A remote evaluation of NAVIFY Oncology Hub using clinical simulation

Study Management Group

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This protocol describes the *A remote evaluation of NAVIFY Oncology Hub using clinical simulation* and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Study Management Group.

This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research. It will be conducted in compliance with the protocol, Data Protection Act 2018 and General Data Protection Regulations (Europe) and other regulatory requirements as appropriate.

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1. INTRODUCTION

1.1 Background

NAVIFY Oncology Hub is a platform that aggregates and organizes disparate data into an intuitive, longitudinal view of the patient's cancer care journey.

The platform is designed to optimize and support oncology workflows and decision-making by providing quick access to the most relevant data in one place, so that providers can make decisions more efficiently and collaborate more seamlessly.

Clinical workflow is critical for the efficient and safe delivery of patient care. In most healthcare settings, clinical workflow is highly complex, and reflects the multidisciplinary collaboration and communication required of most clinical tasks. Studies have demonstrated a positive association between leveraging health information technology workflow tools for care coordination and patient engagement, and improved process quality metrics in preventive screening, diabetes control, as well as maternal and child health (Kruse & Bean 2018; Kranz et al. 2018). Embedded decision support tools have also been proven to improve the performance of risk assessments conducted by providers, as well as enhance patient safety and decrease mortality (Chaudhry et al. 2006; Wells et al. 2008; Jones et al. 2014; Campanella et al. 2015).

This research protocol builds on previous work that validated clinical simulation methods as a means for clinicians to generate useful insights during the testing and development of digital health tools (Gardner et al. 2020).

1.2 Study Rationale

This work seeks to understand current clinical workflow practice and validate use cases for NAVIFY Oncology Hub.

The main purpose of NAVIFY Oncology Hub is to enhance clinical and operational effectiveness, from diagnostic workup to treatment planning and management. This might free up providers' time and capacity to provide better and more personalized care to patients.

Accordingly, this study aims to test the ability of NAVIFY Oncology Hub to increase the work efficiency of oncologists and reduce the cognitive burden/mental fatigue associated with patient care and decision-making.

The insights generated will be used to guide the development of NAVIFY Oncology Hub and optimise user experience, as well as provide a better understanding of the opportunities for it to have maximal impact in the decision-making process.

2. STUDY OBJECTIVES

This work seeks to generate evidence and insights that will inform product development and support go-to-market activities for NAVIFY Oncology Hub.

2.1 Study objectives

This work is designed as a 2-phase study.

Phase 1 objectives (semi-structured interviews):

1. Understand current clinical practice
2. Validate use cases of NAVIFY Oncology Hub

Phase 2 objectives (simulation study):

1. To assess the usability of NAVIFY Oncology Hub
2. To assess the efficiency of using NAVIFY Oncology Hub
3. To assess the mental effort required with using NAVIFY Oncology Hub
4. To gather feedback on the study methods

3. STUDY DESIGN

This study will run over 2 phases.

Phase 1 (semi-structured interviews) – We will conduct a total of 12 semi-structured interviews with 12 US oncologists. These interviews will seek to:

(i) Understand incumbent clinical practice for activities that NAVIFY Oncology Hub is seeking to improve, for example, accessing cancer patient data, and care coordination.
(ii) Validate use cases of NAVIFY Oncology Hub and its perceived benefits, for example, reducing cognitive burden, increasing shared decision-making, etc.

There are 5 proposed use cases for NAVIFY Oncology Hub:

1) New patient consultation
2) Returning patient, follow-up visit
3) Cross team care coordination
4) Facilitating patient discussions and education
5) Enrichment of the patient record

The results from Phase 1 will inform potential adjustments to simulation study procedures for Phase 2, such as the duration of the simulation sessions.

An interview guide has been provided in Appendix B.

Phase 2 (simulation study) – This phase of the study will have approximately 30 US oncologists. We will first conduct a small number of simulation sessions (3-5) to validate study methods and data collection procedures. Study methods may then be refined before conducting simulation sessions with a larger number of participants (approx. 25).

In this phase, each participant will participate in a 90-minute simulation session in which they will use NAVIFY Oncology Hub to review synthetic patient cases. Participants will be tasked with reviewing the cases as if they were preparing to see a patient in a real clinical setting. This task will involve searching for, identifying, reviewing and synthesizing relevant clinical information (demographic information, pathology reports,

clinical course, etc.) that supports decision-making. As such, this task is meant to simulate the same activities they would perform in their typical practice before inviting a patient into the clinic room for a consultation, and will permit this study to examine the usage of NAVIFY Oncology Hub on those activities.

Ultimately, the aim of the study is to investigate how NAVIFY Oncology Hub improves efficiency and reduces cognitive burden associated with reviewing and synthesizing patient information, and having participants engage with the platform requires them to go through those tasks.

4. STUDY POPULATION

US adults, age 18 and older, fluent in written and spoken English who are board-certified oncologists with an MD/DO degree from an accredited institution. Participants will be affiliated with a healthcare institution where they are an active member of a tumor board and spend at least 50% of their time in clinical practice. We will recruit a mix (as equal as possible) of oncologists based in a community setting and those based in larger academic centers. Because prior work demonstrates an influence of oncologist experience on treatment outcomes (Go et al. 2015; Huntington et al. 2018; Shanafelt et al. 2012), we will include a mix of participants in terms of experience and type of practice institution. All participants will perform at least five clinical sessions per week.

5. STUDY PROCEDURES

5.1 Recruitment

We will recruit potential participants working in the United States for a remote study. Potential participants will be identified and recruited by the Prova Health team through email and phone. For those who meet criteria and agree to participate, a digital or written informed consent will be obtained. They will then be scheduled for the remote simulation session.

5.2 Conduct of semi-structured interviews

Semi-structured interviews: Participants will participate in a 60-minute remote (e.g., online) interview. A topic guide for the interview can be viewed at Appendix B. During scheduling, participants will be given a link to use to join the session. This link will take them to a video conference call hosted through Google Meet. The interviewer will use Google Meet to record the participant's audio. At the conclusion of the session, participants will be compensated.

5.3 Conduct of simulation sessions

Simulation sessions: Participants will participate in a 90-minute remote (e.g., online) simulation session. During scheduling, participants will be given a link to use to join the session. This link will take them to a video conference call hosted through Google Meet. At the session, the moderator will facilitate the session and take notes. The moderator will be a member of the Prova Health team with clinical practice

experience. At the beginning of the session, participants will be instructed to share their screen with the moderator so that participants' use of NAVIFY Oncology Hub can be recorded. The moderator will then use Google Meet to record the participant's screen. Participants will be instructed to turn off their camera to preserve anonymity while ensuring data retention. At the conclusion of the session, participants will be compensated.

A timeline of the simulation sessions is provided below.

Activity	**Duration (mins)**
Introductions and consent	5
Review of simulation session guide	5
Training on NAVIFY Oncology Hub	20
Prepare 10 cases using NAVIFY Oncology Hub	50
Post-Simulation Survey	10
Total	90

5.3 Ensuring fidelity during remote participation

Participants will participate in the simulation sessions remotely (e.g., using an online video conference call). To ensure data visual fidelity, we will request that participants close any other programs that involve heavy internet usage (e.g., internet browser other than the one used for participation, video conferencing software) and mute their cell phone to minimize the risk of interruption of the study. They will also be requested to use headphones for the duration of the study, to ensure all instructions are heard clearly.

The only requirements for remote participation will be a web browser and an internet connection. Participation will occur through Google Meet video conferencing software. This platform does not require that participants download anything; participants can join from a standard internet browser. During scheduling for both the training and simulation sessions, participants will be given a link to Google Meet for the session.

Prova Health will provide support to ensure internet connections and access. If the participant is removed from the video conference call, Prova Health's personnel will attempt to re-contact. If the participant's computer is no longer functional or if the participant's computer no longer has internet access, an attempt will be made by Prova Health personnel and the participant to correct the issue. If this is not successful in a reasonable amount of time (accounting for the participant's schedule and any subsequent testing sessions), the session will be terminated. If the session is terminated before the participant has begun preparing cases, the participant will be rescheduled for a new session (if they are interested in continuing to participate). This session will be treated as an entirely new session (e.g., the participant will complete all measures). However, if the participant had already begun preparing patient cases, the participant will not be rescheduled.

5.4 Case Construction

A set of 10 synthetic breast cancer patient cases will be developed by Prova Health. Cases will include history and examination findings, pathology reports, radiology reports and images (USS, mammogram, CT as applicable) and reports on tumor characteristics. The case details will be representative of a long term patient journey, inclusive of treatment lines such as adjuvant and neoadjuvant therapies.

Cases will be selected to span the range of potential case scenarios seen in typical practice. Specifically, cases will be selected to include common invasive breast cancers (eg. IDC, ILC), as well as less common invasive breast cancers (eg. inflammatory). Cases will also represent a range of cancers with different molecular subtypes, such as whether the patient is HER2 positive or negative, hormone receptor (HR) positive or negative or triple negative. Finally, cases will also reflect the presentation of patients at various stages (eg. primary diagnosis, locally and regional advanced breast cancer, recurrent breast cancer, or metastatic advanced breast cancer).

6. STUDY VARIABLES AND MEASURES

6.1 To assess the usability of NAVIFY Oncology Hub

At the end of the simulation session, some of the study's outcome measures will be collected via a **Post-Simulation Survey** (see Appendix A). The usability of NAVIFY Oncology Hub will be assessed using the System Usability Scale (SUS), a 10-item validated questionnaire for assessing the usability of websites and software applications.

In addition, useful information from a product development perspective will be collected on the Post-Simulation Survey, for example:

- Which aspects of NAVIFY Oncology Hub did you find **most useful**?
- Are there any **changes you would make to NAVIFY Oncology Hub** if you could?
- What aspects of NAVIFY Oncology Hub were **most challenging**?
- How **likely would you be to use** NAVIFY Oncology Hub in your typical practice?
- How **likely would you be to recommend** NAVIFY Oncology Hub to your colleagues?

The participant's screen will also be recorded using Google Meet. This will be used to corroborate moderator recordings. These recordings will also be available to the funder to provide user insights to support product development.

6.2 To assess the efficiency of using NAVIFY Oncology Hub

The Post-Simulation Survey will be used to measure the perceived efficiency of using NAVIFY Oncology Hub when compared to standard practice.

The moderator will also note the start and finish time for each case, which will permit measurement of 1) Time spent on each case, and 2) Overall session time.

6.3 To assess the mental effort required with using NAVIFY Oncology Hub

The mental effort required to prepare each individual case will be measured subjectively in the Post-Simulation survey using the **NASA Task Load Index (NASA TLX)**. This 6-item multi-dimensional scale assesses mental demand, temporal demand, performance, effort and frustration. We recommend the use of this measure because it has been well-validated (Hart, 2006) and used widely across a number of domains, including research on those in the medical community (Hoonakker et al. 2011; Mazur et al. 2012; Ruiz-Rabelo et al. 2015; Sartang et al. 2017; Young et al. 2008). It has been specifically designed to assess the workload associated with a given task, one of the key objectives of this study.

6.4 To gather feedback on the study methods

As clinical simulation is a relatively novel methodology to assess digital health technologies, additional questions on the use of clinical simulation will be put to participants on the Post-Simulation Survey. Example questions/topics include:

- How **similar the cases were to the cases the participant typically prepares** in their day-to-day practice in terms of complexity, demographics, information available, prognosis, etc.?
- How **similar was this task** to tasks you complete during a typical week?
- How **difficult did this task seem to you**? What made it more or less difficult?

On the Post-Simulation Survey, additional questions will be asked to provide useful information about each oncologist's clinical experience and familiarity with digital solutions. For example, how many patients the participant typically sees each week, how many many years the participant has spent as part of a tumor board in their career, what information they typically review before seeing a patient, what solutions/technologies the participant might use to prepare for consultations and collaborate with colleagues. See the full Post-Simulation Survey at Appendix A.

7. ANALYSIS

Thematic analysis of interview outputs will be performed by reviewing recordings from study participants in Phase 1. This analysis seeks to validate potential benefits and use cases for NAVIFY Oncology Hub, especially in areas such as accessing cancer patient data, care coordination, cognitive burden and shared decision-making.

Data from the simulation sessions will involve calculating summary descriptives (e.g., means and percentages) on case-specific endpoint measures. Counts or percentages may also be calculated on tabulated responses to survey questions to determine whether certain themes regarding the study participants' participation experience prove common across the participants and, therefore, warrant attention.

8. REGULATORY ISSUES

8.1 Ethics approval

Prova Health will obtain approval from a provider of Institutional Review Board (IRB) services based in the US. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2 Consent

Consent to enter the study must be sought from each participant only after a full explanation has been given, with an information leaflet offered and time allowed for consideration. Signed participant consent should be obtained. The right of the participant to refuse to participate without giving reasons must be respected. All participants are free to withdraw at any time.

8.3 Confidentiality

The Study Management Team will preserve the confidentiality of participants taking part in the study and fulfil transparency requirements under the General Data Protection Regulation for health and care research. Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study.

8.4 Indemnity

Prova Health and its subcontractors hold negligent harm insurance policies which apply to this study.

8.5 Sponsor

Prova Health will act as the main Sponsor for this study.

8.6 Funding

Hoffman-La Roche Ltd. are funding this study under the terms of the Research Agreement for an Investigator Initiated Study entered into between Prova Health and F. Hoffmann-La Roche Ltd.

Participants will be compensated for their time, with the amount varying by level of experience, as specified by Roche HCP Services Fair Market Value Guidelines. For those deemed Local Thought Leaders, compensation will be no more than $400 per hour; those deemed Region Thought Leaders will be compensated at a rate of no more than $520 per hour; those deemed National Thought Leaders will be compensated no more than $660 per hour.

9. STUDY MANAGEMENT

The management of the study will be coordinated by the study team at Prova Health and Roche/Genentech.

Principal Investigator, providing oversight and accountability:

- Dr Saira Ghafur, Chief Medical Officer, Prova Health

Day-to-day management of the study:

- Dr Jack Halligan, Chief Operating Officer, Prova Health

- Dr Ethan Goh, Digital Health Consultant, Prova Health

Significant involvement of senior staff providing advice and guidance:
- Gianluca Fontana, Chief Executive Officer, Prova Health

Additional guidance provided by Roche/Genentech:
- Clinical subject matter expertise (e.g., review of cases) provided Dr Ernie Lo, Senior Director Medical Affairs, Roche Information Solutions
- Study management (e.g., feedback on study design, coordinating access to NAVIFY Oncology Hub) provided by Delphine Chabut, Healthcare Insights Evidence Lead, Roche Information Solutions

10. PUBLICATION POLICY

The results of the study will be written up in a report for Roche Information Solutions. Pseudonymised quotes from participants may be published along-side their job role. Participants will not be named in any reports/publications.

11. APPENDICES

Appendix A: Post-Simulation Survey (attached separately)

Appendix B: Interview guide

Intro

What are semi-structured interviews?

Semistructured in-depth interviews are commonly used in qualitative research and are the most frequent qualitative data source in health services research. This method typically consists of a dialogue between researcher and participant, guided by a flexible interview protocol and supplemented by follow-up questions, probes and comments. The method allows the researcher to collect open-ended data, to explore participant thoughts, feelings and beliefs about a particular topic and to delve deeply into personal and sometimes sensitive issues.

Source: Semi-structured interviewing in primary care research: a balance of relationship and rigour

Objectives of semi-structured interviews:

- **Understand current practice for oncology workflows** in a patient's cancer care journey by:
    - **Identifying and defining common denominators in the oncology workflow** *(characterize from each interviewee's experience: 1. actors involved, 2. workflows and interactions)*
    - **Understanding what kind of data matters, depending on the current phase of a patient's oncology care journey - across diagnostic workup, treatment planning and treatment management** *(which milestones matter? Diagnostic information, treatment response, relapses, treatment-related issues, etc.)*
    - **Understanding how healthcare IT systems are used in the oncology workflow to access data and coordinate care** *(cost and resource effectiveness, cognitive burden, user satisfaction, level of doctor-patient engagement, etc.)*
- **Inform the design of a study protocol and validate use cases** for NAVIFY® Oncology Hub using clinical simulation.
    - **Collect information on actual and/or potential use of NAVIFY® Oncology Hub in the interviewee's practice** with the objective to build the case for integrating NAVIFY® Oncology Hub into the workflow.
    - **Identify the most appropriate outcome measures** for the utility of NAVIFY® Oncology Hub in clinical practice.

NAVIFY Oncology Hub - Interview script

Introduction

Thank you for participating in this interview. We are seeking to understand how oncologists access cancer patient data and coordinate care in clinical practice. This project is funded by Roche/Genentech and the insights will be used to inform the design of a research study to evaluate a clinical workflow and decision support solution.

The interview will be recorded and will be used by Prova Health for note-taking only - it will not be shared with Roche/Genentech or with anybody else outside of the Prova Health team.

Do you have any questions before we start? *Answer any questions.*

Before we begin, are you happy for me to start the recording? *Start the recording.*

Interview Section	**Questions**
(i) Demographics	What is your role at the cancer center? *Probes:* ● How long have you worked here? ● What is the practice size and type? (eg. office based, clinical in-patient unit, academic center etc.) ● How many cancer patients per week would you typically see? ● Can you describe your clinical experience in oncology? ● How many years have you been working in this field? ● Do you work primarily for the cancer center or do you practice at multiple organizations?
(ii) Current clinical practice	We will ask you a number of questions on how you currently manage cancer patients in your practice. It will be important for us to understand as much as possible about how you conduct your consultations with cancer patients. What information/data do you look at **prior to consulting with a cancer patient**? *Probe:* ● Why is this data important? ● How long does it take you to gather this data?

	Can you talk us through, **step-by-step**, how you would come up with a management plan for a cancer patient during a consultation? *Probe:* ● What factors make the consultation productive or challenging?
(iii) Usage of healthcare IT systems	We will ask you a number of questions on how you use healthcare IT systems to access patient data and coordinate care. Can you describe how **healthcare IT systems support your current workflow?** *Probe:* ● What healthcare IT system(s) do you use? ● How easy is this system to use? ● How productive are you able to be with this system? ● Can you walk us through how your healthcare IT systems facilitate complex treatment decisions?
(iii) Barriers with current healthcare IT systems	What factors make the consultation challenging with the current healthcare IT systems? *Probe:* ● Thinking about the entire visit continuum, from pre-visit prep to the consultation, what kind of barriers to care exist with current healthcare IT systems? (e.g. effectiveness, cost, cognitive burden, patient engagement, provider satisfaction) ● How do you assess whether a healthcare IT system in your workflow was a worthwhile investment of your time and resources?
(iv) Use cases for NAVIFY® Oncology Hub	Thank you. We will now ask some questions about potential use cases for NAVIFY® Oncology Hub.

New patient consultation	Can you talk us through, **step-by-step**, how you use healthcare IT systems when assessing a new cancer patient? *Probe:* ● What parts of the consultation do they help with? ● Can you access all data from one system, or do you have to deal with multiple systems?
Returning patient, follow-up visit	Can you talk us through, **step-by-step**, how you use healthcare IT systems when assessing **returning cancer patients**? *Probe:* ● What parts of the consultation do they help with? ● Can you access the most relevant data for follow-up patients quickly? ● What additional information would have been helpful for you to have had on your returning patients?
Cross team care coordination	Can you describe how healthcare IT systems support your workflow in conveying information and **coordinating care** with other providers in the care team? *Probe:* ● Can you talk us through, **step-by-step**, how you would coordinate care with other providers? ● Are you able to quickly and concisely convey information and coordinate care between providers? ● **Overall, do you think healthcare IT systems** improve cross team care coordination? If yes, how do they help? Do you believe they have any impact on outcomes? ● What metrics would you use to help assess a good 'outcome' for cross team care coordination?
Facilitating patient discussions and education	How do you use healthcare IT systems to **facilitate discussion or to educate your patients** (if at all)? *Probe:* ● Have healthcare IT systems improved your patient interactions? ● Has it hurt your interactions with patients in any way? ● How much time do you spend communicating with patients?

Enrichment of patient record	How do you access and synthesize unstructured data on patient records? For example, a PDF report of a patient's biopsy results.

Conclusion

This brings us to the end of our interview. Thank you very much again for taking the time out to speak with us. As a next step, we will share a payment form for you to complete so that we can process payment for this interview. Before we finish, do you have any further questions?