



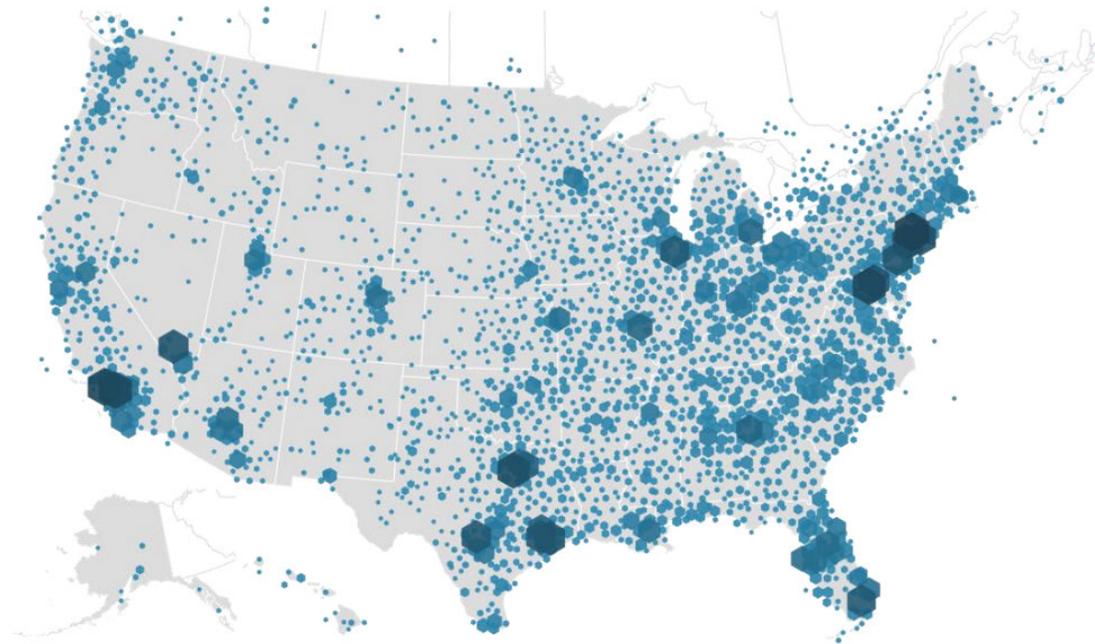
## ANONYMIZED SAMPLE PROPOSAL

### Study Protocol Title

A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study To Assess The Safety, Tolerability, And Pharmacodynamics Of Study Drug In Adults With Type 2 Diabetes Mellitus

**Phase:** II

**Therapeutic Targeting:** 200 subjects ages 18 to 75 years old



**Relative Distribution of Target Population**

**Anticipated Active Sites:** 37

**Expected Patients Contacted:** ~1,500-2,000 patients per month

**Expected Patients Interested in Participation:** 65%

Simulated Phone Screen Criteria	Qualifying Response	Pass Rate
Have you been diagnosed with Type 2 Diabetes?	Yes	97%
Are you taking metformin (Glucophage, Fortamet)?	Yes	62%

Are you taking any other oral anti-diabetic medications, not including metformin?	Yes, No, Unsure	100% *31%
Are you taking any of the following injectable anti-diabetic medications? - insulin - Victoza (liraglutide) - Actos (pioglitazone) - Trulicity (dulaglutide) - Avandia (rosiglitazone) - Ozempic (semaglutide) - Byetta (exenatide) - Symlin (pramlintide)	No, Unsure	52%
In the past 6 months, have you had any of the following cardiac events? - heart attack - unstable angina - stroke - revascularization procedure - mini-stroke (TIA) - history of heart failure	No	93%
Have you ever undergone bariatric (weight loss) surgery?	No	91%
Have you been diagnosed with Type 1 Diabetes?	No	97%
Do you have active Crohn's disease or ulcerative colitis?	No	99%
Do you have a history of Hepatitis B or Hepatitis C infection?	No, Unsure	96%
Have you been diagnosed with or treated for cancer in the past 5 years, excluding skin cancer?	No	98%
Total Expected Pass Rate		<b>24%</b>

\* Percentage of respondents who answered Yes to pre-screener

**Expected Referrals Per Month:** ~234-312 patients per month

**Anticipated Entered Screening Per Month:** ~16-22

**Anticipated Demographics:**

White/Caucasian: 54%

Black/African American: 36%

Hispanic or Latino: 10%

**Reported Screen Fail Rate:** 35%

**Potential Randomizations Per Month:** ~11-14

**Price Per Randomized Patient:** \$8,500

## **Assessment Methodology**

The conclusions presented in this assessment are based on data gathered over a two-week period via a real-world simulation of SubjectWell's recruitment efforts. Data collection included:

- Telephone conversations with a minimum of 100 patients who have registered into the SubjectWell Marketplace and reported having the target therapeutic condition.
- Feedback from those patients regarding their interest in participating in this study, based on the patient burden of the protocol (such as study length, number of visits and patient activities).
- Analysis of site-reported activity data gathered from past recruitment efforts of similar studies
- Calculation of inclusion and exclusion criteria pass rates using constantly updated percentages from a repository of responses to over 10k individual prescreening questions.

All assumptions are based on information provided at the time of the assessment. Incomplete or inaccurate information or material changes to the protocol, screen fail rates or site lists may affect volume and pricing estimations.

## **The Solution**

SubjectWell is the risk-free clinical trials marketplace for patient recruitment that engages the 96% of the general population who have never participated in a clinical trial. Our technology continuously identifies interested patients, at times when they're not thinking about their condition, on tens of thousands of general interest websites, and engages them with an easy online introduction. This process is faster and more effective than traditional advertising and database marketing campaigns, which typically focus on a single study and a limited geographic area.

SubjectWell will provide the following services:

- Site setup and training on SubjectWell tools
- Identification of patients in SubjectWell's marketplace who may be a potential match for the studies
- Outreach and phone interview to gauge patient interest in the study, along with a phone screen using mutually agreed upon, IRB-approved criteria
- Live phone transfer to research sites along with secure transmission of data collected by SubjectWell
- Patient concierge service continues to nurture the relationship with the patient after the referral to the research site.
- Regular reporting of performance of SubjectWell's services

All services are included as part of SubjectWell's per-patient pricing.

SubjectWell collects the following data to monitor patient referrals and to optimize the efficacy of its recruiting engine:

- Individual web activity, profile information and health data collected through SubjectWell's websites
- Patient-reported demographic and health data during the online or phone screen process

- Patient-reported activity data after completion of the phone screen, including appointment time and qualitative feedback on the enrollment process
- Site-reported activity data including screen fail reasons, appointment scheduling, and patient contactability

Promoting patient engagement is critical to optimizing both the quantity and quality of referrals sent to individual research sites. The technology behind SubjectWell's marketplace monitors and optimizes production across all sites associated with a study, and will automatically promote referrals to high performing sites while balancing production so as not to overwhelm individual sites with referrals.

We engage patients throughout the screening and enrollment process to ensure that the sites stay in contact with the patients and that the patients follow through on appointments. This service delivers randomization rates that are 50% - 300% higher than those of typical referrals.