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

Submission date 05/01/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 07/01/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 05/01/2022	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
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

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 Phases:
-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

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
ML41539

Study information

Scientific Title
Evaluating the use of a smartphone application and biosensor by cancer patients undergoing systemic treatments

Study objectives
The aim of this study is to evaluate the feasibility and usability of the patient-facing smartphone application (APP) and Sensor technology in participants with cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/12/2021, FRED HUTCH Institutional Review Board (Hutchinson Institute for Cancer Outcomes Research 1100 Fairview Avenue North, M3-B232 Seattle, WA 98109; no telephone number provided; IRO@fredhutch.org), ref: 15/11/2021

Study design
Phase IV multi-centre prospective cohort-based observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied

Cancer (Solid Tumour)

Interventions
Vanguard Phase Cohort: Participants will be asked to wear the Sensor and use the APP for 2 weeks. At the end of the observation period, participants will be asked to complete the modified versions of the “Standalone Mobile Health App for Patients” modified mHealth App Usability Questionnaire (MAUQ) and the Modified Quebec User Evaluation of Satisfaction with assistive Technology (QUEST) questionnaires within the APP. Some participants will be asked to take part in a phone or video conferencing qualitative interview or focus group based on adherence to APP electronic patient-reported outcomes (ePRO) Survey and Sensor.

Operational Phase Cohort: Participants will be asked to wear the Sensor and use the APP for 2 weeks after the last dose of cancer therapy or till the end of the 6-week observation period, whichever comes first. At the end of the observation period, participants will be asked to complete the modified MAUQ and QUEST questionnaires within the APP. Some participants will be asked to take part in a phone or video conferencing qualitative interview or focus group based on adherence to APP ePRO Survey and Sensor.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Smartphone application and biosensor

Primary outcome(s)
1. Feasibility of the study recruitment protocol measured by the number of participants screened each month during enrolment in Vanguard and Operational phase
2. Feasibility of the study recruitment protocol measured by the percentage of screened participants who are eligible each month during enrolment in Vanguard and Operational phase
3. Feasibility of the study recruitment protocol measured by the percentage of eligible participants who consent each month during enrolment in Vanguard and Operational phase
4. Feasibility of the onboarding protocol as measured by the percentage of consenting participants with a successfully activated app and sensor in Vanguard phase of 2 weeks and Operational phase of 6 weeks
5. Feasibility of the onboarding protocol as measured by the percentage of consenting participants who successfully complete the APP electronic participant-reported outcomes (ePRO) survey and record and store or transmit sensor data within 24-hours of onboarding in Vanguard phase of 2 weeks and Operational phase of 6 weeks
6. Completeness of data capture as measured by the percentage of completed ePRO APP surveys successfully transmitted, stored, and retrieved from the secure cloud environment during the observation period or prior to discontinuation in Vanguard phase of 2 weeks and Operational phase of 6 weeks
7. Completeness of data capture as measured by the percentage of the sensor data collected from the participants successfully recorded or transmitted, stored, and retrieved from the secure cloud environment during the observation period or prior to discontinuation in Vanguard phase of 2 weeks and Operational phase of 6 weeks
8. Completeness of data capture as measured by the number of days sensor data was successfully collected during the observation period in Vanguard phase of 2 weeks and

Operational phase of 6 weeks
9. Participant assessment of usability of the APP measured using the Modified mHealth App Usability Questionnaire (MAUQ) Average Score in Vanguard phase of 2 weeks and Operational phase of 6 weeks
10. Participant assessment of usability of the APP measured using the average time to complete the emergency department (ED) visits/inpatient (IP) admissions questions and the symptoms questions within the ePRO APP survey in Vanguard phase of 2 weeks and Operational phase of 6 weeks
11. Participant assessment of usability of the APP measured using the time spent on each screen in Vanguard phase of 2 weeks and Operational phase of 6 weeks
12. Participant assessment of usability of the APP measured using the screens on which participants selected/pressed more cancelation operations in Vanguard phase of 2 weeks and Operational phase of 6 weeks
13. Participant overall satisfaction with the APP as measured by item 12 of the Modified MAUQ in Vanguard phase of 2 weeks and Operational phase of 6 weeks
14. Participant satisfaction of the sensor as measured by the Modified Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) average score in Vanguard phase of 2 weeks and Operational phase of 6 weeks
15. Participant adherence to the APP ePRO survey as measured by the ratio of the completed ePRO surveys to the number of required completed ePRO APP surveys prior to discontinuation or end of the observation period in Vanguard phase of 2 weeks and Operational phase of 6 weeks
16. Participant adherence to wearing and synchronizing the sensor as measured by the ratio of days with any sensor data to the number of days prior to discontinuation or end of the observation period in Vanguard phase of 2 weeks and Operational phase of 6 weeks
17. Participant adherence to wearing and synchronizing the sensor as measured by the percentage of the total required time the participant wears the sensor during the observation period prior to discontinuation or end of the observation period in Vanguard phase of 2 weeks and Operational phase of 6 weeks
18. Validity of Self-reported ED and In-patient hospital visits as measured by the percentage of true positive Self-reported ED visits/IP admissions compared to a chart review in Operational phase of 6 weeks
19. Feasibility of electronic case report form (eCRF) data collection and submission as measured by the number of participants with electronic data capture (EDC) flags (incomplete or incorrect eCRF entries) in Operational phase of 6 weeks
20. Feasibility of electronic case report form (eCRF) data collection and submission as measured by the number of EDC flags for those participants at the end of the Operational phase (week 6)

Key secondary outcome(s))

1. Participant persistence with ePRO APP survey completion measured from the first day the participant completes the ePRO APP survey to the first 2 consecutive days of an incomplete or missing ePRO APP survey within the Vanguard phase of 2 weeks and Operational phase of 6 weeks
2. Participant persistence with wearing and synchronizing sensor measured from the first day the sensor data is recorded on the sensor or transmitted to and stored in the secure cloud environment to the first 2 consecutive days without any sensor data recorded on the sensor or transmitted to the secure cloud environment within the Vanguard phase of 2 weeks and Operational phase of 6 weeks

Completion date

31/10/2023

Eligibility

Key inclusion criteria
1. Participants must be between 18-80 years of age
2. Have a biopsy-proven current diagnosis of cancer. Cancer may be metastatic or non-metastatic, but the cancer type must be a solid tumour. Participants with current blood cancers are not eligible but those who have a history of a blood cancer, have completed therapy at least 12 months prior to enrolment, and are considered NED (no evidence of disease) are eligible
3. Scheduled to receive, or within 4 weeks following first dose of intravenous (IV) or oral cancer systemic therapy as an initial or a new line of treatment for their current disease
4. Able to wear the selected Sensor daily and as advised by the manufacturer's device instruction manual
5. Able to provide informed consent, understand and provide information for study forms and in APP ePRO survey and questionnaires in English
6. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-2 at enrolment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. Plan to receive radiation or hormone therapy only
2. Diagnosed with non-melanoma skin cancer or haematological malignancies only
3. Wearing pacemakers, implantable cardioverter defibrillators, cochlear implants, and/or neurostimulator devices
4. Living in a nursing home or skilled nurse facility at the time of enrolment
5. Participating in a clinical trial
6. Citizen of the European Union
7. Pregnant

Date of first enrolment
10/01/2022

Date of final enrolment
10/07/2022

Locations

Countries of recruitment
United States of America

Study participating centre
PeaceHealth
United General Sedro Woolley
Sedro Woolley
United States of America
98284

Study participating centre
Skagit Valley Hospital; Regional Cancer Center
Mt Vernon
United States of America
98273

Study participating centre
Virginia Mason Medical Center
Seattle
United States of America
98101

Sponsor information

Organisation
Roche (United States)

ROR
https://ror.org/011qkaj49

Funder(s)

Funder type
Industry

Funder Name

F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to participant-level data not being a regulatory requirement.

IPD sharing plan summary
Not expected to be made available