This notice is applicable to participants of the original *CTRIAL-IE (ICORG) 08-01 CADY study*: *Detection of Cardiac Dysfunction in Patients Treated with Trastuzumab for HER-2 Positive Breast Cancer* which was conducted at the following hospitals:

Mater Misericordiae University Hospital/ Mater Private Hospital
Beaumont Hospital
Our Lady of Lourdes Hospital, Drogheda
St Vincent's University Hospital
St James' Hospital
Tallaght University Hospital
Cork University Hospital
Bon Secours Hospital, Cork
University Hospital Galway
University Hospital Limerick
University Hospital Waterford
Sligo University Hospital
Letterkenny University Hospital

In the original study we asked participants for consent for future testing in the event that further tests related to breast cancer research became available in the future. The data and biological samples for the original study were stored for this purpose at the following facilities, respectively, in connection with the original study:

HRB Clinical Research Facility Galway, University Hospital Galway, Newcastle Road, Galway (study data)

Clinical Chemistry laboratory, Tallaght University Hospital Laboratory, Tallaght, Dublin 24 (biological samples)

This notice serves to describe the further research (sub-study) and the processing of personal data and the biological samples collected from the original study participants who consented in connection with the further research. The new research is sponsored by Cancer Trials Ireland and is being conducted together with Abbott Laboratories.

The sub-study will involve re-testing the biological samples with newly available, more sensitive test kits for an additional cardiac biomarker, Galectin 3. We will also collect Major Adverse Cardiovascular Event (MACE) and survival data of participants through a medical record review. The research aims to assess the predictive power of biomarker test results and the MACE data in forecasting cardiac dysfunction in breast cancer patients treated with Trastuzumab and to develop a predictive model using machine learning techniques for cardiotoxicity from the new biomarker test results, the MACE and survival data together with the left ventricular ejection fraction (LVEF) data that was collected in the original study.

We would hope that this research would enable identification of patients at risk of cardiovascular events as a result of trastuzumab treatment for breast cancer, and benefit future breast cancer patients by reducing risk of serious illness or death.

Cancer Trials Ireland, RCSI House, 121 St Stephen's Green, Dublin 2, D02 H903, Ireland is responsible for the personal data being processed in this study. As the data will be transferred to Abbott Laboratories which is located outside the European Union/ European Economic Area, the data will be protected by Abbott according to the EU-U.S. Data Privacy Framework.

The legal basis for processing the personal data is legitimate interest for scientific research purposes, specifically breast cancer research.

Personal data will also be shared with the HRB Clinical Research Facility Galway at the University Hospital Galway which will perform the statistical data analysis. The Clinical Research Centre at the Department of Medicine at the University College Dublin, Belfield, Dublin 4 will perform the biomarker analysis.

Data will be identified (coded) by the original study participant numbers - study participant names are never shared beyond the hospital site where participants were enrolled in the original study. The coded data and samples are stored securely and access is limited to only authorised staff who require it to manage, analyse and report on the study. The data will be stored for 7 years after the study is completed.

Data including health and medical history, test results, study treatments, disease course, response to study treatment will be collected from participants' medical records as follows:

- Vital status: alive, dead (date of death, reason of death, cardiovascular death), lost to follow up, date of most recent follow up, date of recurrence (second breast cancer), treatment on recurrence
- Cardiovascular Event Information including relevant dates: heart failure: symptomatic/asymptomatic, symptom assessment, admission to hospital; myocardial infarction; revascularization (balloon/stent; percutaneous coronary intervention, coronary artery bypass grafting); stroke; arrythmia - atrial/ventricular
- Attendance at Cardiology Outpatient Department (OPD) including relevant dates/reasons.

Data subjects have the following rights related to their personal data:

Participants in the original study who consented to future research have the right to withdraw consent to participation in the sub-study at any time without having to give a reason. Participants also have the right to request access to and rectification or erasure of personal data, the right to object to processing, the right to data portability meaning participants can obtain and reuse their personal data for their own purposes. These rights are possible until such time that the data is irrevocably anonymised.

To exercise these rights, the study doctor at the cancer clinical trials unit at the hospital site of enrolment to the original study should be contacted in the first instance to preserve your identity. However you may also direct any queries about how personal data will be collected, used and shared in the sub-study to the Cancer Trials Ireland Data Protection Officer at dataprotection@cancertrials.ie or as follows:

Cancer Trials Ireland, RCSI House, 121 St Stephen's Green, Dublin 2, D02 H903, Ireland
Tel: +353 (0)1 6677211
Fax: +353 (0)1 6697869
Email: info@cancertrials.ie

Participants also have the right to lodge a complaint to the supervisory authority . Refer to the following for online contact form / current contact details:
https://www.dataprotection.ie/en/contact/how-contact-us