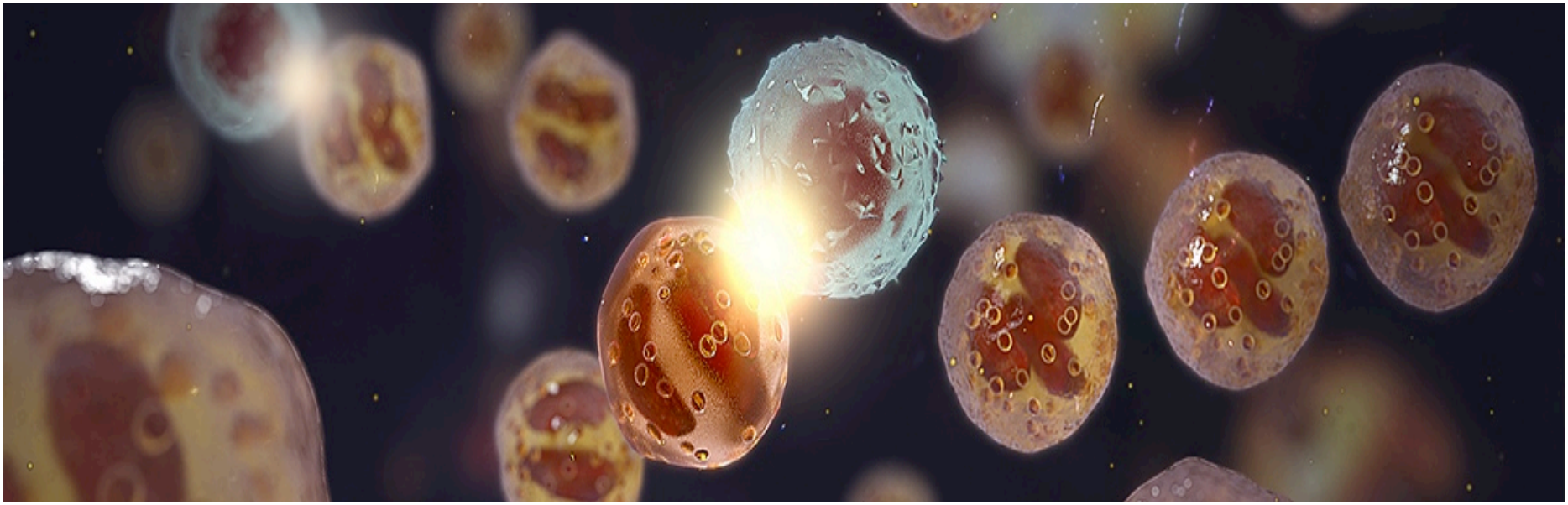
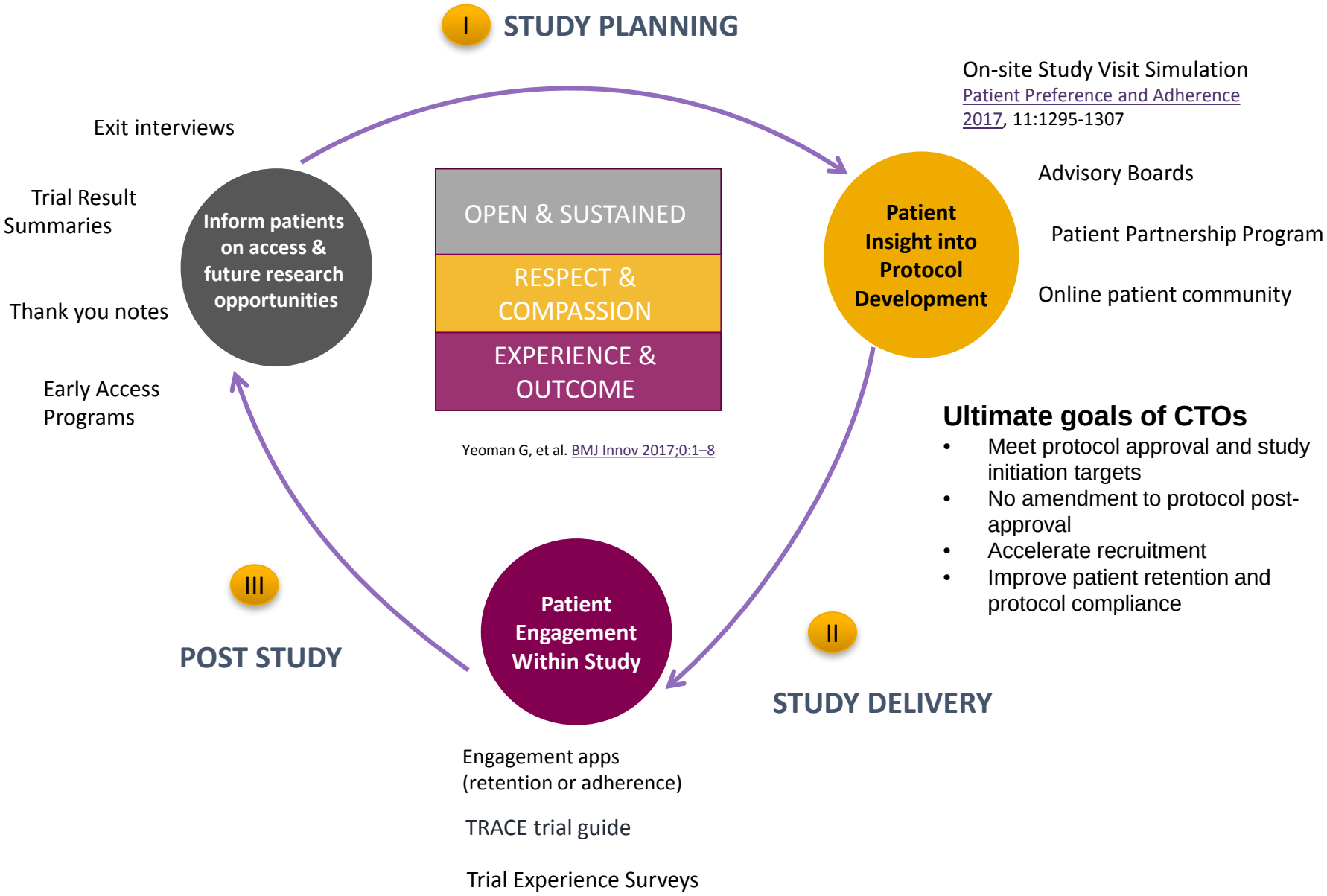
Patient-Centered Clinical Trials

Perfecting the Clinical Trial Optimization (CTO) framework

Dr. Lynn Hagger
Patient Engagement Director, Respiratory & INA, AstraZeneca



Consistent Patient-Centered Research Framework in Clinical Ops



On-site Study Simulations: lupus Ph2 and Ph3

Methodology

- 18 patients (6 African American, 12 Caucasian) with dx SLE or LN
- Two study sites (Atlanta, GA and Altoona, PA)
- Simulate informed consent procedure, a mock screening visit, a mock dosing visit, and a debriefing period for patients and staff.
- Patients and staff interviewed to obtain sentiments and perceptions related to the simulated visits.

Findings

Patients desired:

- Simple background material (hard copy and online)
- Knowledgeable and trusted staff
- Personal results available after study
- Comfortable settings
- Value patient's time and greater scheduling flexibility
- Transportation and child care help during the visits
- Confidentiality of patient data

Value and challenges

- Using these results, improvements study procedures to increase retention, recruitment, and compliance for clinical trials
- **However,** the on-site simulation was very expensive and time consuming for professional staff, patients, and AZ … with few recommendations requiring an "on-site" study simulation.

CTOs using patient advisors or patient communities

Gather data regarding patients' experiences, perceptions, and feedback on the description of a particular study design or protocol

ONLINE PATIENT COMMUNITY

Phase3 study for Patients with severe Nasal Polyposis

•**Simplify protocol design:**

•-Simplify the visit procedures and PROs

•-Source medication centrally so patients receive it at the site

•**Enhance site conduct of study procedures**:

•-Study portal for sharing study documents and information

•-Difficult procedures only in experienced sites and read centrally

•-All ePRO questionnaires to be done at home by patient

•**Enhance clarity of study documents for patients**:

•-Simplification of Informed Consent Form

•-Implement information booklet and website

•-Capture correct symptoms and use laymen terms in diary

•**Improve study experience for patients**:

•-Patient support in travel arrangements and costs

•-Minimize number of site visits

•-Lay Language summary at the end of the study

PATIENT PARTNERS or ADVISORS

Phase 2b Type-2 Diabetes Mellitus

Simplify protocol design:

-Home delivery of medication for the subjects

❖-Remove certain PRO's and reduce frequency of admin

Enhance site conduct of study procedures:

-Study portal for sharing study documents and information

-Develop a visit guide, visit calculator

Enhance clarity of study documents for patients:

-Simplification of Informed Consent Form

-Implement information booklet and website

-Provide patients with a simple study app

Improve study experience for patients:

-Patient support in travel arrangements and costs

-Provide trial experience survey pre-, during and post-trial

Measuring patient sentiment

Patient experience in a clinical trial impacts four generalized dimensions

Empowerment through information

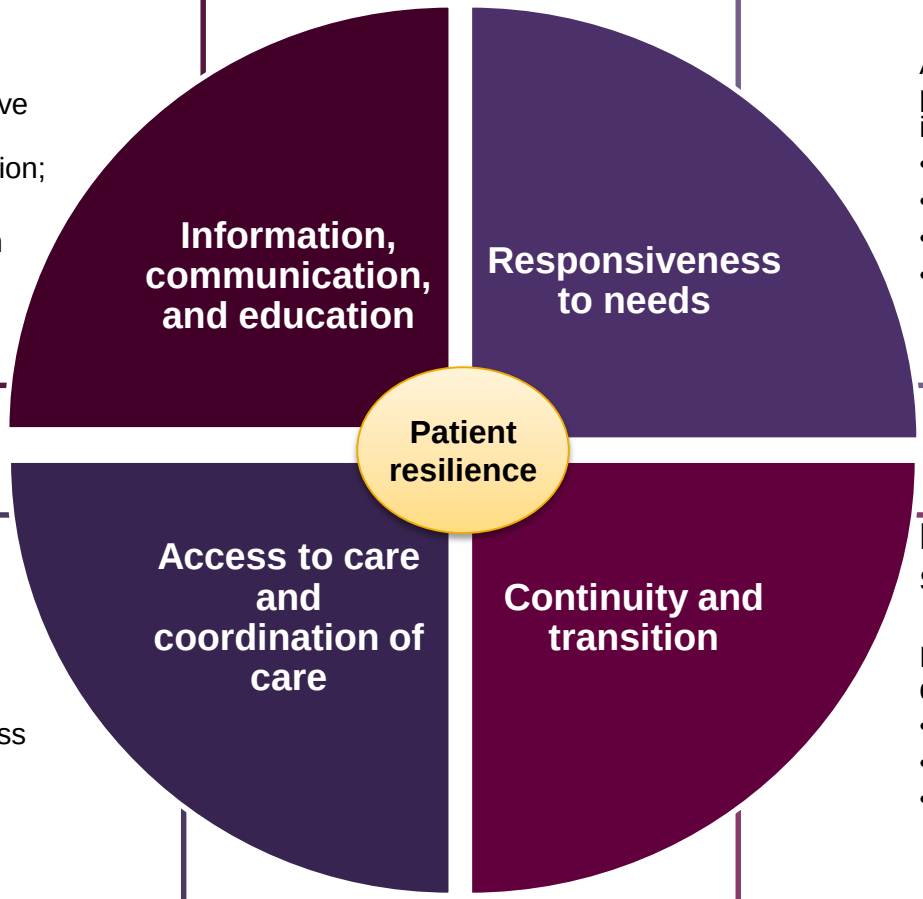
Patients feel better when they have access to understandable, meaningful and relevant information;

- Understand the study
- Exploit the opportunity to learn about disease status
- Disease management
- Social empowerment

Patients as individuals

Are the needs, values and preferences of the patient taken into account?

- Physical comfort
- Emotional support
- Logistics
- Responsiveness



Quality of care, medical and extra-medical

How are the vulnerabilities of patients being addressed?

- Transportation / physical access
- Scheduling / availability
- Access to physician
- Waiting times
- Visit efficiency

Entering and leaving a study

Knowing what will be different during the study and afterwards;

- Follow-up and aftercare
- Transparency on outcomes
- Personal progress during study

Based on Picker and the IoM frameworks for measuring patient centered care