INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**American College of Cardiology Foundation / "TRANSFORM^3: Evaluation of Implementation Strategies of Teaching, Technology, and Teams to Optimize Medical Therapy in Cardiovascular Disease (T^3)"**
Protocol Number:	**2021-12**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

KEY INFORMATION

You are invited to take part in a research study evaluating strategies to improve use of guideline-directed medical therapies, or medicines, because you have been identified as living with one or more of the diseases being studied; heart failure, atrial fibrillation and/or type 2 diabetes/ atherosclerotic cardiovascular disease (ASCVD). Your heart failure can make it hard for your heart to pump enough blood to the rest of your body. If you have atrial fibrillation, your heart may beat too quickly or irregularly. Type 2 diabetes is the type of diabetes that you have when your blood glucose, also called blood sugar, is too high and your body doesn't make enough insulin or doesn't use insulin well.

Before you agree to participate in this study, we would like to help you understand the research. Please read through this informed consent and let us know if you need additional clarification.

PURPOSE OF STUDY

This study aims to redesign your 20-minute outpatient office visit with your doctor to:

1) Ensure that you understand the medications used to manage your condition(s) as recommended by evidence-based scientific guidelines, also known as **G**uideline **D**irected **M**edical **T**herapy (GDMT).
2) Help you manage your heart failure, atrial fibrillation and/or type 2 diabetes/ASCVD.
3) Give your doctor the option to refer you to a team specialized in GDMT for treatment and management of your heart failure, atrial fibrillation, and/or Type 2 Diabetes/ASCVD).

Similar to other health conditions such as asthma, cardiovascular disease requires ongoing monitoring and management. Treatment, even when you are not feeling sick, can help you feel better, live longer, and stay out of the hospital. That is why it is so important for you to take an active role in caring for your heart failure, atrial fibrillation, and/or Type 2 Diabetes/ASCVD from the start and report how you're feeling on a regular basis to your care team.

The American College of Cardiology (ACC) is sponsoring this research study. This study is funded by Bristol Myers Squibb and Pfizer.

With short visits with your doctor (cardiologist and/or primary care), it is hard for your doctor to assess the optimal medications for you. Our study aims to redesign this visit so that your doctor has tailored information to make the best recommendations for your condition(s) along with tools to manage your care.

During a "normal" follow-up appointment, the doctor caring for you has numerous things to consider. Your medical history, current medicines, surgeries, and many other parts to your care are all discussed. Your doctor may not be able to explain what to expect with your new medicines or follow expert guidelines by adjusting your medicines if necessary. In fact, your doctor may not be willing to change your medicines if you appear to be doing well (stable) and your condition is not getting worse—even when science tells us that making changes early rather than waiting can keep people with cardiovascular disease healthier and out of the hospital.

Living with heart failure, atrial fibrillation, and/or Type 2 Diabetes/ASCVD means finding time to go to the doctor, changing and checking on new medicines (to make sure they are working) and learning to do your part (with your doctor) to find success. It is important that you work with your doctor to learn about these new medicines and treatments and use the tools and resources from this study to set goals. The goal of this study is that you will feel more confident and capable in managing your disease and living a healthier life.

STUDY PROCEDURES

If included, your participation in this study will last about 9 months to monitor your progress through routine exams, potential medication changes and bloodwork, all of which will be part of your standard of care.

Because we do not know which approach to delivering Guideline Directed Medical Therapy will help your doctor best assess your options, we need to compare the information your doctor will receive. To do this, we put people taking part in this research into three groups. You may end up in a group that:

1. Will receive care from your doctor as usual; or
2. Your doctor will receive recommendations on ways to optimize your medications. Biofourmis (BF) Care will review information from your electronic health record and recommend a treatment plan to your doctor prior to your office visits. You should expect that your medicines could be adjusted and/or new medicines added; or
3. You will receive a referral from your doctor to meet with a virtual GDMT team, which provides more specialized care for managing cardiovascular disease. *Biofourmis (BF) Care* will review information from your electronic health record and recommend a

treatment plan to the virtual team. You should expect that your medicines could be adjusted and/or new medicines added.

Though GDMT will consist of your typical standard of care treatments, we are investigating which of these combinations of care are the most effective at helping you maintain a routine.

Your study staff will also provide you with educational tools and resources on how to manage your heart failure, atrial fibrillation, and/or Type 2 Diabetes/ASCVD.

Screening and Enrollment:
Before the survey is administered, you will be asked to read, sign, and date this consent document. You then will be screened to see if you fit into the study inclusion criteria, listed below:

- Equal to or over the Age of Majority.
- Personal access to a computer and/or smartphone for app download.
- Heart Failure (reduced and preserved ejection fraction) AND/OR
  Atrial Fibrillation with CHA2DS2-VASc score greater than or equal to 2 in men and greater than or equal to 3 in women AND/OR
  T2D and ASCVD, defined as follows:
  --Known CAD, prior ACS, or coronary artery revascularization.
  --Prior TIA/stroke or known carotid or intracerebral atherosclerosis.
  --Prior PAD including requiring revascularization.

We will be asking about 750 individuals to take part in this study. When we reach our goal, we will close the study to anyone else who wants to participate. It is possible that you could be getting ready to begin the study, and we might reach our target. If that happens, you will be unenrolled.

RISKS OF ROUTINE AND STUDY PROCEDURES
There are some minor risks that come from participating in this study. Possible risks of routine care include:

- Blood samples: Possible side effects from taking your blood include faintness, swelling of the vein, pain, bruising, or bleeding at the site where the needle went in. There is also a slight chance of infection.
- Changes in Medication: Your doctor may change your medication and/or the amount you take; this could result in side effects related to the new or change in current medication dosing.

Possible risks of study procedures include:

- Surveys: Information or data will be collected about your care. The study staff will do everything possible to protect the data collected during the study, but there is a chance that it could be hacked or leaked. Some people feel uncomfortable when answering questions about the quality of their life. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

TERMS OF USE RISK
As part of this research, you may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor.

While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research subject.

UNFORESEEN RISKS
Since the study is investigational, there may be other risks that are unknown.

BENEFITS
You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from participation in this study. Information learned from the study may help other people in the future.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

COMPENSATION FOR PARTICIPATION
«Compensation»

You will not receive any monetary compensation for your participation in this study.

COSTS
There will be no charge to you for your participation in this study.

VOLUNTARY PARTICIPATION
Your participation in this study is voluntary. You decide whether you will participate or not. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. If you decide to participate, you will be required to fill out the fields below for your consent to confirm your participation. If you decide to stop participating during the study, please let your study doctor know. This will not affect your relationship with your study doctor. However, please note that the Food and Drug Administration requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

ALTERNATIVES

This research study is for research purposes only. The only alternative is to not participate in this study.

CONFIDENTIALITY

Records of your participation in this study will be kept confidential except when sharing the information is required by law or as described in this informed consent. The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

FUTURE RESEARCH STUDIES

Identifiers might be removed from your identifiable private information collected during this study and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

❒YES (If yes, please complete the information below)
❒NO

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00060259.

CONSENT

I voluntarily give my consent to participate in this study. I have read the information above. I was given the opportunity to ask questions and these were answered satisfactorily and to my contentment.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this **TRANSFORM^3** study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers. Health data may also be obtained from data captured on you in clinical registries.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of *American College of Cardiology*
- Representatives of *St. Luke's Health System*
- Representatives of *Massachusetts General Hospital*
- Representatives of *Brigham and Women's Hospital*
- Representatives of *Biofourmis*
- Representatives of *Veradigm*
- Representatives of *Bristol Myers Squibb,* study sponsor (de-identified data)
- Representatives of *Pfizer,* study sponsor (de-identified data)
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the study staff and sponsor and need to access your information to conduct this study.
- Other study doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- For other research activities related to cardiovascular outcomes in subjects with heart failure, atrial fibrillation, type 2 diabetes and atherosclerotic cardiovascular disease

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date