



# Clinical Trials:

## A Primer for Potential Participants with Alopecia Areata

Sameh Hanna, MD  
Dermatology on Bloor  
ResearchToronto  
University of Toronto, Division of Dermatology  
Toronto, ON

# AA Clinical Trials

- What is a Clinical Trial
- Trial Phases
- The “Rules”
- Trial designs
- Who are the People in your Trial Neighbourhood?
- What happens at a visit
- Pros & Cons of Trial Involvement
- Subject Compensation
- After the trial?
- Importance of Participant Diversity
- Children and Adolescents in Clinical Trials
- How to Participate

# What is a Clinical Trial

A systematic approach to new drug development, assessment & approval



## SAFETY

### Is the investigational medication/treatment safe?

- Are there side effects?
- How does it affect or move through the body?
- Is it safe to use at the same time as other medications?

#### Who's in it?

Small group of healthy people—generally less than 100



PHASE  
1

## EFFICACY

### Is the investigational medication/treatment effective in treating the targeted condition?

- Does it relieve, reverse or stop the progression of the condition?
- How safe is it?
- What is the most effective dosage?

#### Who's in it?

Generally 100-300 people with the exact condition being studied



PHASE  
2

## FOLLOW UP

### After the investigational medication/treatment is approved, how does it work for other patients with the condition?

- More safety/efficacy information is gathered
- Are there long-term benefits?
- Are there long-term risks?

#### Who's in it?

Often several thousand people who have been prescribed the investigational medication



PHASE  
4

## CONFIRMATION

### How does the investigational medication/treatment compare to the standard treatment for the condition?

- More effective, less effective, or the same?
- Longer-term adverse effects?
- How does it affect quality of life, or survival?
- How might it be used along with existing treatments?

#### Who's in it?

Often 300-3,000 people with the exact condition being studied



PHASE  
3

# The “Rules”

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## ICH-GCP

- Informed Consent
- Right to Withdraw
- Privacy & Confidentiality



# The “Rules”

## The Protocol/Trial Design

How many visits/when

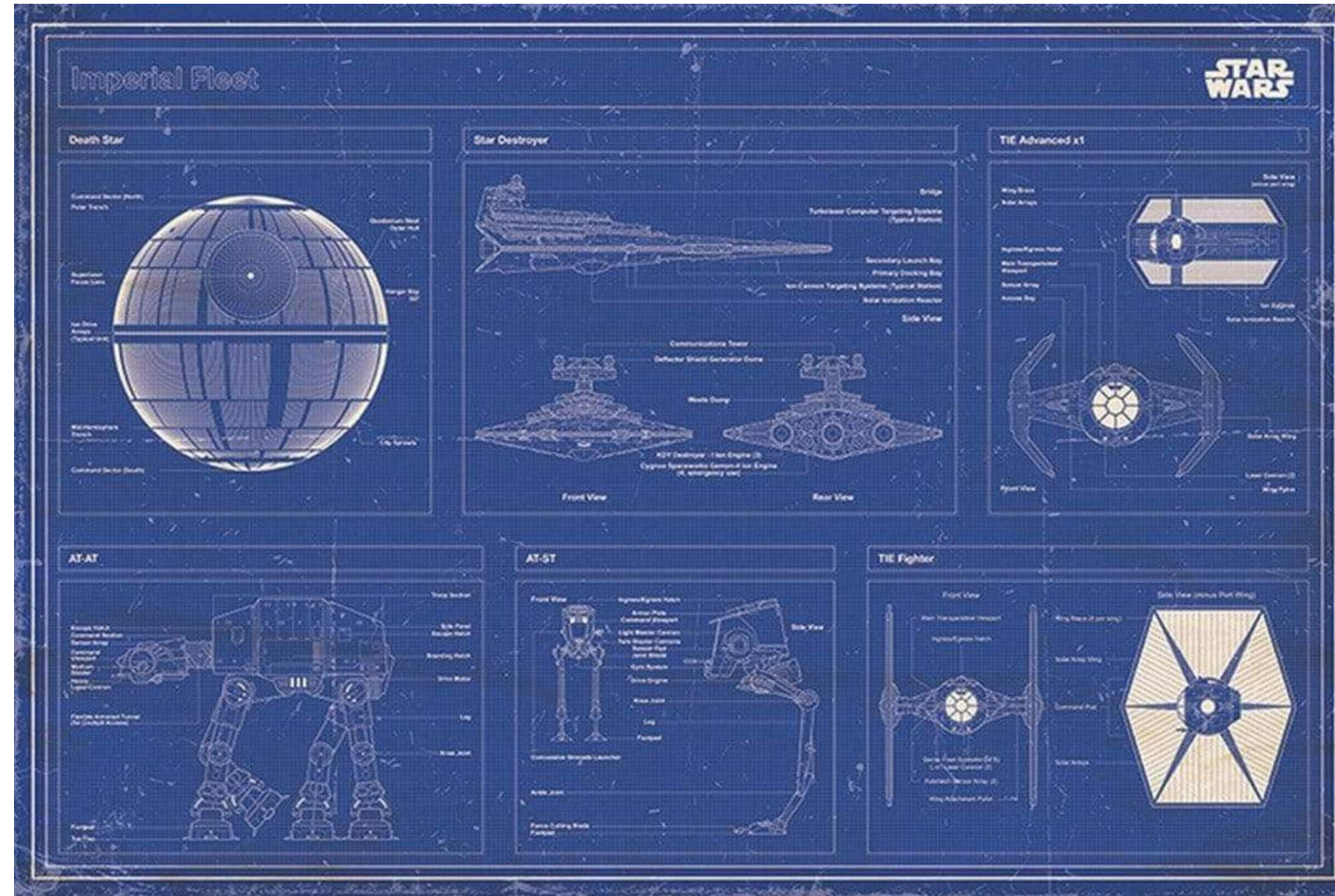
How long is trial

What are we assessing

What are inclusions/exclusions

What is to be avoided

What are stopping criteria



# The “Rules”

## Inclusion & Exclusion Criteria

Condition

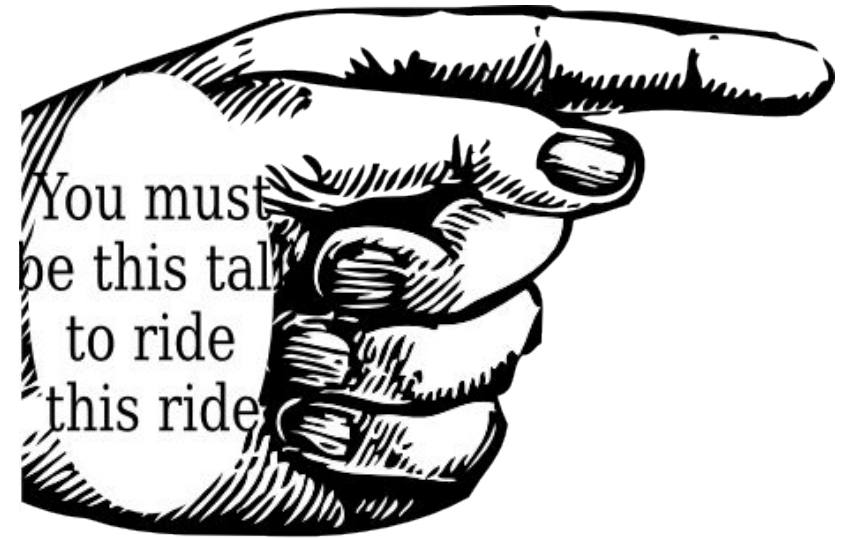
Age

Severity

Medical History

Pregnancy

Medications





# The “Rules”

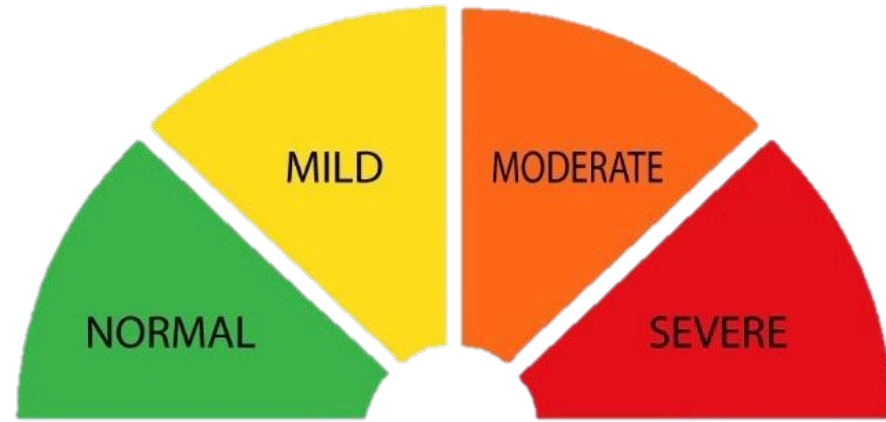
## Assessments & Endpoints

Where did we start?

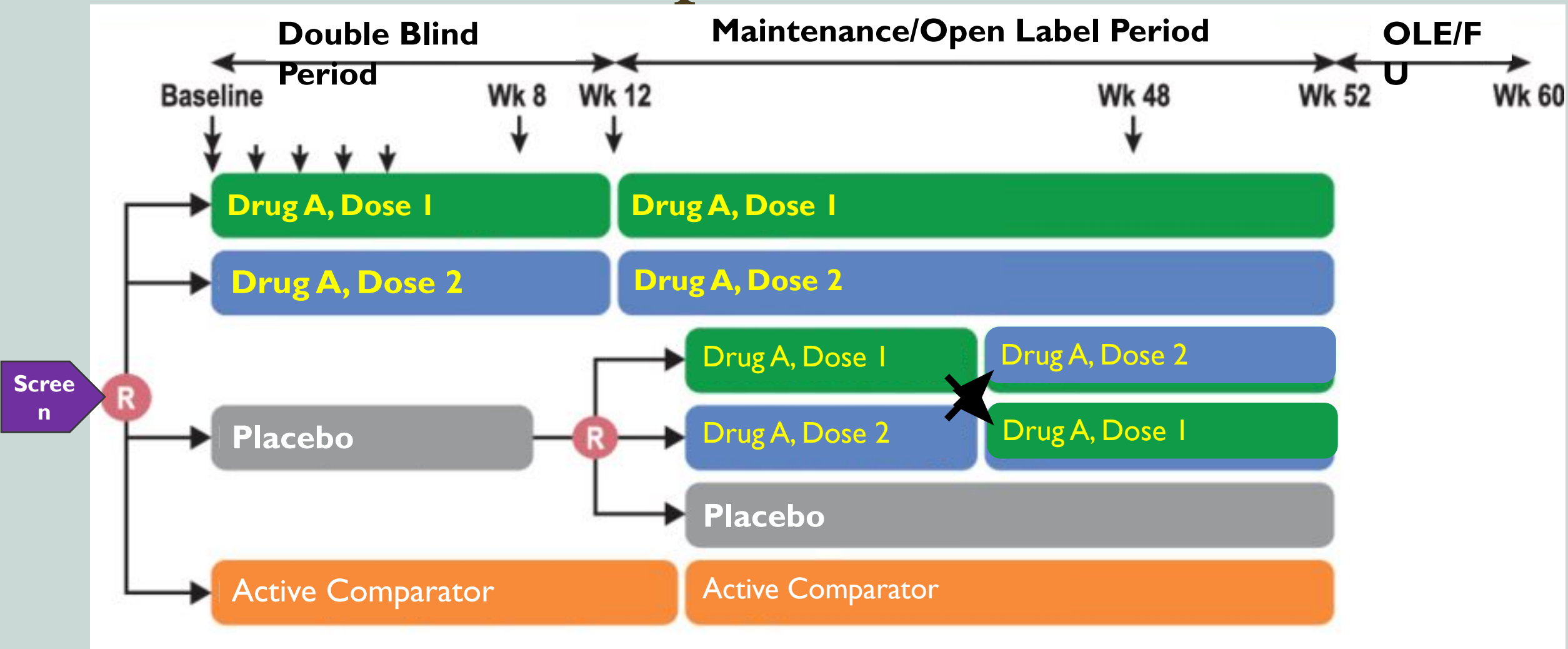
Where do we want to get?

Did we get there?

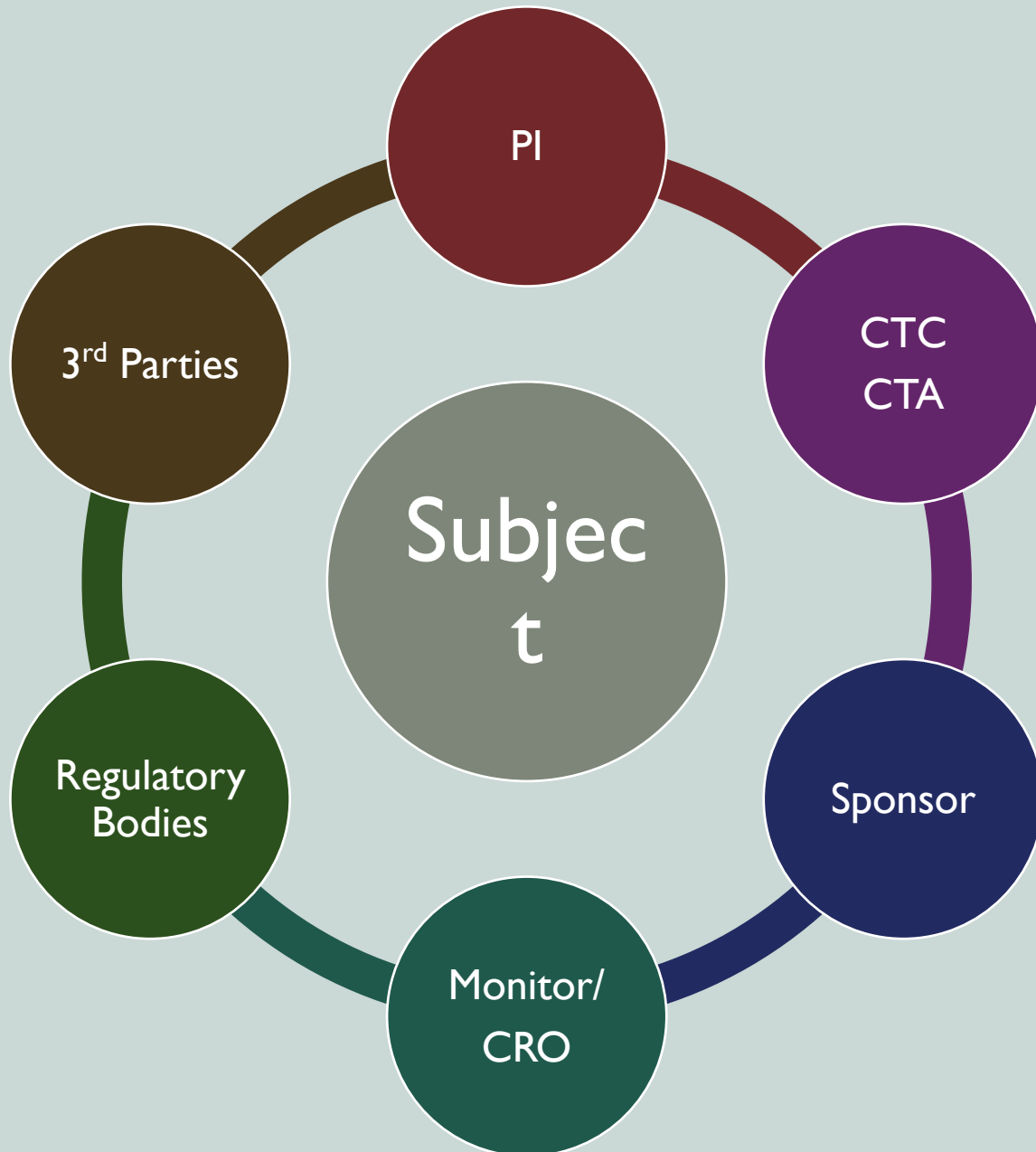
E.g. SALT Score



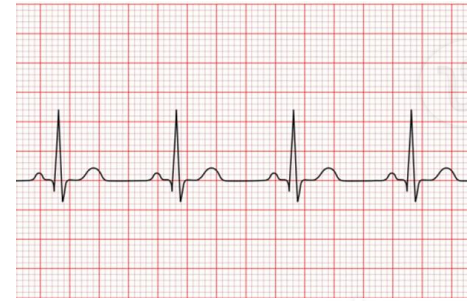
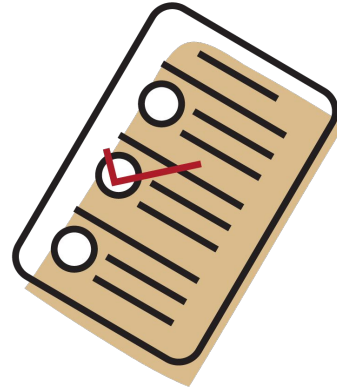
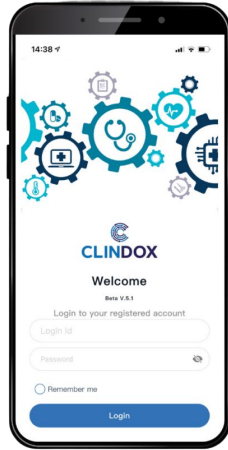
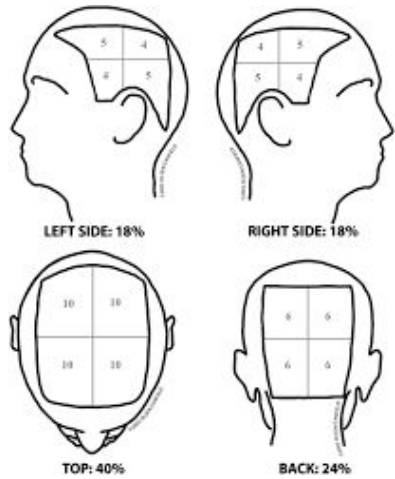
# Randomized Double-Blind, Placebo-controlled Dose Ranging Trial with Active Comparator



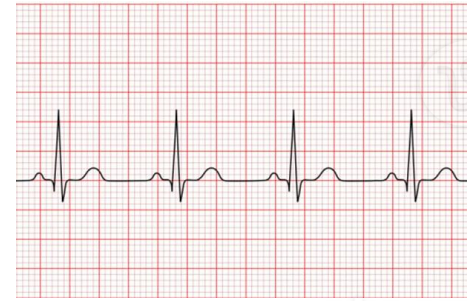
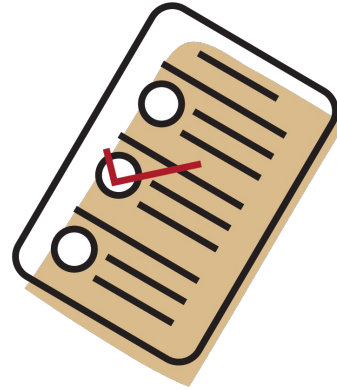
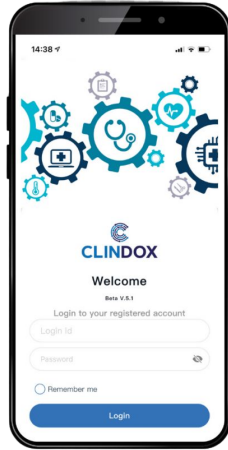
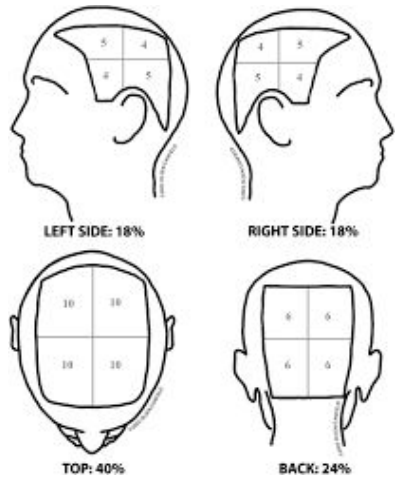
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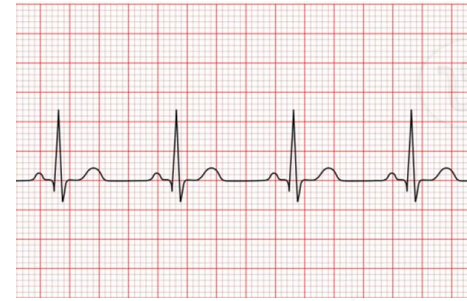
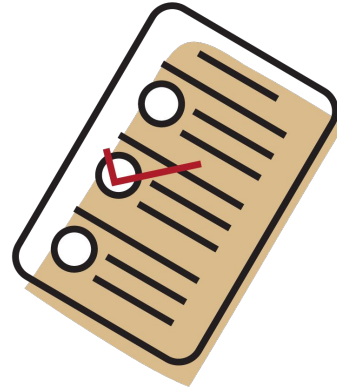
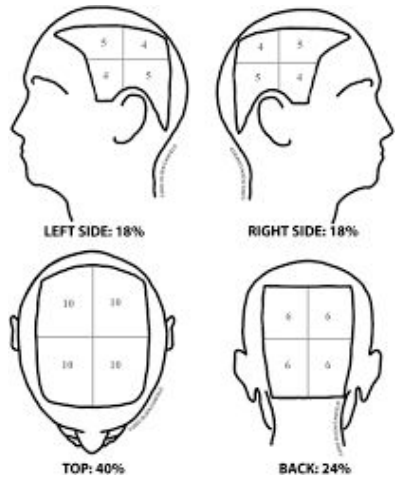
# What Happens at a visit?



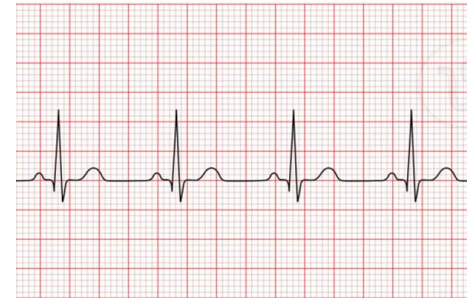
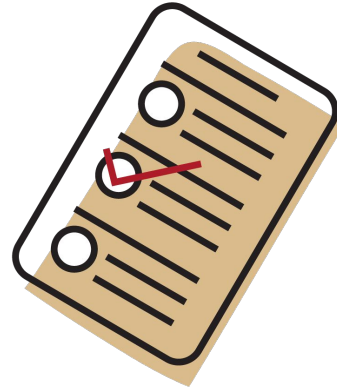
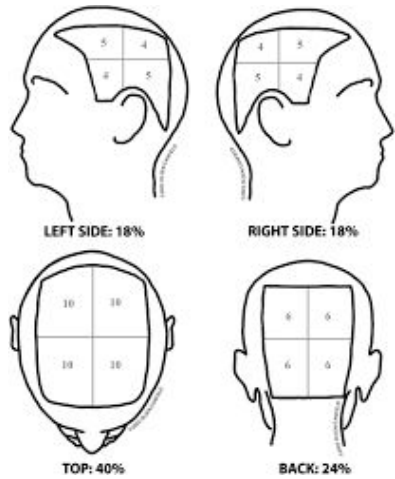
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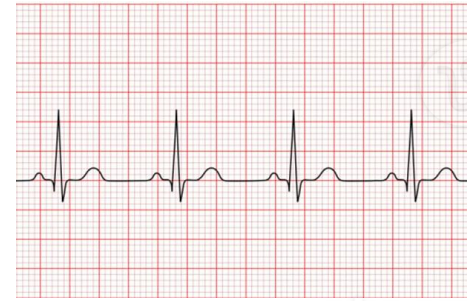
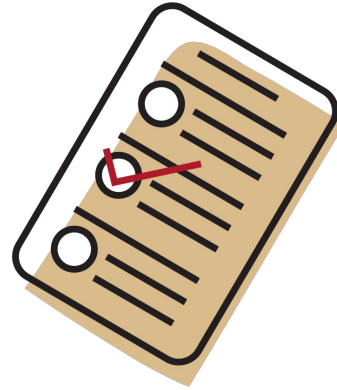
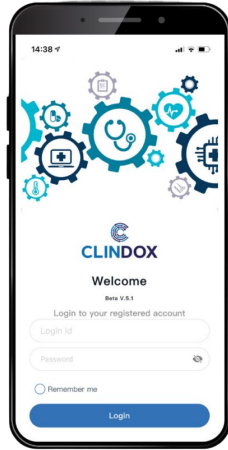
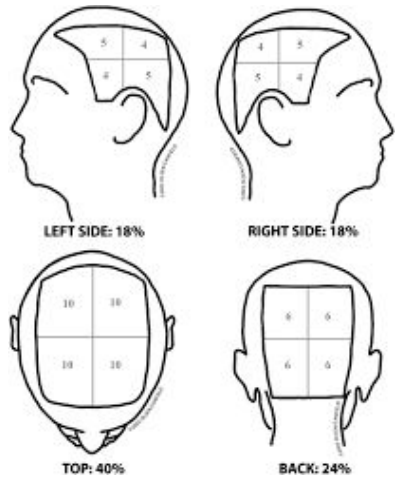
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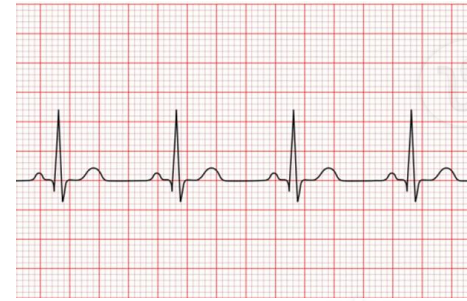
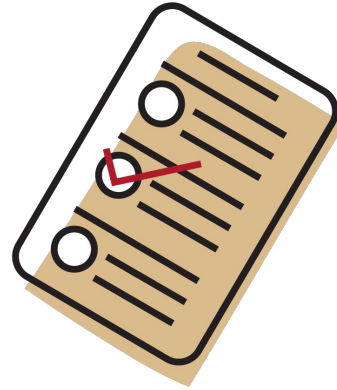
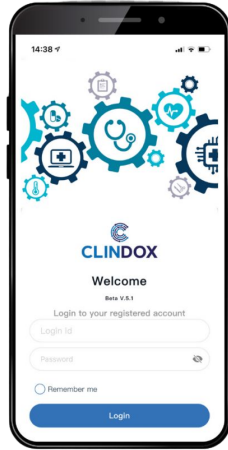
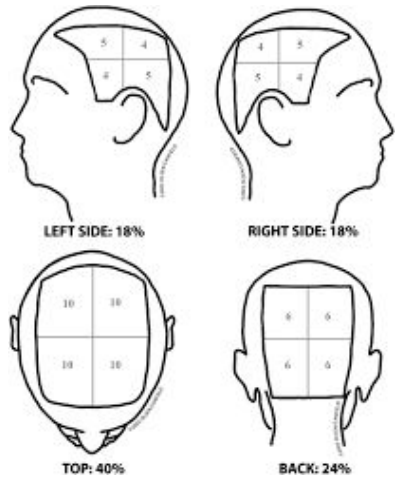


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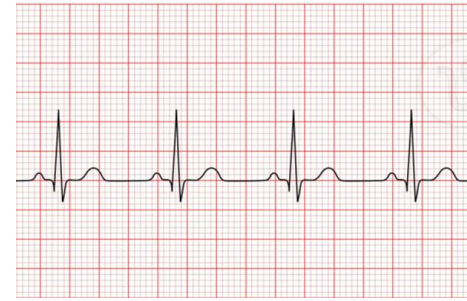
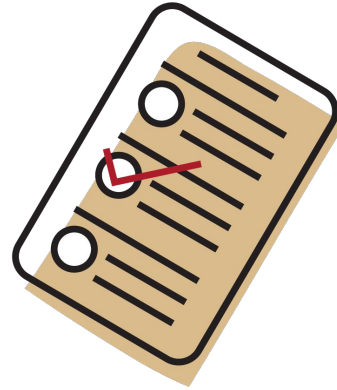
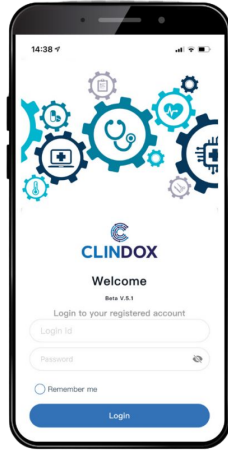
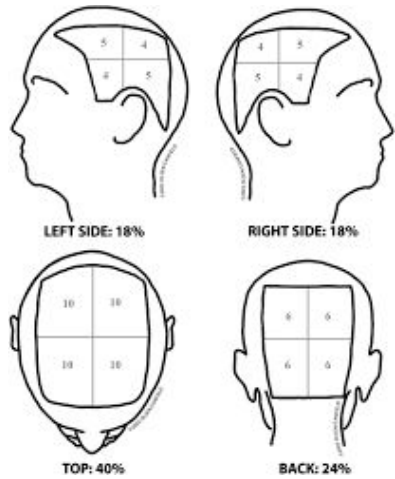




# What Happens at a visit?



# What Happens at a visit?



# Pros & Cons of Trial Involvement



- Access to new medications
- Close monitoring
- Contributing to scientific advances

- Placebo randomization
- Doing the work
- Possible side effects

# Subject Compensation



After the trial?



# Importance of Participant Diversity

- **Ensuring Generalizability**
- **Understanding Variability**
- **Ethical Considerations**

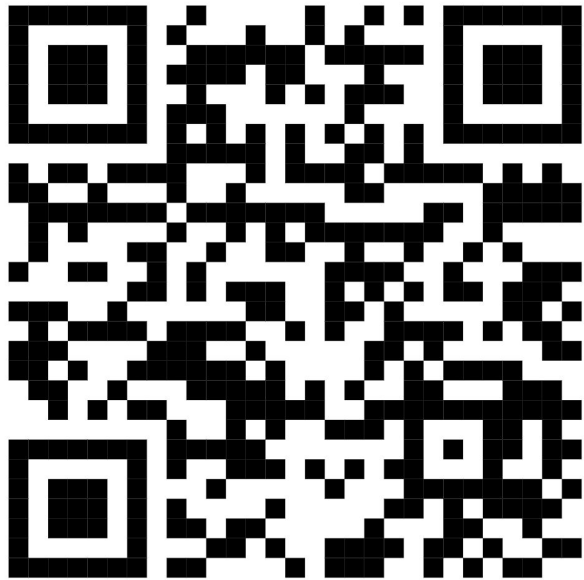


# Children and Adolescents in Clinical Trials

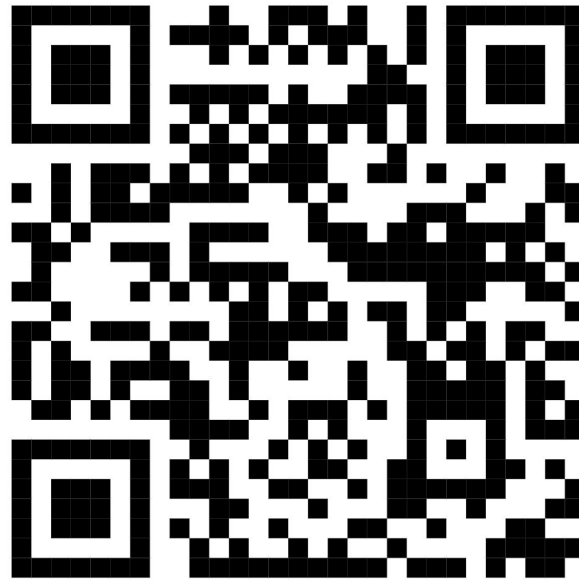


# How to Participate

Health Canada  
Clinical Trials  
Database



Clinical  
Trials.gov



ResearchTrial  
s.org







Thank you!

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