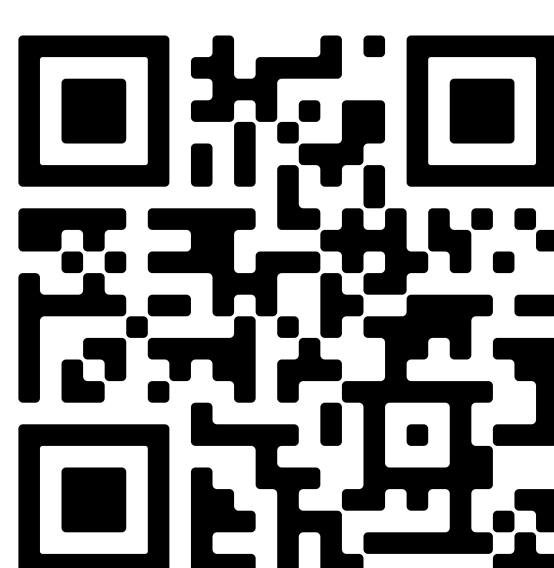


# Clinical Trial Recruitment from a Public Health Perspective

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## Abstract

Without clinical trials, there would be no medicine on the shelves of pharmacies. Clinical trials are an essential component to progressing the field of medicine to enhance treatment and build targeted therapies that overall prevent disease. We aim to further understand the intersection between Public Health and clinical trials in hopes of improving educational outreach in communities. To do so, we will be comparing the effects between a study centric and patient centric approach on clinical trial engagement.

Specifically, we will be working in collaboration Type 1 Diabetes (T1D) Bone Health Connection (PI: E. Yu, MD; Co-I: V.Aroda, MD). Previous studies have shown an increased risk for bone fractures in adult patients with T1D. T1D Bone Health Connection is an observational, cohort study that aims to identify factors that contribute to this increased risk in hopes of developing future treatments to strengthen bone health in patients with T1D.

To convey the purpose of T1D to physician and patient populations, we will be creating versions of materials (ad template, letter, phone script, Rally Website post) in both a study and patient centric manner and measure T1D Bone Health Connections' clinical trial recruitment engagement. We hypothesize that the patient centric approach will result in greater engagement and participation in the study.

## Introduction

Clinical trials are an effective process to advancing medicine and improving care. However, previous studies show that there are several challenges in engaging patients in clinical trials. For instance, 11% of sites fail to enroll a single patient, 37% of sites do not meet their enrollment goals and 40% of adults surveyed do not understand what a clinical trial entails (2013 Journal of Clinical Oncology). Complex trial protocols that are less relevant to the patient are correlated with diminishing likelihood of patient participation.

## Methods

The materials that will be developed for this study are an ad template, letters, phone scripts and a Rally website post. A study and patient centric (Figure 3) version of these materials have been created. A questionnaire will be developed to assess the patient population's attitudes towards clinical trial engagement which will allow for a baseline. The use of these materials will be alternated every month for the trial recruitment period. A survey will be collected to measure the participants' knowledge of the study and likelihood of participating after each exposure to the materials.

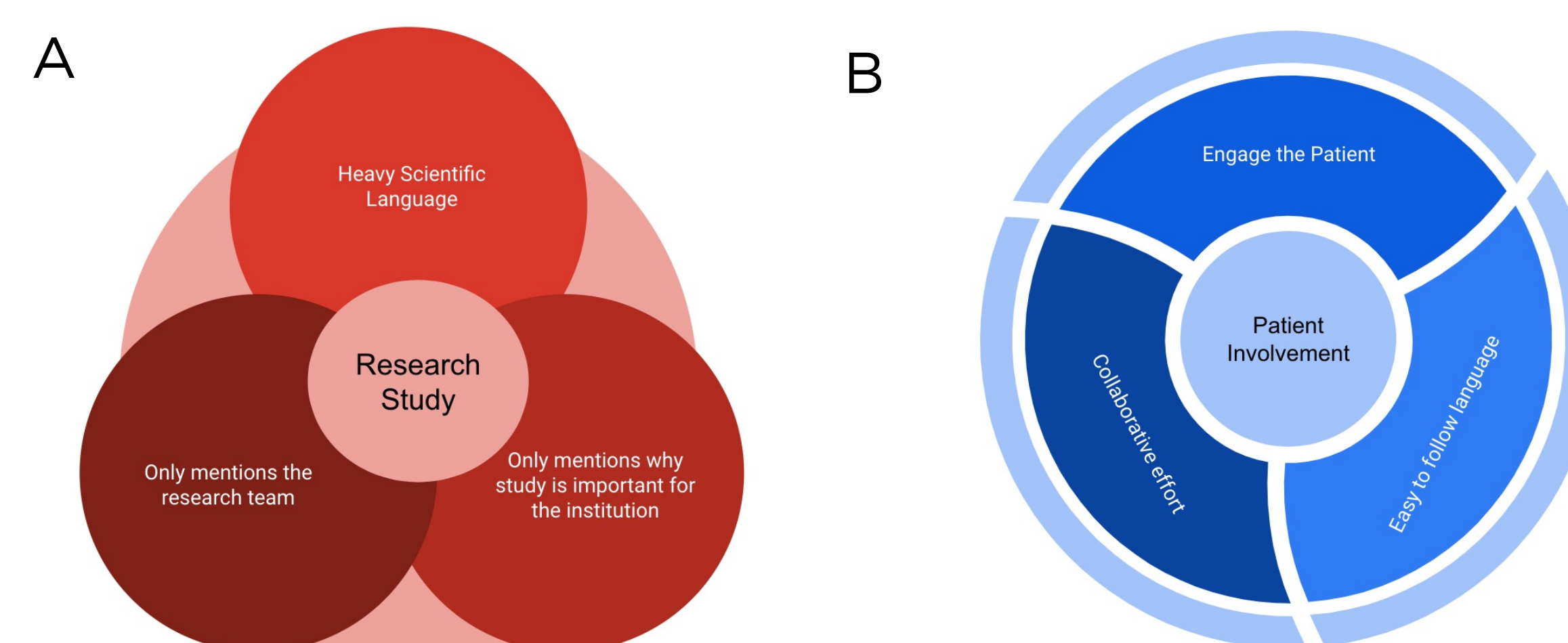


Figure 3. Study Centric (A) Patient Centric (B)

## Study Centric Approach

### ADULT VOLUNTEERS WITH AND WITHOUT TYPE 1 DIABETES NEEDED FOR BONE HEALTH STUDY

The Endocrine Unit at the Massachusetts General Hospital is performing a research study investigating the effect of type 1 diabetes on bone strength in adults. The goal of this research is to understand differences in underlying bone structure that may contribute to the increased hip fracture risk experienced among adults with type 1 diabetes.

Emphasis on institution's research study goals  
Adults with type 1 diabetes who are 50 years and older are eligible to join the study. We are also recruiting adults without diabetes for a comparison group. Participation involves 2 visits to Massachusetts General Hospital over the course of 2 years. The visits include blood and urine tests, bone density scans, and medical history questionnaires. Each visit will last approximately 3 to 4 hours and volunteers will receive up to \$150 compensation. We hope that this research will allow us to design future treatments to strengthen bones in people with diabetes.

## Patient Centric Approach

Engagement with patient

### Do you have type 1 diabetes (T1D)?

We invite you to be part of the T1D Bone Health Connection study to understand and optimize bone and overall health in patients with type 1 diabetes.

Permission

Did you know that people with type 1 diabetes (T1DM) have an increased risk for bone fractures? Beyond bone health, this increased risk may impact overall health.

Collaborative effort

We invite you to learn more about the T1DM Bone Health Connection study as we collectively aim to understand why people with T1DM have an increased risk of fractures, and how this risk impacts overall health.

We are inviting adults with type 1 diabetes who are 50 years and older to collaborate with us in this study at Massachusetts General Brigham. With your consent, volunteers and professionals will work together to collect blood and urine tests, bone density scans and medical history questionnaires to evaluate bone and overall health. The study participation will involve 2 visits to the Massachusetts General Hospital over the course of 2 years for these assessments. Each visit will last approximately 3 to 4 hours and volunteers will receive up to \$150 compensation.

This study will shed light on factors that influence bone health, and the connection to other health risks. We hope this research will provide a better understanding of bone health to design future treatments to improve care for people with T1D, with diabetes. Your participation can make a difference.

Patient Impact

Importance to patient

## Acknowledgements

I would like to acknowledge mentorship and collaboration of Dr. Vanita R. Aroda and Dr. Elaine Yu, respectively, in providing the means to develop this study and create this poster.

## References

1. Weisfeld, V. D., English, R. A., & Claiborne, A. B. (2012). *Public engagement and clinical trials: New models and disruptive technologies: Workshop summary*. Washington, D.C.: National Academies Press.
2. About Us. (n.d.). Retrieved from <http://cctawareness.org/about-us/>
3. Dr. Elaine Yu's Protocol for Longitudinal bone health in adults with Type 1 Diabetes

### Begins with a Question.

A study investigator finds an interesting correlation they want to look at further. They may begin by looking at previous studies.

### Materials are prepared to share vision.

The research team prepares an IRB protocol, advertisements for trial, letters, phone scripts from institutionalized templates.

### Recruitment

The materials are shared with other physicians and patients to educate more people about the vision of the study in hopes of gaining participants.

Figure 1. Clinical Trial Development

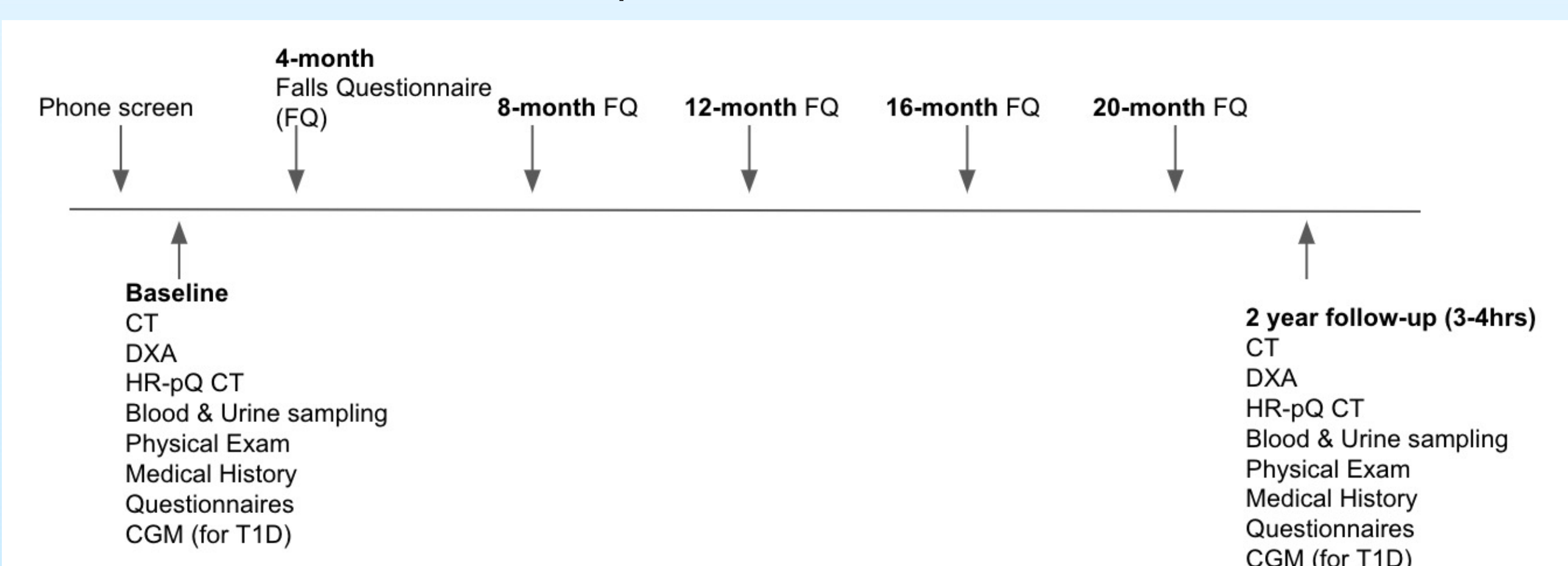


Figure 2. T1D Bone Health Connection Study Flow

In Figure 1, the steps towards clinical trial recruitment are illustrated. We aim to improve steps 2 and 3 as the materials are developed and the mission for T1D Bone Health Connection is shared with possible participants and physicians.

In the T1D Bone Health Connection study, the MGH research team strives to: (1) compare 3D bone density, structure and strength of the hip and age-related changes in these outcomes in older adults with T1D to nondiabetic controls and (2) determine the influence of glycemic control, microvascular disease and advanced glycation end products (AGEs) accumulation on changes in femoral bone density, structure and strength in older adults with T1D.

The increased risk can be partially explained by lower bone mineral density (BMD) in patients with T1D or deficits in AGEs. To explore this further, the research team will work with participants to perform several measures indicated in Figure 2 over a 2-year study period. Certain measurements such as Continuous Glucose Monitoring (CGM) can be useful for the participant's knowledge as well. This study will include 2 visits to MGH that will last 3-4 hours. Participants will be compensated by receiving up to \$150. Our goals are to add a new perspective that will enhance the clinical trial recruitment process for T1D Bone Health Connection.