Clinical Trials

Overview

Hologic is committed to preserving the health and dignity of individuals with whom we interact. This includes conducting our clinical trials in compliance with the highest scientific, ethical and regulatory standards.

Clinical Trial Governance

All clinical trials are designed to comply with applicable U.S. and international regulations, standards and guidelines for human subjects protection and ethical review of clinical trials, including Standard 14155 (Clinical investigation of medical devices for human subjects – Good clinical practice) of the International Organization for Standardization (ISO) and the Declaration of Helsinki. This includes obtaining participants' free and prior informed consent before they participate in any clinical trial. When we can use leftover remnant samples for which we do not know the identity of the individual who provided it in our clinical studies, we seek to ensure the samples are collected ethically. All clinical trial protocols are reviewed by an independent Institutional Review Board (IRB) or Ethics Committees (EC) as required for each region. These IRBs and ECs have the authority to approve, modify or stop clinical trials. We have departments of highly trained employees dedicated to conducting clinical trials in the U.S. and globally. These personnel are governed by Hologic policies and procedures designed to meet regulations, standards and best practices in clinical trials.

Confidentiality and Privacy Assurance and Grievance Mechanisms for Clinical Trial Participants

Hologic recognizes the importance of maintaining the privacy of an individual's health information when participating in a clinical trial. We must comply with applicable U.S. and international regulations such as those limiting the health information we are allowed to collect for our trials, and those requiring strong security of clinical trial databases. A Principal Investigator (PI) at clinical sites is responsible for participant care. The PI is aided by Hologic's Technical Support and Clinical Affairs, who act as first-line contacts for our investigational clinical sites.

Reporting on Violations in Clinical Trials and Corrective Actions

Some of our clinical trials are subject to clinical trial site and sponsor audits under global regulatory bodies including FDA's Biomedical Research Program. To date, these regulatory

audits and inspections of clinical trials have resulted in no major findings at either the clinical site or Hologic. Hologic is committed to a quality system approach and conducts regular internal audits of procedures and policies.

Risk Management

Prior to and During Ongoing Clinical Trials Our clinical trials are managed by Hologic's Clinical Affairs department. The Clinical Affairs teams, in partnership with R&D, is responsible for ensuring compliance with product development procedures, which include phase exit reviews. In addition, our core teams have internal department-level documents that contain risk mitigation processes.

Registration of Clinical Trials in Publicly Available Databases

When required, we must register clinical trial data and results, including terminated clinical trials, on public websites such as ClinicalTrials.gov. This transparency helps our customers make informed decisions about the safety and efficacy of our products

The Company is also committed to preserving the health and dignity of individuals with whom we interact, including, but not limited to, conducting our clinical trials in compliance with the highest ethical, scientific and clinical standards.

TRANSPARENCY

We are committed to the principle of transparency. We uphold high ethical, scientific, and medical standards in our R&D activities, and this includes reporting of clinical trial results,

Diversity in Clinical Trials

Aligned to our commitments to diversity, equity, and inclusion, we continue to seek ways to remove barriers to clinical trial participation and provide equitable and inclusive participation.