

The background features a white space with vibrant, abstract ink splatters. A large, dense cloud of bright blue ink dominates the left and center, with smaller, more delicate splatters of pink and purple ink scattered to the right and bottom. The overall effect is dynamic and artistic.

CLINICAL TRIALS 101

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Agenda

- What is a clinical trial?
- Am I a good candidate?
- What / who is involved?
- Informed Consent
- Risks / benefits
- Where can I learn more?

What is a clinical trial anyway?

- Clinical research study – protocol to evaluate the effects and efficacy of experimental medical treatments
- Phase I – **safety** and finding the proper dose (small 15-50 patients)
- Phase II – Focus on **effectiveness** and side effects (slightly larger < 100 patients)
- Phase III – compares **new treatment** to an existing treatment (hundreds of patients)
- Phase IV – Treatment is **approved and available**, long-term effects are observed (thousands of patients)

Am I a good candidate?

- Not all clinical trials are right for all patients
- Strict rules that doctors must follow in order to decide who may join a clinical trial – **eligibility criteria**
 - You and your overall health – age and gender
 - Other health problems
 - Other medications you are taking
 - Results of medical tests
 - Disease type and stage
 - Prior treatments
 - How long has it been since you were last treated?

What / who is involved?

- Treating physician and clinical team, research / study team (study coordinator, research nurse), sponsor (
- Stages
 - Consent with your physician
 - Screening / enrollment
 - On study – on treatment : for as long as you respond and tolerate the treatment
 - End of treatment
 - Follow-up

Informed Consent

- **Treatment**

- The reason for the clinical trial and what doctors hope to learn
- Who is eligible
- What is known about the type of treatment being studied
- Possible risks and benefits (based on what is known so far)

- **Tests**

- Labs, procedures – scans, EKGs, echos, bone marrow

- **Costs**

- Who pays for all of this?

- **Schedule of Assessments**

- Treatment schedule
- Additional testing – labs, , scans, procedures, disease assessments
- Possibility of multiple schedules
- How long the study last?

Risks vs. benefits

- Risks
 - Side effects
 - New treatments may not turn out to be better or as effective as standard treatment
 - As with standard treatment, it may not work for you even if it works for other patients
 - You may not have the time
- Benefits
 - If it works, you may be one of the first people to benefit
 - Helping future cancer patients and moving science forward
 - The trial sponsor may pay for some of your medical care or tests
 - Closer monitoring

Resources

- <https://sparkcures.com/>

The logo for SparkCures, featuring the word "Spark" in a blue sans-serif font and "Cures" in a bold, blue sans-serif font.

- <https://www.cancer.gov/research/infrastructure/clinical-trials/nctn>

The logo for the National Cancer Institute, featuring the letters "NIH" in white on a dark grey background, followed by a red chevron symbol pointing right, and the words "NATIONAL CANCER INSTITUTE" in red, all-caps, sans-serif font.