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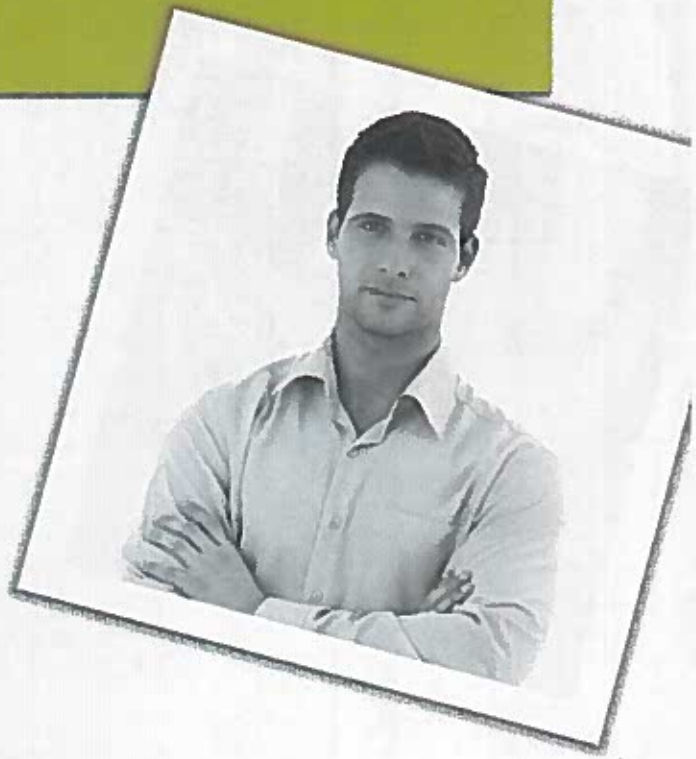
Clinical Research Volunteers and Professionals are Medical Heroes

What is a clinical trial?

- Scientific study that answers a medical question.
  - Is a treatment safe?
  - Does it improve a certain medical condition?
  - Does it have side effects?
  - How should people take it?
  - Is it any better than medicines that are already on the market?



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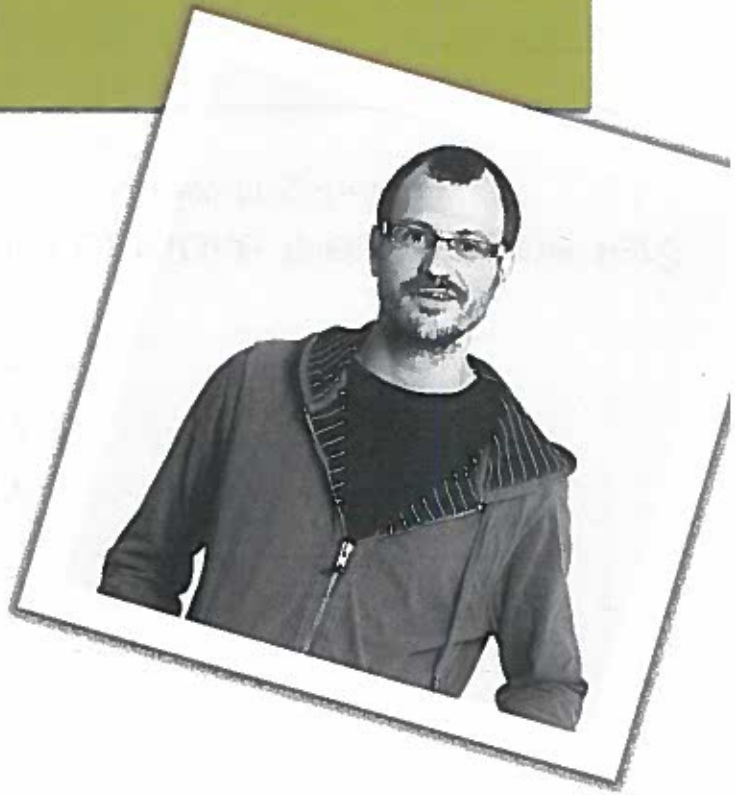
A clinical trial is NOT the same as standard of care



- Standard of Care
  - Routine care
  - Has been tested and approved
  - Works for most people
- Clinical Trial
  - Looks for answers to a question
  - Still learning how it works

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Clinical trials: a 4 phase process

1 Is it safe? And what should be the dose in patients?

2 More safety and dosing data. Early data on whether it works (efficacy)

3 Does it improve patients' health or make them feel better?
-May be new treatment or comparison to an existing therapy
-Tested in large and diverse group of patients

4 Real world experience

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Clinical trials

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Principal Investigator (PI)

Like the head coach

- Organizes the study
- Records and studies the data
- Directs the study staff
- Follows a protocol (play book)

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Clinical Research Coordinator (CRC)

Like the assistant coach

- Handles day-to-day activities
- Works with principal investigator (PI)
- Main contact for volunteers

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Volunteer Protections

Like the referees

- Review the study before it starts
- Make sure the team follows the rules
- Keep you safe and informed

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Volunteer Protections

Institutional Review Boards (IRB)

- Make sure a trial is ethical and fair
- Make sure a trial is not too risky for volunteers
- Receive continuous updates on trial status
  - Serious side effects from study drugs
  - Change in study plan
- Can end a trial if it feels volunteers are not safe

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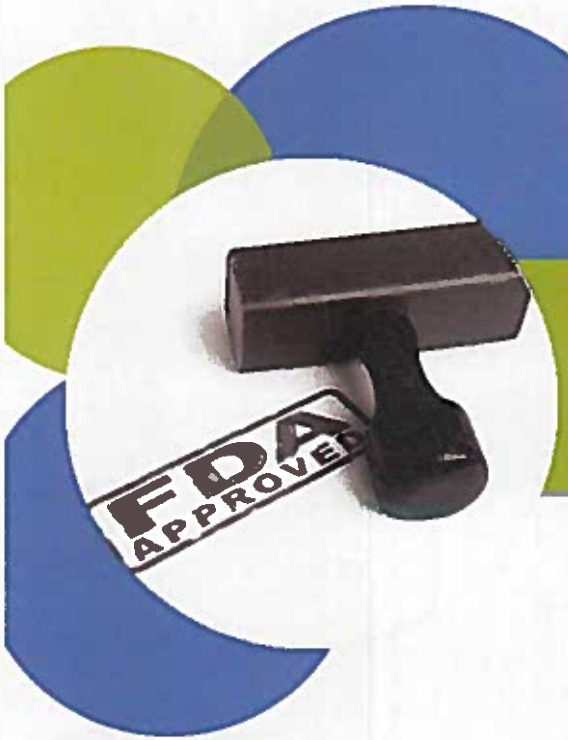

Volunteer Protections

Food and Drug Administration

- Reviews studies
- Inspects research centers
- Monitors research groups
- Has the final say as to whether or not a treatment is approved

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Where should you go to learn more?

- www.clinicaltrials.gov
- www.centerwatch.com
- www.researchmatch.org
- www.ciscrp.org

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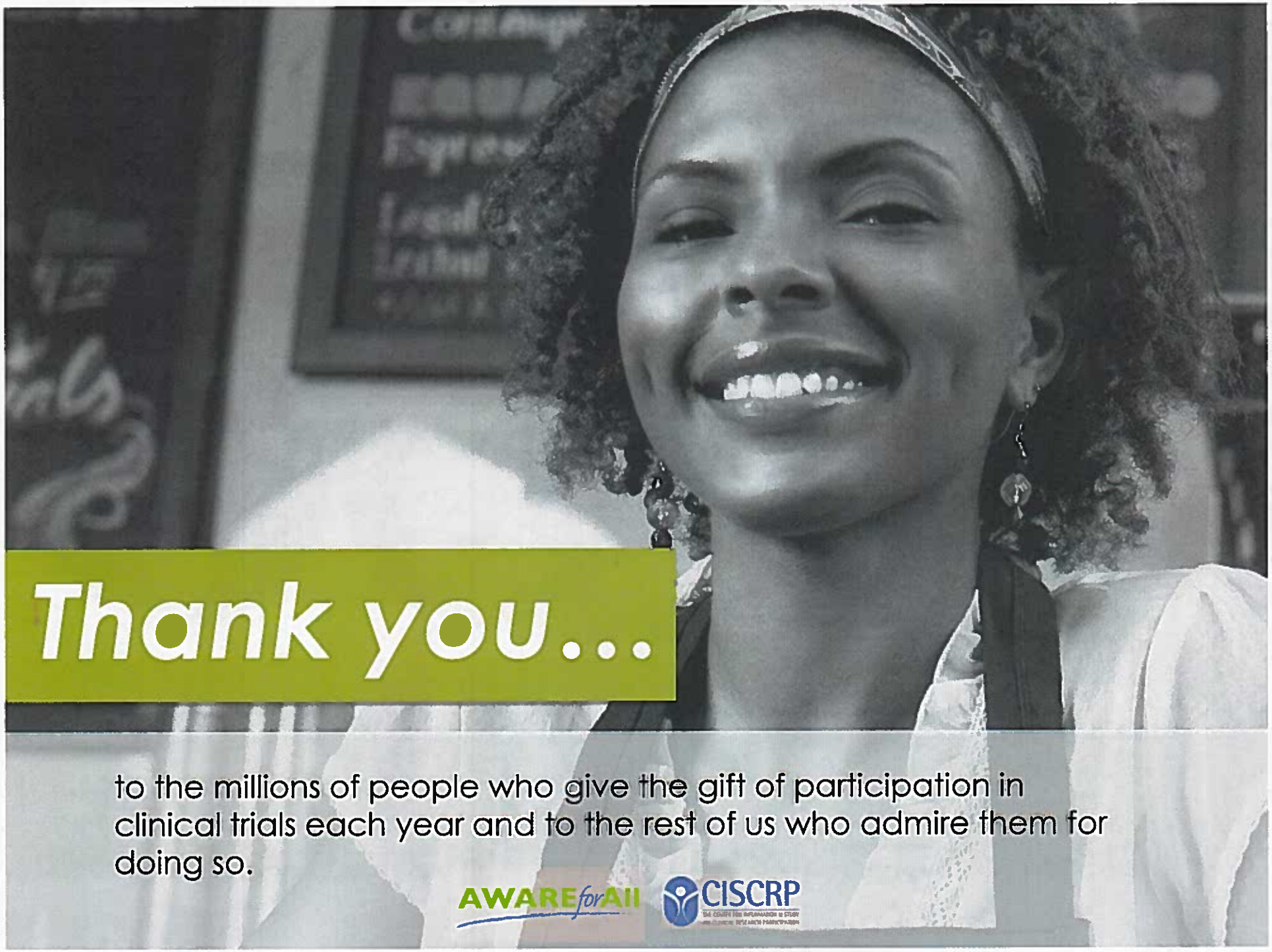
Thank you...
to the millions of people who give the gift of participation in clinical trials each year and to the rest of us who admire them for doing so.
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