

Patient Involvement in the Design of Clinical Trials

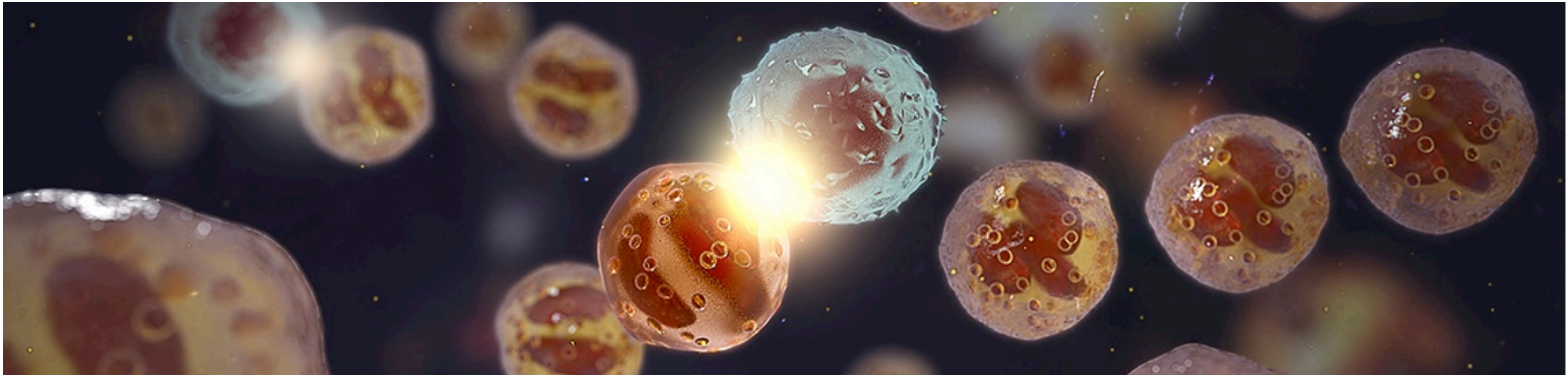
Center for Devices and Radiological Health
PEAC Meeting

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“Patient-Centered” definition

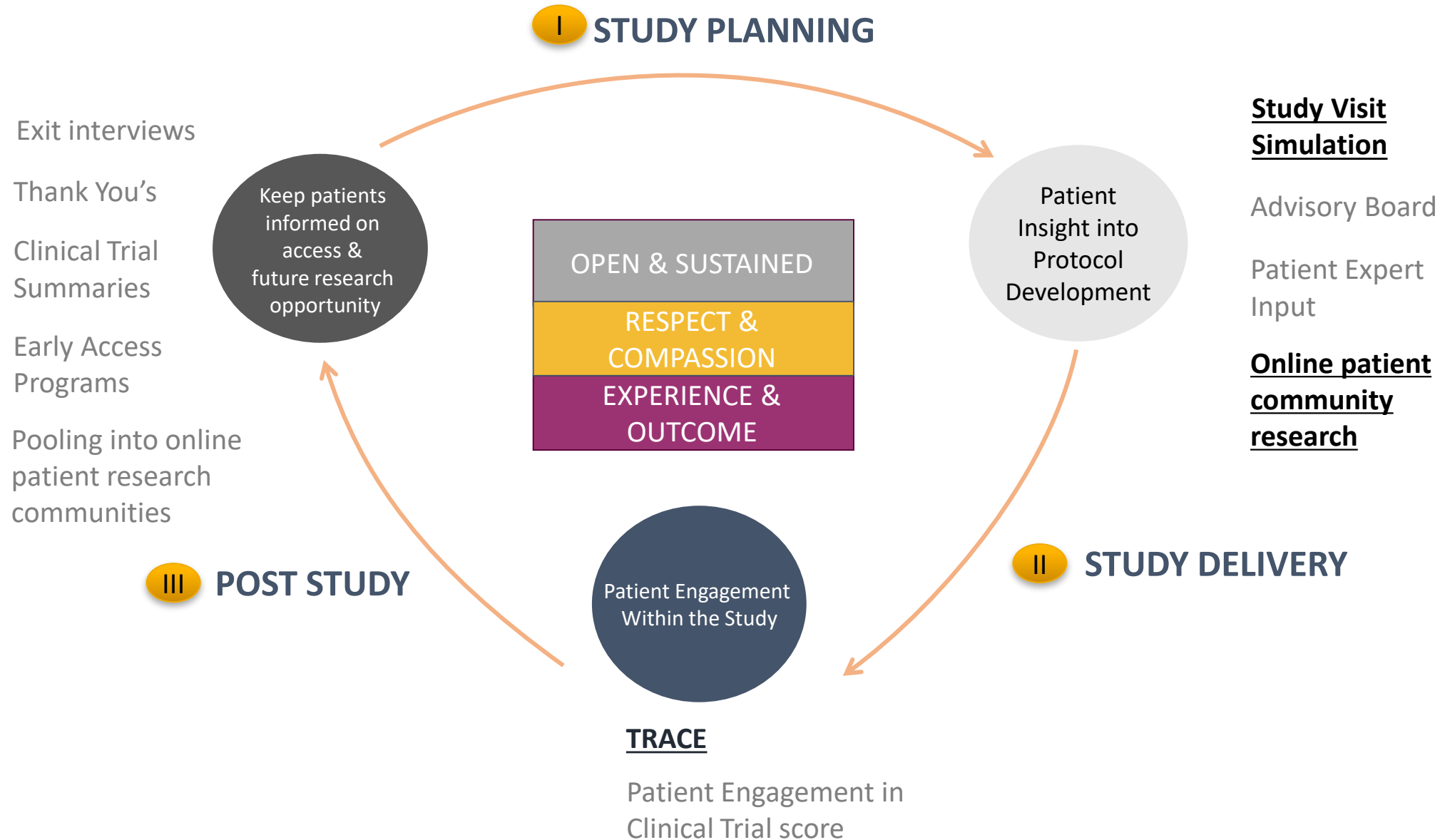


Putting the patient first is
an open and sustained
engagement of the patient to
respectfully and compassionately
achieve the best possible
experience and outcome
for that person and their family

Patient-Centered Research



Patient-Centered Research Framework at AstraZeneca



Study Planning: Online Patient Community Research Feedback

Insight from online health communities shapes clinical studies

Through AZ's collaboration with PatientsLikeMe we can ...

See patient-generated health data ...

- Impact of symptoms
- Outcomes that matter to patients
- How patients describe their disease experience and goals

Survey patient views on study design ...

- Biggest barriers to participation?
- What might impact retention?
- What would make a difference?



Resulting in ...

Optimised study designs

Clearer study materials

Improved study experience for patients

Study Planning: Study Visit Simulation

“Subjects no more”

Our simulation explored the contribution patients can make to study design*



Site Characteristic	Atlanta Study	Altoona Study
Practice type	Grady Hospital Emory Investigator	Private Practice Rheumatology
Lupus Clinical trials completed	>25	>34
Patient Characteristics	N=6 N (%)	N=12 N (%)
African-American	6 (100)	-
White	-	12 (100)
Female	5 (83)	12 (100)
Age range, years	27-60	32-75

We wanted high-quality patient feedback before finalizing the protocol

Our hypothesis: engaged patients will improve recruitment, retention & compliance

“Subjects no more”




* Simulating clinical trial visits yields patient insights into study design and recruitment, Lim SS, Kivitz AJ, McKinnell D, Pierson ME, O'Brien FS [Patient Preference and Adherence 2017](#), 11:1295-1307

Clinical Trial Simulation Approach

Mock clinical trial environment created at a clinical site familiar with lupus clinical trial process


Patients representative of lupus clinical trial population recruited for simulation participation



Patients signed a participation agreement form and consented to interviews with simulation team



Simulation “playbooks” describing procedures and activities provided to site



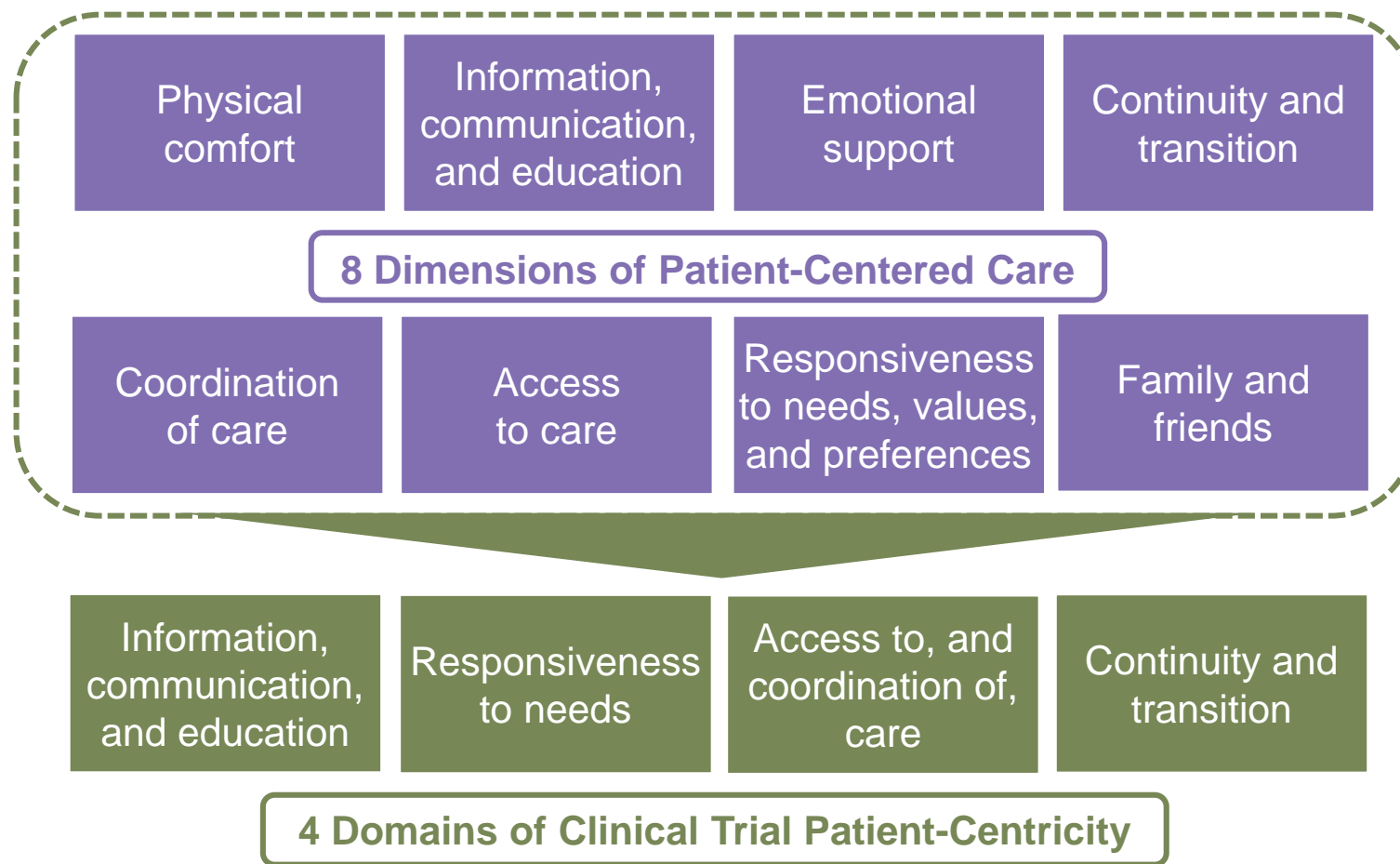
Informed consent process simulated



Screening visit and Visit-1 study procedures simulated

Clinical Trial Simulation: Analytical Methodology

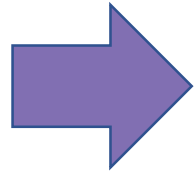
Analytical approach for simulation based on patient-centric frameworks¹ developed by the Picker Institute and The Institute of Medicine



¹Rathert C, et al. *Med Care Res Rev.* 2013;70;351–79.

Elements Important to Patients in the Four Dimensions of Patient-Centric Care

1. Information, Communication, and Education



Patients can be overwhelmed by the amount and complexity of information provided during the conduct of the clinical study

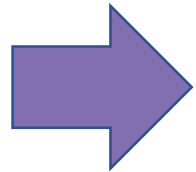
Patients value help and support to discuss their conditions and options with family and friends

Study booklet/website (TRACE) was received positively

Study sponsors should engage the lupus community through lupus community leaders

2. Responsiveness to Needs

Strong online and community support is important to patients



Extent of disruption to patient lives due to study participation is a major factor for potential study withdrawal

Limited work schedule and limited child care flexibility, which lead to financial burden, are significant concerns

Increased heat and humidity during summer months are issues for retention and compliance

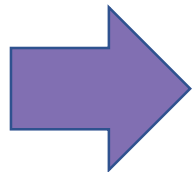
3. Access to Care and Coordination of Care

Maintaining patient comfort during study visits is important to the patients' experience of study participation

Staff members recommended condensed and/or electronic versions of informed consent form in text or audio format

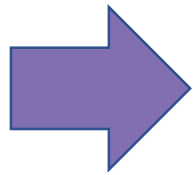
Infusion visits require coordination between relevant parties, consider shortening post-infusion observation times

Duration of study visits (2+ hours) is a patient concern and makes them sensitive to wait time between procedures



4. Continuity and Transition

Not all patients understood commitment degree, despite completing consent form



Patients want feedback on the assessments they undergo in the course of the study and how they relate to their general health status and progression of their disease status

Patients are motivated by being part of developing a possible cure

Patients see the possibility of an open-label extension as a potential benefit

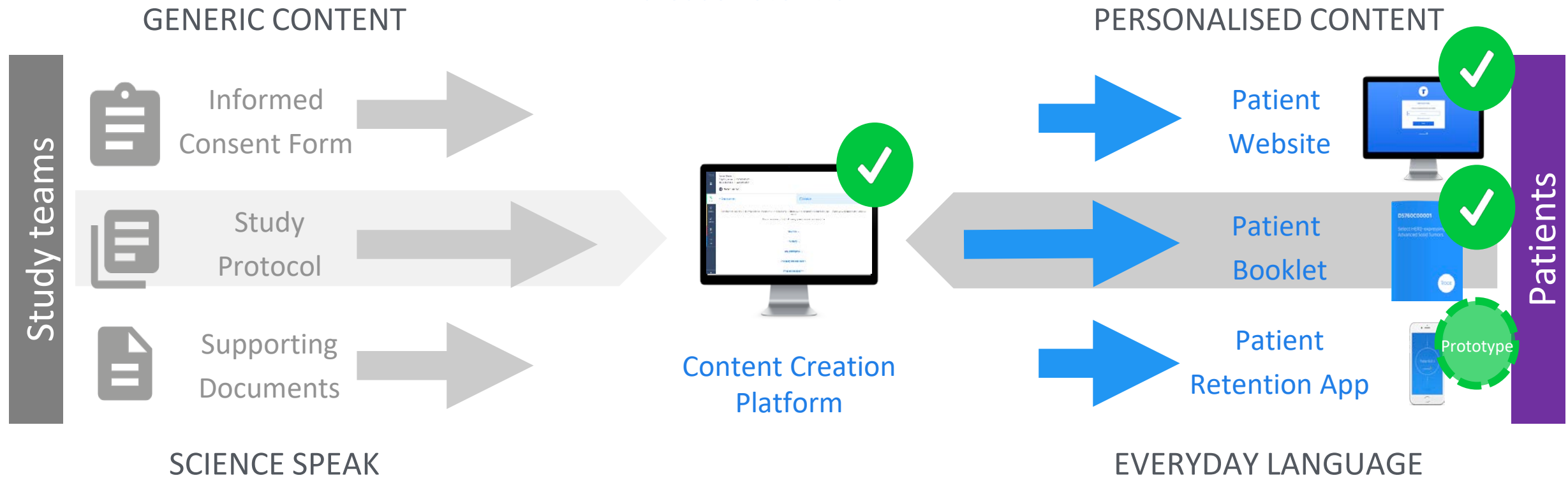
Study Delivery:

Utilizing the Patient Booklet/Website (TRACE)

TRACE is an online system that transforms study materials into patient-friendly content

Value of TRACE

- Improve clinical trial experience
- Speed up recruitment
- Increase retention



... Putting patients first means delivering for patients with patients

Start with Patient Insights

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graph TD; A[Start with Patient Insights] --> B[Use Insights to Co-Create Solutions with Patients]; B --> C[Measure Meaningful Impact];
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There are many ways of generating patient insight including patient advisory boards, patient community forums and patient interviews.

Use Insights to Co-Create Solutions with Patients

Clinical study performance can be improved by co-creating study protocols with patients, making studies more attractive to patients and their families. As a result, trials are likely to accelerate recruitment and improve patient retention and protocol compliance.

Measure Meaningful Impact

Measuring the impact of our work with patients will help us to quickly identify what solutions work, scale up those solutions that demonstrate positive impact, and disinvest in programs that fail to demonstrate value to patients.