CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Meaningful Approaches to Patient Engagement:

Adding the Right Tools to Your Toolbox

Annick Anderson, Director, Research Services
Jill McNair, Senior Director, Patient Engagement

Welcome!

- Introduction
- Trends in patient engagement
- Importance of engaging patients as partners
- Maintaining patient engagement long term
- Driving culture change

- ***Patient Engagement Tools***:

  - Patient Advisory Boards
  - Patient Clinical Trial Journey Workshops
  - Communicating Trial Results Program

- Q&A

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

About CISCRP

- 15 year-old Boston-based independent nonprofit organization

MISSION:

- To educate, inform and engage patients and the public
- Promote greater awareness, understanding of and trust in clinical research participation and its role in public health
- Provide resources and services for the research community to better partner with study volunteers, patients and the public

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Trends in Patient Engagement

Increasing Protocol Complexity

Typical Phase III Pivotal Trial (means)	2001 - 2005	2011-2015
Total Number of **Endpoints**	7	13
Total Primary and Key Secondary Endpoints	4	5
Total Number of **Eligibility Criteria**	31	50
Total Number of **Procedures**	110	187
Total Number of Planned Volunteer **Visits**	12	15
Number of Investigative **Sites**	40	65
Number of **Countries***	5	10
Number of **Patients** Randomized	729	597
Total **Data Points** Collected**	494,236	929,203
Proportion of Data 'Non-Core'	18%	32%

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

*Source: Tufts CSDD ; *DRI; **Medidata Solutions*

Enrollment and Retention Challenges

50% fail to enroll a single patient or under enroll

average drop-out rate of **30%** across clinical trials

Source: Forte Research, 2016
Source: Tufts CSDD 2017

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

The Burden of Participation

Top Dislikes After Reviewing ICF

After reviewing ICF, what led you to decide NOT to participate?	% of Total *
Too many visits to study center	20%
Medical procedures too invasive	19%
Too many medical procedures	14%
It was too much of a burden on my family/caregiver	9%

Source: 2017 CISCRP P&I Study, n=337 those chose not to participate after reviewing ICF

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

The Burden of Participation

Top Dislikes During Participation

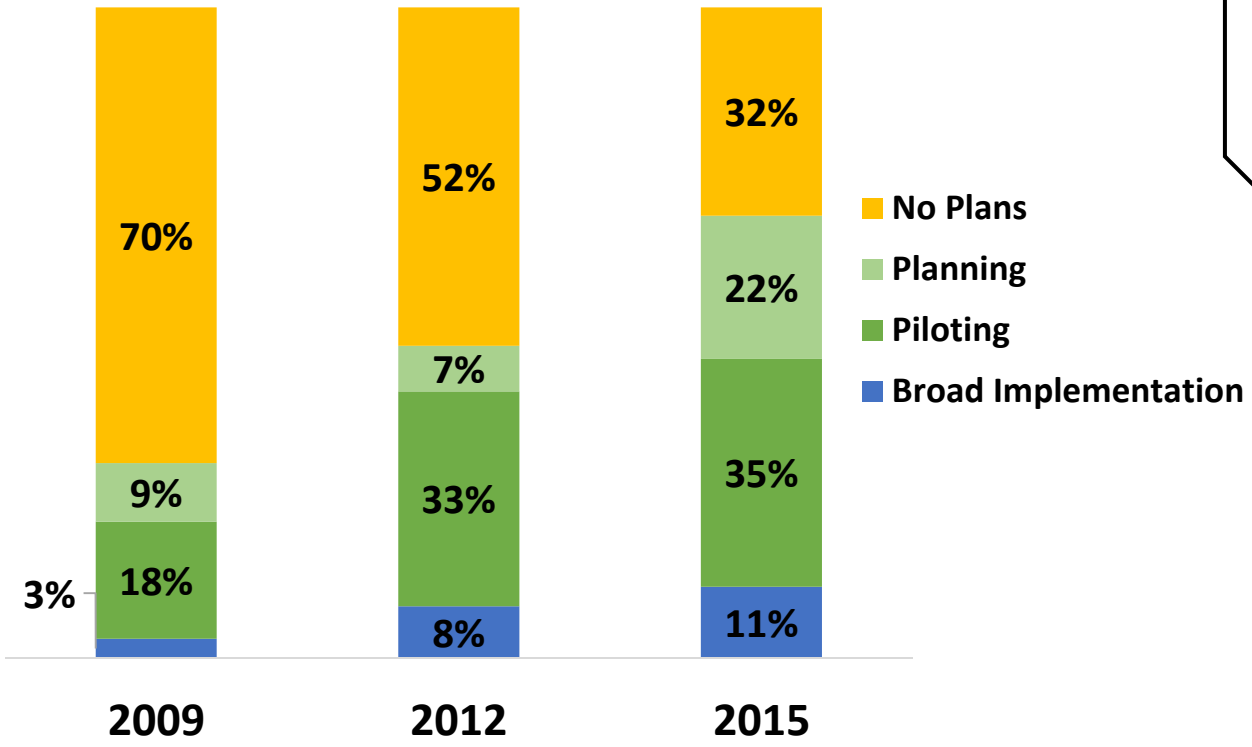
Top Dislikes during Participation	% of Total **
Possibility of getting placebo	24%
Location of study center	23%
Study visits too time-consuming	11%
Side effects of study drug	11%
Compensation was not enough	9%
Overall time commitment was too much	8%

Source: 2017 CISCRP P&I Study, n=2,194 those that participated in a clinical research study

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Adoption & Barriers

Plans to Implement Patient-Centric Initiatives



Primary Barriers

- Regulatory
- Operational
- Cultural
- Financial

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Source: CenterWatch N= 95 companies

Rationale for Patient Engagement

	Avoid One Amendment			Improve Convenience	
	Phase II	Phase III		Phase II	Phase III
ENPV Impact on $100,000 Invested	+$3.8 million	+$15.0 million		+$30.1 million	+$57.0 million

For engagement activities resulting in avoiding an amendment and/or an improved patient trial experience, the benefits in cost and ENPV vastly outweigh the resources spent on engagement

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Source: CTTI, 2017

And Patients Want to be Involved!

Activities Interested In (% mentioning)	TOTAL (n=12,427)	Participated (n=2,194)	Never Participated (n=10,233)
Being involved in the design and planning of a clinical research study	30%	35%	28%
Being part of an advisory committee helping companies plan clinical research activity	30%	37%	28%
Speaking with other patients considering participation in a clinical research study	37%	41%	36%

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Source: 2017 CISCRP P&I Study

The Patient Engagement Toolbox

Partnering Opportunities: The Toolbox

Study Planning	Study Start Up/Recruitment	Ongoing Study Conduct	Post-Study
✓ Unmet patient needs ✓ Relevant outcomes ✓ Study design ✓ Eligibility criteria	✓ Easing participation burden ✓ Recruitment & other patient materials ✓ Study medication administration ✓ Study updates/communication ✓ Assessing ongoing study experiences		✓ Communicating trial results ✓ Assessing study experiences ✓ Study volunteer appreciation

- Patient Advisory Boards
- Patient Clinical Trial Journey Workshops
- Study updates
- Communicating trial results
- Thank you cards
- *…and many other tools!*

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Tools for Patient Engagement

Patient Advisory Boards

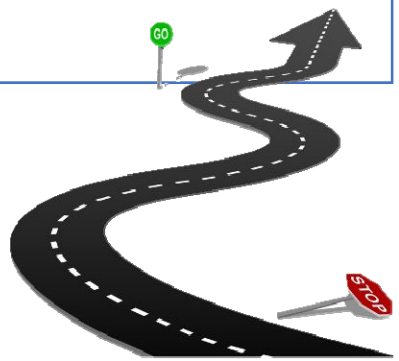
IDEAL FOR:

- ✓ Understanding challenges of condition and current treatments.
- ✓ Assessing perceptions of clinical trials and motivations to participate.
- ✓ Determining receptivity to clinical trial designs & related study materials.
- ✓ Identifying ways to enhance future study volunteer experiences.

Patient Journey Workshops

IDEAL FOR:

- ✓ Gaining a better understanding of patient clinical trial journeys from start to finish.
- ✓ Identifying TA-specific challenges and barriers during the journey.
- ✓ Building the ideal journey together with patients and optimizing future study volunteer experiences.



Patient Advisory Boards: Structure and Format

FORMAT:	Structured, facilitated in-person meeting *(single meeting or ongoing series)*
COMPOSITION:	6 to 8+ Patients / Caregivers
TIMING/LOCATION:	Half-day meeting in convenient metropolitan location

DISCUSSION TOPICS:

- ✓ Study design elements
- ✓ Informed Consent Form
- ✓ Branding and study positioning communication
- ✓ Patient recruitment promotional messages; other patient facing study materials
- ✓ Clinical trial medicine kit design and administration
- ✓ New technology solutions

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Clinical Trial Journey Workshops

Clinical Trial Journey Workshops provide deep insights into the patient clinical trial experience and highlight opportunities for improved patient engagement

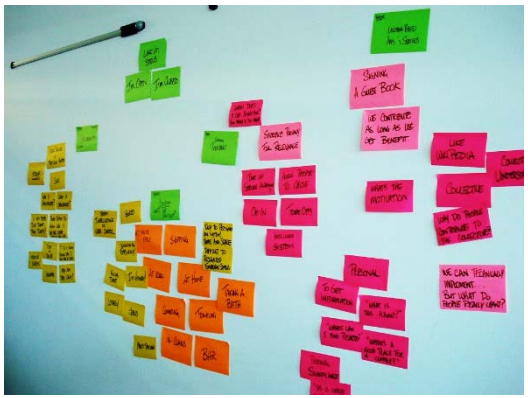
CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Patient Journey Workshops: Structure and Format

FORMAT:	Structured, facilitated in-person meeting *(add-on to Patient Advisory Board or stand-alone)*
COMPOSITION:	6 to 8+ Patients / Caregivers
TIMING/LOCATION:	Half-day meeting in convenient metropolitan location

DISCUSSION TOPICS:

- ✓ Learning about clinical trial
- ✓ Informed Consent process
- ✓ Screening Visit
- ✓ Treatment Period
- ✓ Study follow-up



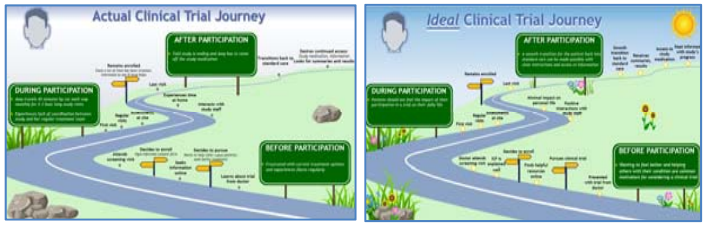
CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Clinical Trial Journey Workshops

PATIENT PROFILE

Custom patient profile to help team connect with patient and better understand needs

ACTUAL vs. IDEAL

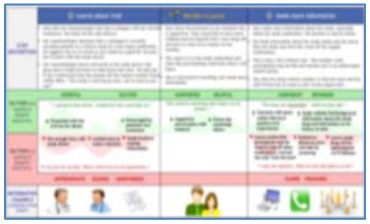


Patient's 'actual' clinical trial experience vs. desired 'ideal' experience to identify challenges and build solutions

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Clinical Trial Journey Workshops

KEY INSIGHTS, CONSIDERATIONS



Key insights highlight opportunity areas:

- ✓Motivators for participation
- ✓Enrollment barriers
- ✓Common communication channels
- ✓Trusted sources of information
- ✓Desired clinical trial information
- ✓*And more….*

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Sampling of Patient Recommendations

Protocols

- Frequency of Testing
  - Increase in monitoring assessments for aggressive condition
  - Decrease in painful diagnostic exams
- Schedule Burden
  - Home Visits
- Critical study-specific information to provide prospective study volunteers

Patient Materials

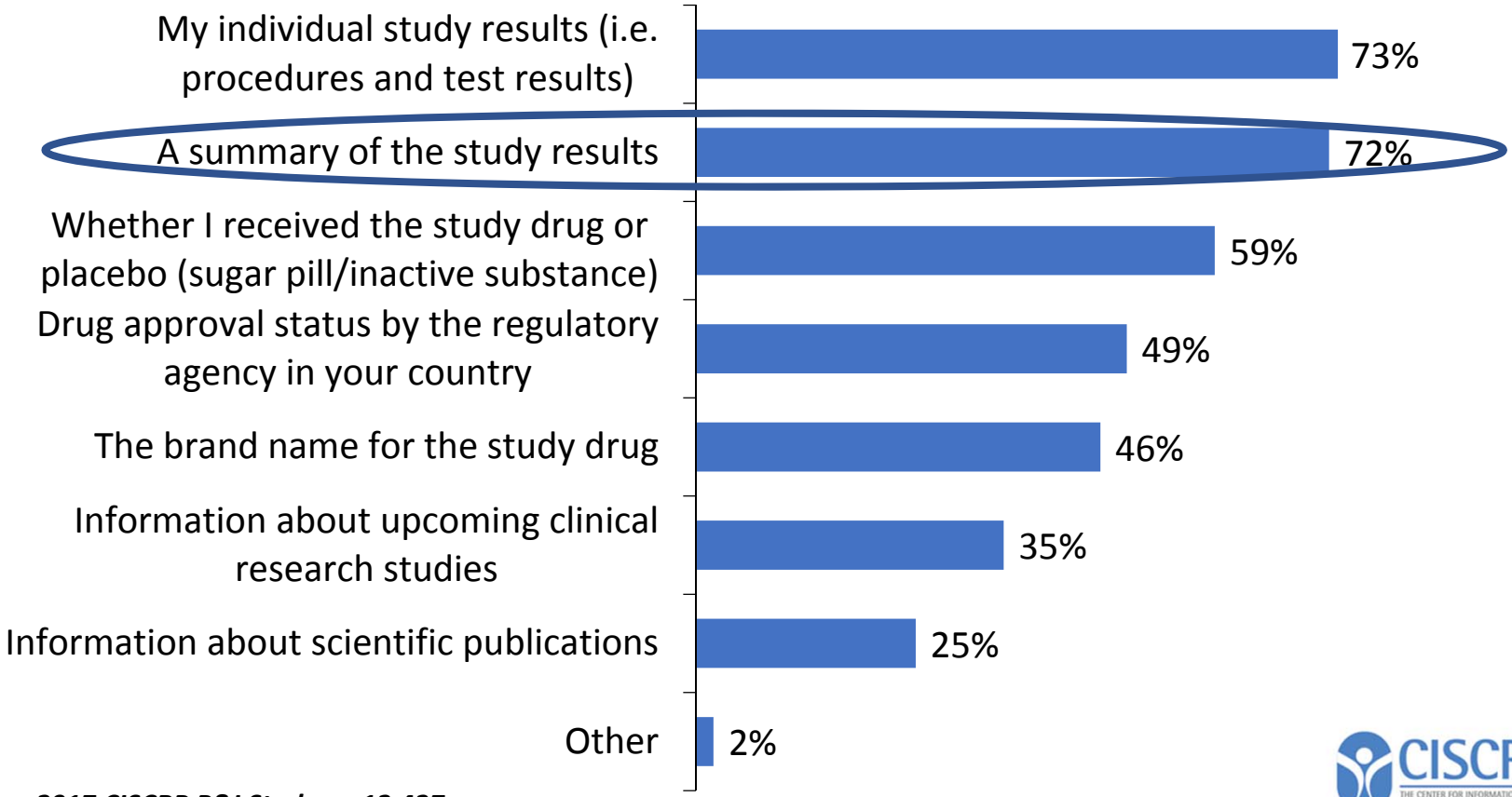
- Culturally appropriate wording & color schemes
- Relatable images for condition
- Addition of tables and search features
- Clarification of patient instructions
- Preference of styles and formats
- Preference for distribution of information

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Maintaining Patient Engagement

Patient Engagement – After Participation

Information Most Interested In Receiving After Participating in a Clinical Trial

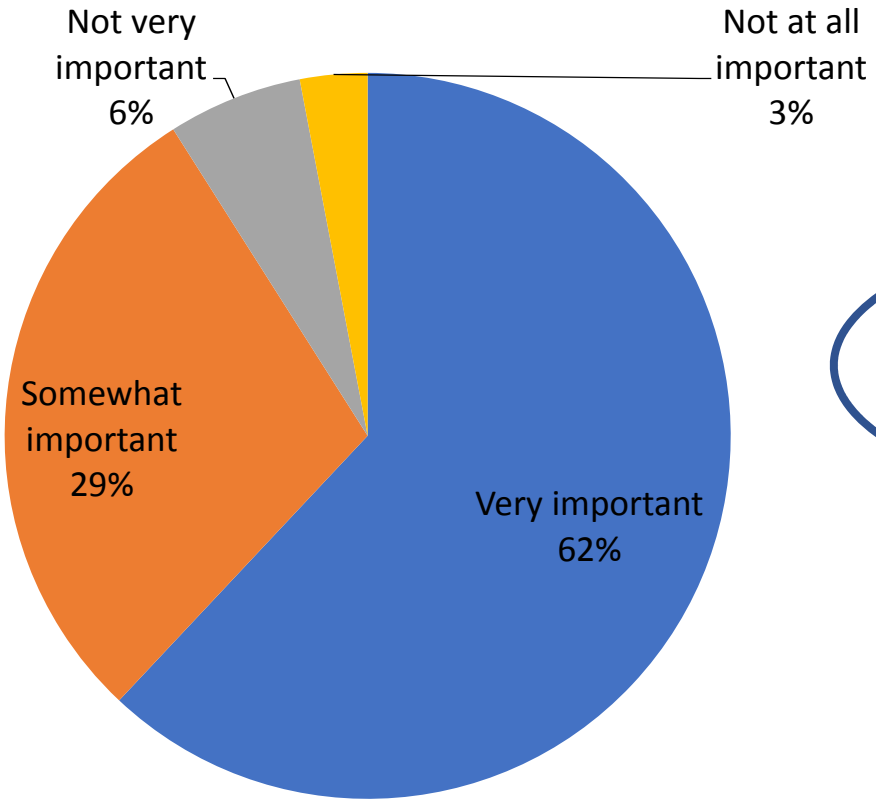


Source: 2017 CISCRP P&I Study, n=12,427

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Patient Engagement – After Participation

Importance of Receiving Trial Results Summaries



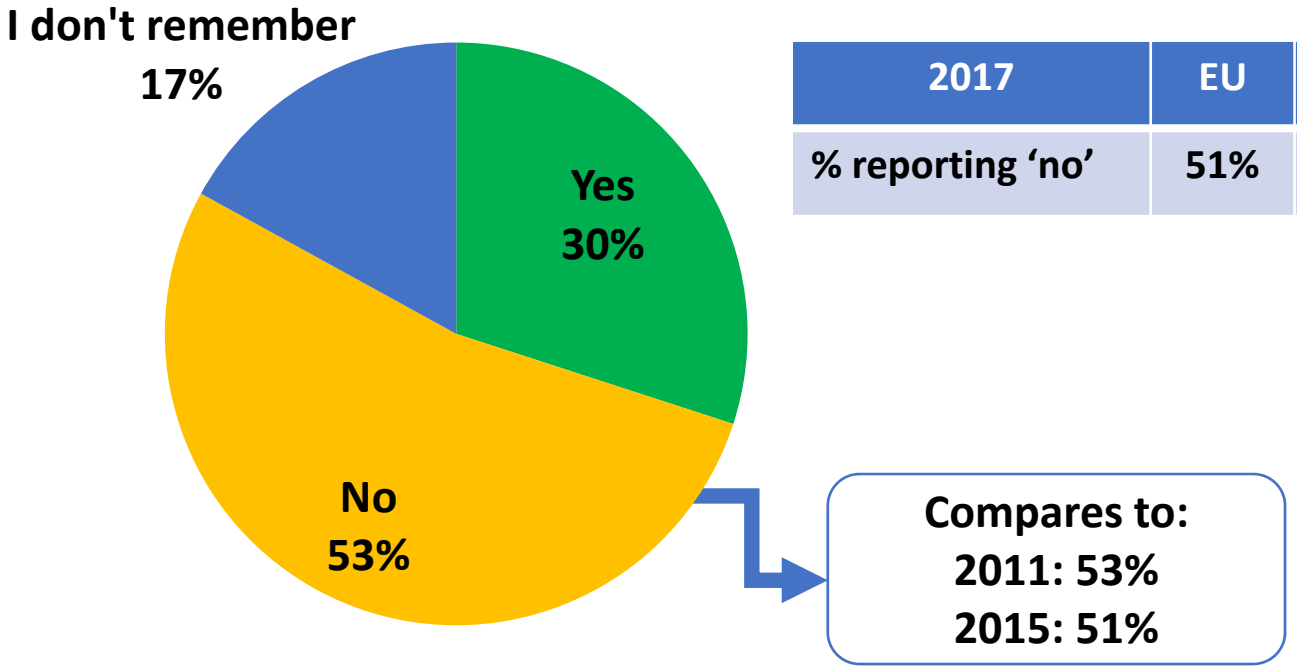
91% report somewhat or very important

Source: 2017 CISCRP P&I Study, n=12,427

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Patient Engagement After Participation

Did you receive any reports or updates on the results of the study once you finished the clinical research study?

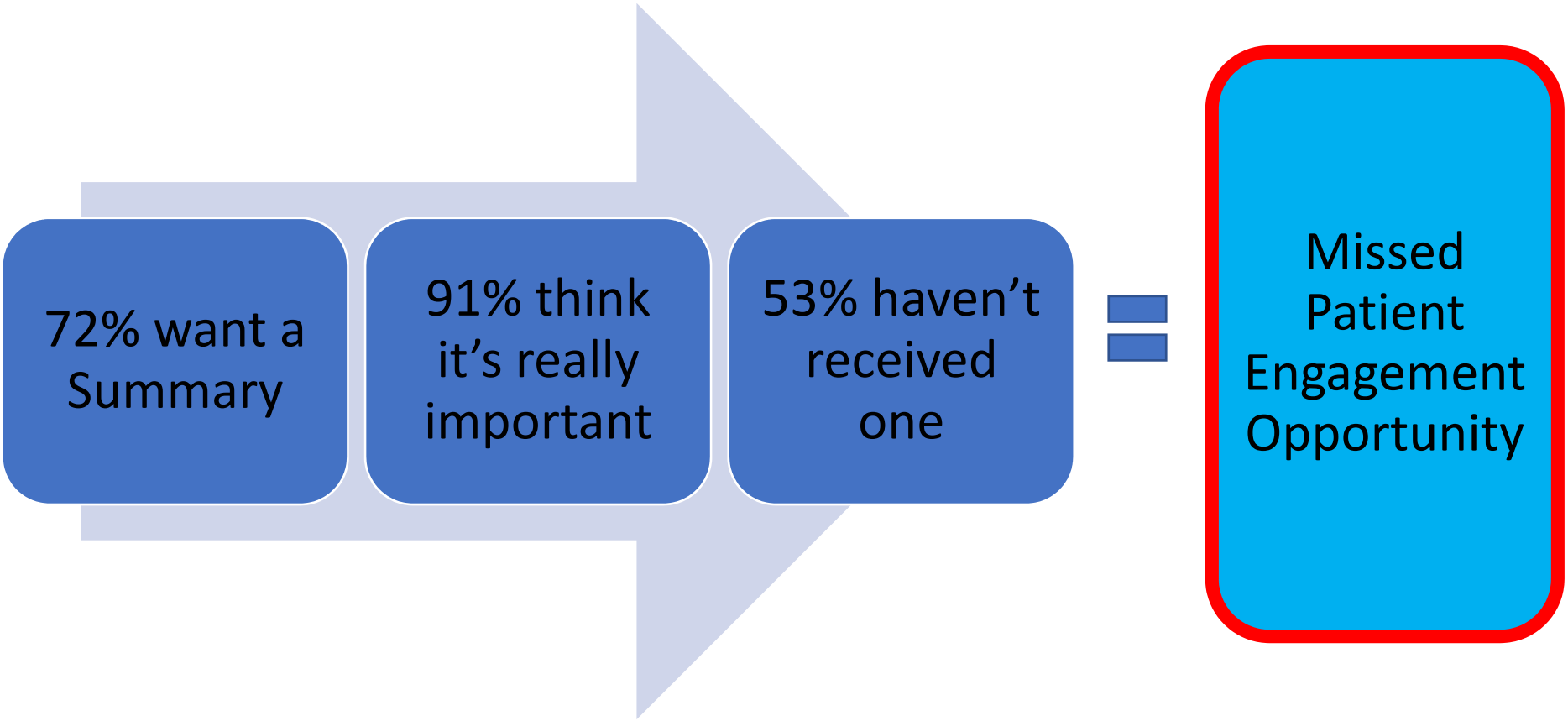


2017	EU	NA	SA	APAC
% reporting 'no'	51%	59%	25%	42%

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Source: CISCRP P&I 2017; n= 2,194 Participated

Unmet Need



Source: 2017 CISCRP P&I Study, n=12,427

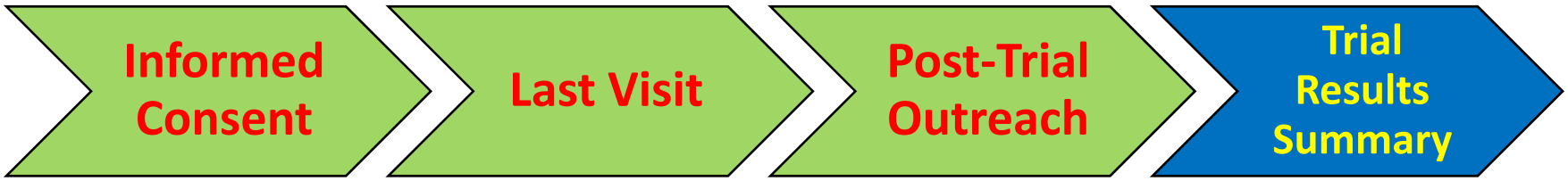
CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Lay Summaries: 5 Main Goals

1. Meet participant expectations
2. Demonstrate appreciation
3. Reinforce meaningful experience
4. Build trust and research literacy
5. Improve recruitment and retention

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Four Point Communication Process



Set Expectations

Inform volunteers – they will receive Trial Results Summary (TRS) in plain language

Thank Volunteers

"Thank You" communication at last visit – explains timing of receipt of TRS

Maintain Connection

Continue engaging patients until the TRS is complete – periodic ongoing communications on expected trial end date

Report Trial Results

Delivered by investigative sites to study volunteers – print, posted online or both

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Frequent Engagement is Key

Thank you cards, frequent communications and Lay Language Summaries **signal** to patients they are valued contributors to the process.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Key Program Attributes

Credible, Trustworthy & Independent

- Independent established, recognized non-profit
- Extensive development & implementation experience with pilot, single-study and portfolio-wide programs
- Ongoing interaction with regulatory & guidance-influencing consortia

Proven & Integrated

- User tested & continuously refined
- Leverage priced to reflect non-profit positioning
- Integrated process minimizing burden for sponsors, CROs, & investigative sites
- Distribution & translation in over 40 countries

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Minimizing Operational Burden

The Role of the Sponsor

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

Editorial Panel Review

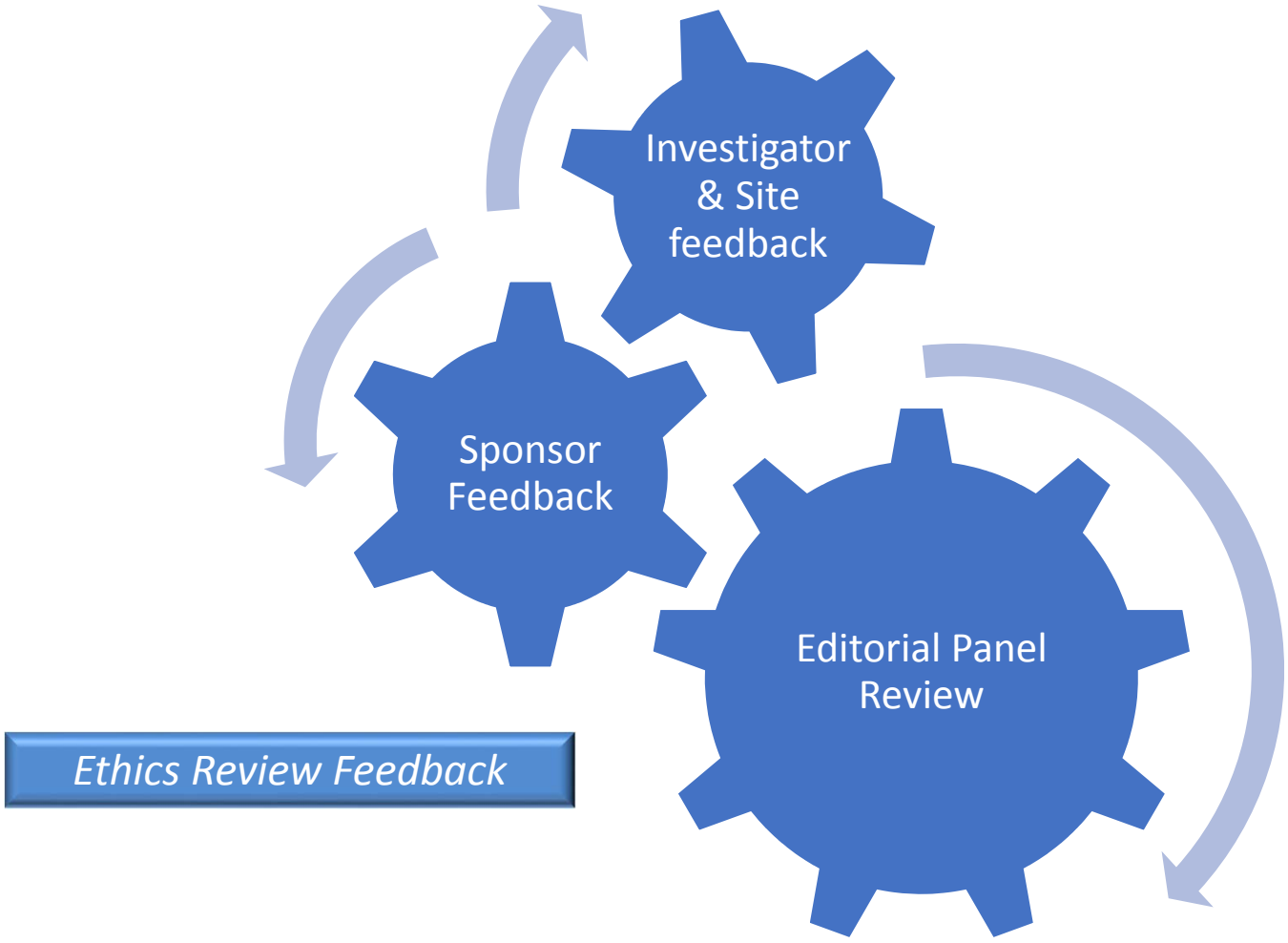
Every TRS is reviewed by an editorial panel as part of our standard process

- Long standing health literacy best practice
- Ensures TRS is non-promotional & understandable
- NHS/HRA EU Lay Summary Guidance

"Sponsors should consider testing the readability of an initial version of the study results summary with a small number of people who represent the target population. Depending on the nature of the study, this could be patients with a particular disease or it could be members of the public."

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

TRS Template – Continuous Improvement



CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

What's Next?

Driving Culture Change

- **Secure senior management support & adopt a patient-centric culture**
- **Create a function to manage patient engagement (centralized/de-centralized)**
- **Dedicate a budget to patient engagement activities**
- **Measure impact of patient engagement activities and disseminate best practices across organization**

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

How to Get Started

1. Schedule informational meeting with CISCRP and your team:
   - Overview of process
   - Review study team objectives and potential timeline
   - Answer questions
2. CISCRP develops and submits proposal to you
3. You review/accept proposal
4. Contracting process
5. Schedule project Kick Off Meeting with CISCRP and your team

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

CISCRP Clients

Any Questions?

Annick Anderson, MBA
Director, Research Services
annickanderson@ciscrp.org
617-725-2750, x400

Jill McNair, MBA
Senior Director, Patient Engagement
jillmcnair@ciscrp.org
617-725-2750, x101

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION


THANK YOU!