ForPatients
by Roche

Solid Tumors

#A#study#to evaluate#the use of a smartphone application and biosensor by cancer participants undergoing systemic treatments.

Evaluating the Use#of#a#Smartphone#Application#and Biosensor by Cancer#Patients Undergoing Systemic Treatments

Trial Status	Trial Runs In	Trial Identifier
Not Yet Recruiting	1 Countries	ML41539

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

Cancer#is#a disease in which abnormal cells divide without control and can invade nearby tissues.#Cancer cells can also spread to other parts of the body through the blood and lymph systems.#Cancer#can be of different types, with one of them being#solid tumours.#Solid cancers are defined as abnormal cellular growths in "solid" organs such as the breast or prostate#and#does not contain cysts or liquid areas.#The treatment for such tumours#involves#surgery, chemotherapy, chemoradiation, etc. While on treatment, participants may#require#emergency visits#to the hospital due to#treatment-related symptoms such as pain, nausea#(the#uneasiness of the stomach that often comes before vomiting), and dehydration.#These symptoms may be preventable with earlier symptom management#by#monitoring#them.#The study aims to resolve this by helping#doctors and the#participant#care team with real-time data so that they may help#participants#before their symptoms reach critical levels to reduce emergency department visits and inpatient hospital stays.#The main purpose of this study is:

- To evaluate the feasibility and usability of the#patient-facing smartphone application (APP) and Sensor technology
- To determine how well the APP captures, stores, transmits, and retrieves from the cloud the participant data that has been collected
- To assess the overall participant satisfaction with the Sensor and APP
- To assess the participants' compliance to use the Sensor and the APP
- To validate#self-reported emergency department (ED) visits and in-patient (IP) hospital visits
- To evaluate the feasibility of Electronic Case Report Form (eCRF) data collection and submission

F. Hoffmann-La Roche (USA)
Sponsor

ML41539
Trial Identifiers

ForPatients
by Roche

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	**18-80 years**	**No**

Who can participate?
People aged between#18#to#80#years#with a confirmed diagnosis of solid tumours.

What does the study involve? Participants may be asked to be in the study for#a maximum of#12 months.#This includes:

- Initial Survey: The participant will be asked to fill up a 10-min basic survey regarding#demographics (education, marital status, income, etc.), health information and technology ownership and technology use for health purposes
- Observation Phase:#Participants will be provided with a pre-paired Samsung Galaxy Watch3 and a Samsung Galaxy A12 smartphone with the pre-installed Project Zebra app. The participant will be asked#to wear a Samsung Galaxy Watch3 biosensor device, which#will automatically measure#the#vital signs (heart rate, oxygen level in blood, activity, sleep and falls), and to complete daily surveys regarding the symptoms and any unplanned visits to the hospital or emergency department, daily, for a#2-week#or 6-week#period
- Interview or Focus Group:##After#completion of the Observation Phase, some participants#may be asked to participate in an interview or focus group via phone or video conferencing. If#selected, they#will be asked questions about#the#experience with the sensor and the app
- At the end of the study period, participants will be asked to return the Samsung Galaxy Watch3 biosensor and Samsung Galaxy A12 smartphone to the care team and complete a qualitative survey

Participants will be#recruited#in one of the following#Phase:

- Vanguard Phase:##The participants will be asked to wear the Sensor and use the APP#24-hours, daily#for#a period of#2 weeks
- Operational#Phase:#If the Vanguard Phase is completed, the participants will#be#recruited in this phase and will#be asked to wear the Sensor and use the APP#24-hours, daily#for up to 6#weeks.

What are the possible benefits and risks of participating?
Participants will not receive any#direct medical#benefit from participating in this study, but the information#will#help researchers and doctors to learn more about improving side effect management and reducing unnecessary trips to the emergency department and hospital.#Also, they#will receive a total of $115#in two-parts#for#their#participation in the study.

There are no#major risks from participating in the#study,#but participants may#experience the following:

- Wearing the Samsung Galaxy Watch3 may cause skin irritation and discomfort
- A#small risk of becoming distressed from reflecting on#the#symptom and emergency department and hospital visits while completing the in-app questionnaire and study surveys
- Although the sponsor takes great care to protect participant's information, there is a slight risk of loss of confidentiality.
- There are potential safety risks associated with the use of the Samsung Galaxy Watch3 which include inhalation or swallowing of small parts can be dangerous or even fatal, burns and explosions if batteries are exposed to fire, etc.
- There are potential safety risks associated with the use of the Samsung Galaxy A12 smartphone which include electric shocks, if the device is wet or used with wet hands while charging, prolonged use might increase the device temperature

Where is the study run from?
Genentech (USA)

When is the study starting and how long is it expected to run for?
December 2020 to October 2023

Who is funding the study?
F. Hoffmann-La Roche (USA)

Who is the main contact?
Dr Elaine Yu, global-roche-genentech-trials@gene.com