Health literacy in clinical trials

Health literacy through the clinical trial process

Recruitment

Effective and useful recruitment materials

- Fliers
- Social media messages
- Website design
- Print and multimedia
- News releases

Consent

Truly informed consent

- Effective, understandable, and legal informed consent forms

Retention

Engaging retention materials

- Patient information
- Helpful reminders
- Data collection forms

Results

Health-literate results

- Plain-language clinical trial summaries
- Journal articles
- All medial types

Evaluation

Improving all materials and processes via rigorous evaluation

- Formative
- User testing via focus-groups and interviews
- Multimedia

Communication

Collaborative communication between study staff and participants

- Effective, valid, and reliable frameworks for best practice adoption

HLM

Example
informed consent

Before

The study is divided into 3 parts:

- **Screening:** The study doctor will check that you meet the requirements to be in this study. This is called screening. You must sign this informed consent form before any procedures are done. Screening must be completed 5 days before you start taking the study drug.
    - There are two visits during Screening. The first part of the eligibility screening is completed between 2 to 4 weeks before starting study drug. This part will consist of a general health assessment and an assessment of your
    - If you meet the criteria you will then undergo the second part of screening. The second part of screening occurs between 5 days to 2 weeks before starting study drug. During this time, you will stay overnight at the study clinic for 2 consecutive nights. You will have sleep assessments done during this time.
- **Treatment:** Treatment lasts up to 32 days. You will come to the study clinic 4 times during Treatment.
    - On Day 1 you will be admitted to the study clinic for study drug dosing. You will stay overnight and be discharged during the afternoon of Day 2.
    - Day 2- Day 6: you will take the study drug at home.
    - Day 7: you will return to the study clinic for admission and dosing. You will remain through Day 8 and be discharged during the afternoon of Day 9.
    - For the next 7 to 14 days you will not take any study drug. You will return to the study clinic to begin Day 1 for your second treatment period.
- **Follow-up:** You will return to the study clinic 1-2 weeks after your last dose of study drug.

Below is a list of what is done during the study. There is also a table in this form to show what is done at each visit.

- Informed consent
- Review medical history
- Review of medications and any plans for surgery or procedure
- Physical exam
- Vital signs: blood pressure and pulse

After

What is done at the study visits?

You will visit the study clinic 11 times during the entire study. You may have extra visits for certain things, such as extra lab tests. This table shows what is done at each visit.

	Screening Starts after you decide to join the study, but before you begin taking the study drug.		**Treatment periods** **(You will go through this treatment period 2 times)** When you start taking the study drug.						**Follow- up**
	About 12 days before treatment	About 2 weeks before treatment	Day 1	Days 2 to 6	Day 7	Day 8	Day 9	Rest period 7-14 days	A visit after your second rest period
Fast before visit			◆	◆	◆	◆	◆		
Height	◆								
Weight	◆		◆						◆
Blood tests	◆		◆	◆	◆	◆	◆		◆
Urine drug screen	◆	◆	◆		◆				
Alcohol breath test	◆	◆	◆		◆				
Physical exam	◆						◆		◆
ECG	◆		◆						◆
Vital signs	◆		◆	◆	◆	◆	◆		◆
Receive study drug			◆	◆	◆	◆			
Resident at clinic			◆	◆	◆	◆	◆		
Sleep assessments		◆	◆	◆	◆				
Questionnaires		◆	◆	◆		◆	◆		
Complete diary	◆	◆		◆		◆	◆		
Review medications and side effects	◆	◆	◆	◆	◆	◆	◆		◆
Review health history	◆		◆						◆

Example
participant study guide

Before

Injection Guide for Study Drug or Placebo
Panel A (Days 1-5) and Panel B (Days 6-10)

Instructions for Use

Study Drug or Placebo Injection

Each vial contains 1 mL of study drug or matching placebo. The volume removed from the vial determines the dose administered. The study staff will tell you how much to inject from each vial.

Important Information

- **Refrigerate kit box: Do Not Freeze.**
- **Vials should only be used one time.**
- **Only uncap the vials that you are preparing to inject.**
- **Only inject the volume instructed by study staff. Do not inject the entire contents of either vial.**
- **Always use a new site-provided syringe/needle for each injection.**

Step 1: Prepare Vials

- Remove 2 vials from the kit box and return kit box to the refrigerator.
- Allow vials to come to room temperature for at least 15 minutes.
- Vials should then be inverted a minimum of three times.
- Wash your hands with soap and water.

Step 2: Prepare Syringe

- Remove the cap from one of the vials and wipe the top of the vial with an alcohol swab.
- Open a new syringe and needle.
- By pulling back on the plunger, draw air into the syringe up to the mark of the volume to be injected and then slowly inject the air into the vial.
- Keep the needle in the vial and turn the vial upside down. Make sure that the needle tip is well below the surface of the liquid in the vial.
- With the tip of the needle in the liquid, pull slowly back on the plunger to get the right volume into the syringe.
- Check the syringe for air bubbles. If there are bubbles, hold both the vial and syringe in one hand, and tap the syringe with your other hand. The bubbles will float to the top. Push the bubbles back into the vial, then pull back to get the right volume of study drug/placebo.
- When there are no bubbles, take the syringe out of the vial. Put the syringe down carefully so the needle does not touch anything.

Step 3: Injection

- Clean an injection site that is about 2-3 inches away from your belly button on your abdomen with a new alcohol swab. Let dry thoroughly.
- Hold the syringe in the hand that you will use to inject study drug. Use the other hand to pinch a fold of skin at the cleaned injection site.
- Use the injection technique shown to you by the study staff.
- After the needle is inserted and while pinching the skin, pull the plunger back slightly. If no blood appears, steadily push the plunger all the way down until the study drug is injected. **Note:** If blood enters the syringe, remove the syringe, clean and prepare another spot on your abdomen and using the same syringe/needle, inject the product.
- Leave the syringe in place for about 6 seconds after injecting (the pinch may be released) and remove. After the needle is removed, you can apply light pressure with clean gauze or cotton ball but, do not rub the site.
- Place used syringe/needle (do not re-cap the syringe) in a sharps disposal container provided by the site.

After

How to give yourself the study medicine
Panel A (Days 1-5) and Panel B (Days 6-10)

Study medicine
Each bottle holds 1 mL of active drug or placebo.

The study staff will tell you how much medicine to use each time (this is called your dose). Only give yourself the dose the study staff told you. Do not use all the medicine in the bottle.

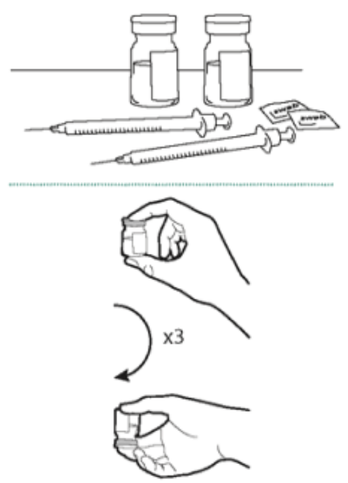
The study staff will tell you how much to inject from each bottle.

Important safety information
- Refrigerate the kit box – Do not freeze.
- Only use each bottle 1 time.
- Use a new syringe and needle each time.
- Only uncap the bottles when you use them.

Steps to give yourself the study medicine

Get ready

1. Gather your supplies:
   - 2 syringes
   - 2 bottles of medicine
   - 2 alcohol swabs
2. Take out 2 bottles from the kit box and put the kit box back in the refrigerator.
   - Let the bottles sit on the counter for at least 15 minutes to get to room temperature.
   - Turn the bottles upside down and then right side up at least 3 times.
3. Wash your hands with soap and water.



Example
clinical trial results summary

Before

Conclusion:

The results of the study indicate that significantly more patients with moderate to severe HS treated with CJM112 versus placebo showed a treatment response, with a favorable safety and tolerability profile in this population.

After

In this clinical trial, researchers studied how patients with a skin condition

What was learned in this clinical trial?

Researchers found that after getting high doses of CJM112 for 16 weeks, HS was less severe in patients and that CJM112 did not show safety concerns for the patients in this clinical trial.

- How much CJM112 got into patients' blood
- The effects of CJM112 on patients' immune system
- Any medical problems that patients reported during the clinical trial

What type of clinical trial was this?

This study was a Phase 2 clinical trial. That means the clinical trial tested how well the trial drug CJM112 worked for people with HS.

How was safety tested?

Researchers looked for any medical problems, called adverse events, that happened during this clinical trial. Patients reported a number of adverse events, including 2 serious adverse events, a groin abscess and chest pain. The trial drug is not believed to have caused any serious adverse events.

What was learned in this clinical trial?

Researchers found that after getting high doses of CJM112 for 16 weeks, HS was less severe in patients and that CJM112 did not show safety concerns for the patients in this clinical trial.

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I’ve been to countless doctors all telling me what to do or what to take…I never really understood what my condition was, what was going on with my body, until I read this summary.

- Clinical trial summary user interview