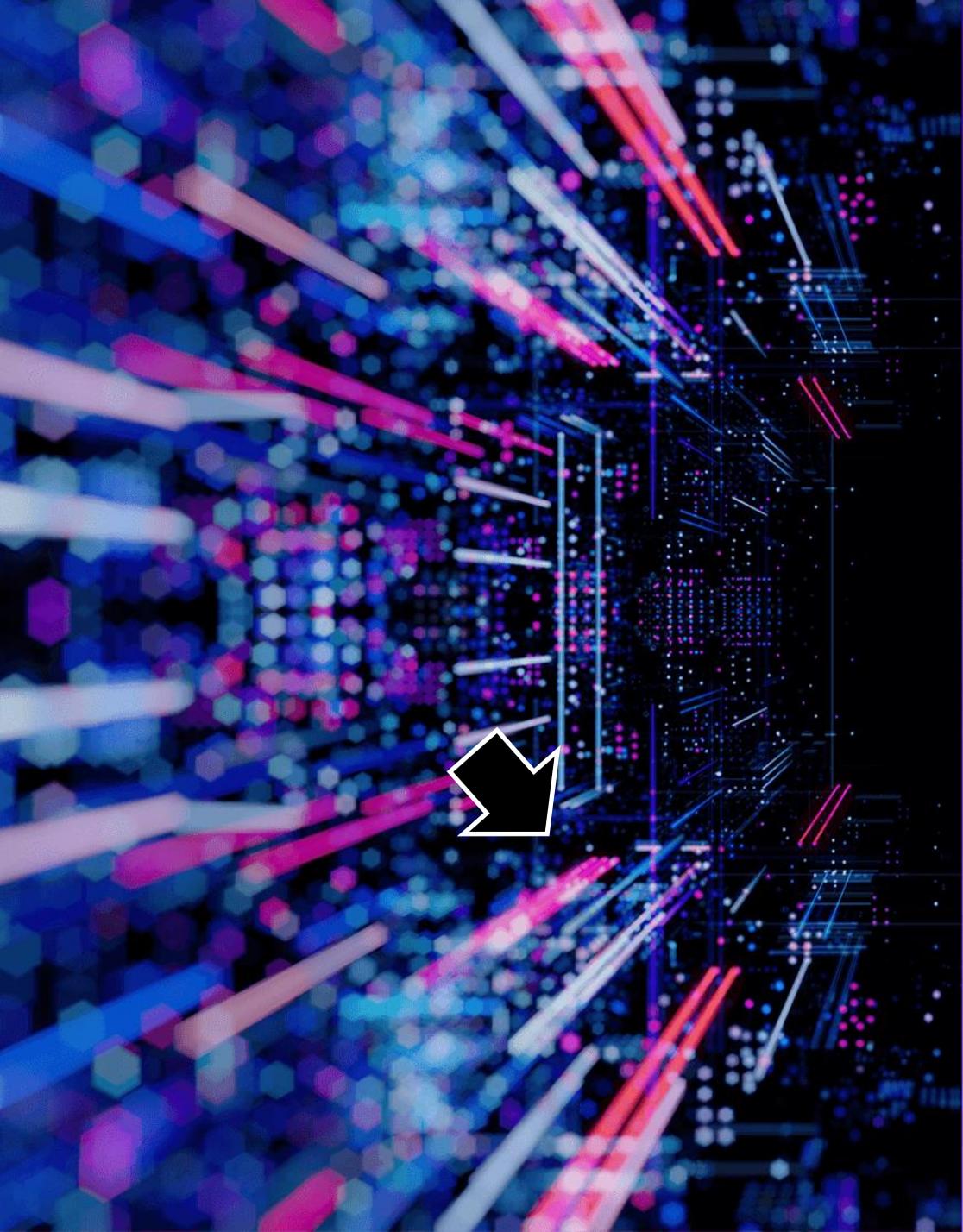
- **Outcomes:**

- Site satisfaction
- Increased enrollment
- Increased site comfort level



Closing Thoughts

- Research is evolving, and we need to evolve with it
 - Innovative solutions for these innovation problems
- Novel drug classes pose nuanced challenges to operationalizing clinical development
 - The need for functional area expertise is more present than ever
- Patients should not experience the burden of a complex study
 - Better supported sites = better supported patients, and every patient counts



Thank you!

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