How Can the Informed Consent Process Better Address the Needs of Parents/Children?

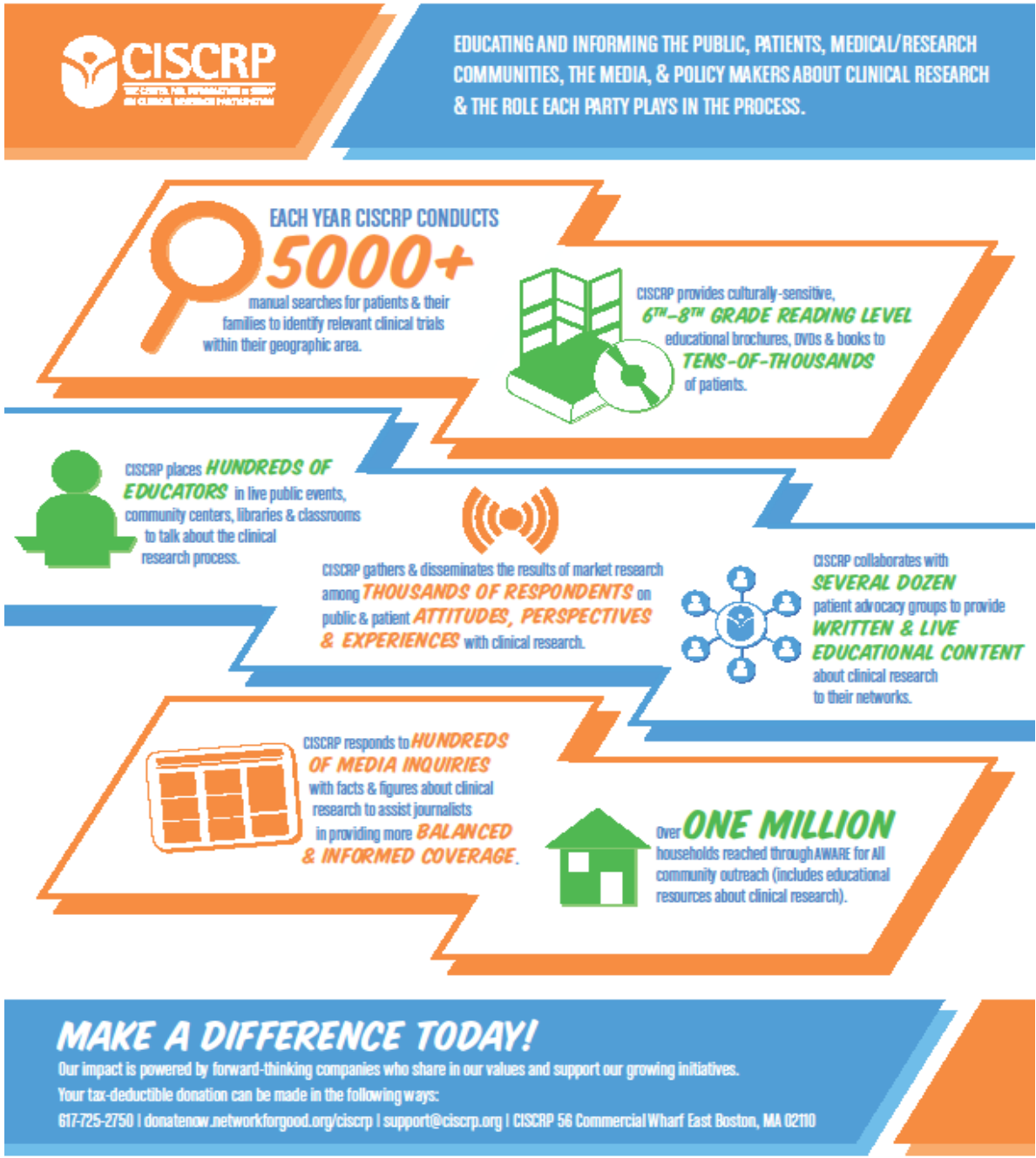
Educating Parents/Children About Clinical Research: Encouraging Participation Without Distorting Expectations

Redefining the Informed Consent "Process"

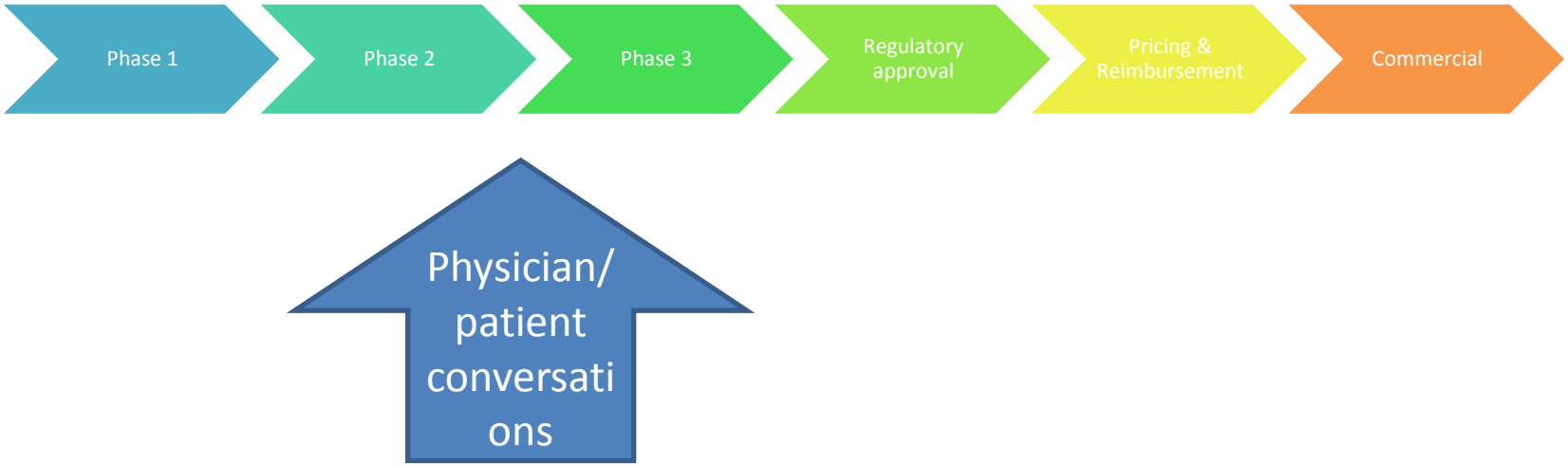
- Not just signing a document
- Involves raising the scientific and clinical research literacy of the potential research population and of IRBs/ECs
- Education about the process of clinical research as well as about the details of a specific clinical trial
- What tools can industry and other groups provide to serve the interests of research participants?
  - **CISCRP**—Center for Information and Study on Clinical Research
  - **EFGCP**—European Federation For Good Clinical Practices
  - **ICAN**—International Children's Advisory Network

Center for Information and Study on Clinical Research

https://www.ciscrp.org/



Paediatric clinical drug development research for the EnprEMA meeting



- Describing potential benefit:risk to families/patients to facilitate recruitment and retention in clinical trials
  - Best practises
  - Positive and negative experiences
  - Regional and cultural differences
- Visualization of benefit:risk for families/patients

Issues, Misconceptions that Could be Addressed as Part of Educational Process

Problem

- Therapeutic misconception that research is like treatment
- Power and endpoints for studies of efficacy and safety
- “New” drug must be better than the “old” drug
- If approved, the new drug will be available

Addressing the Problem

- Research is about conducting an “experiment”
- Role of totality of data: surrogate endpoints, extrapolation, M&S, adaptive design
- Placebo control, vs. natural history control, vs. active comparator control
- Post trial access: IP supply, formulations, commercial considerations

Is there an opportunity to make the informed consent process more informative?