SCHEDULE 4: LETTER OF APPOINTMENT

Medicines & Healthcare products Regulatory Agency

Dear Sirs

Letter of Appointment for the Public research project to evaluate the perception of risk associated with breast implants.

This letter of Appointment dated 29 November 2021, is issued in accordance with the provisions of the DPS Agreement (RM6018) between CCS and the Supplier.

Capitalised terms and expressions used in this letter have the same meanings as in the Contract Terms unless the context otherwise requires.

Order/Agreement Number:	C57378
From:	The Secretary of State for Health, acting through the Medicines and Healthcare products Regulatory Agency, whose office address is 10 South Colonnade, Canary Wharf, London E14 4PU (the "Customer" – also referred to as the MHRA in some instances).
To:	ESRO Limited T/A Revealing Reality, of The Ballroom, Maritime House, Grafton Square, Clapham, London SW4 0JW, registration number 05438122 (the "Supplier"). *Please note the Supplier intends to use the following sub-contractors for support in delivering this research project:* Yonder – Provider of the Omnibus Survey Taylor Mckenzie - Provider of some of the qualitative sample.

Effective Date:	01/12/2021
Expiry Date:	End date of Initial Period: 29/04/2022 End date of Maximum Extension Period: None Minimum written notice to Supplier in respect of extension: Not Applicable

Services required:	As set out in Section 2, Part B (Specification) of the DPS Agreement and refined by:

	The Customer's Project Specification contained at Annex A and the Supplier's Proposal contained at Annex B below. These form the required Statement of Work.

Key Individuals:	**Supplier's Key Individuals/Personnel:** ○ Project Director: Redacted under FOIA Section 40 Personal Info ○ Project Manager Redacted under FOIA Section 40 Personal [redacted] (key contact - Redacted under FOIA Section 40 Personal Info) ○ Project Advisor: Redacted under FOIA Section 40 Personal Info ○ Quantitative Lead: Redacted under FOIA Section 40 Personal Info Details of roles and responsibilities have been included in Annex B below. Summary CVs have been provided and can be found for review in the full Tender proposal. **Contact points for Customer:** ○ Research Account Manager: Redacted under FOIA Section 40 Personal Info - Redacted under FOIA Section 40 Personal Info ○ Project/Contract Manager: Redacted under FOIA Section 40 Personal [redacted] Redacted under FOIA Section 40 Personal Info
[Guarantor(s)]	Not Applicable.

Contract Charges (including any applicable discount(s), but excluding VAT):	Total Charge/Price up to **£47,637.50** excluding VAT (noting some fees may be variable). For the avoidance of doubt, the Contract Charges shall be inclusive of all third party costs. A breakdown has been provided and can be found in Annex B below.
Insurance Requirements	Employers' liability insurance with a minimum limit of £5 million. Professional indemnity insurance adequate to cover all risks in the performance of the Contract with a minimum limit of indemnity of £5 million for each individual claim. Public and Products liability insurance, with a minimum limit of £5 million for each individual claim.
Liability Requirements	**Suppliers limitation of Liability** In relation to any Defaults occurring from the Effective Date to the end of the Contract, the Supplier's liability shall be limited to a sum up to £100,000.
Customer billing address for invoicing and payment profile:	All invoices must be submitted electronically to accounts.payable@mhra.gov.uk and in arrears in accordance with this payment profile: Milestone 1: On approval/sign off the Qualitative Research materials - payment of 50% of the anticipated Charges around mid-December 2021.

	Milestone 2: On completion of the research project with the acceptance of the agreed project outputs/deliverables – payment of outstanding Charges anticipated around the end of April 2022.

GDPR	See Schedule 7 of the Call-Off Terms for the completed PROCESSING, PERSONAL DATA AND DATA SUBJECTS schedule.
Alternative and/or additional provisions (including Schedule 8 (Additional clauses)):	Not Used.

FORMATION OF CONTRACT

BY SIGNING AND RETURNING THIS LETTER OF APPOINTMENT (which may be done by electronic means) the Supplier agrees to enter a Contract with the Customer to provide the Services in accordance with the terms of this letter and the Contract Terms.

The Parties hereby acknowledge and agree that they have read this letter and the Contract Terms.

The Parties hereby acknowledge and agree that this Contract shall be formed when the Customer acknowledges (which may be done by electronic means) the receipt of the signed copy of this letter from the Supplier within two (2) Working Days from such receipt

For and on behalf of the Supplier:

Name and Title: Redacted under FOIA Section 40 Personal Info

Signature: Redacted under FOIA Section 40 Personal Info

Date: 13/12/21

For and on behalf of the Customer:

Name and Title: Redacted under FOIA Section 40 Personal Info

Signature: Redacted under FOIA Section 40 Personal Info

Date: 16/03/2022

ANNEX A

Customer Project Specification

Section 1. Title

Public research to evaluate the perception of risk associated with breast implants.

Section 2. Summary

The MHRA requires this research to provide the patient and public perception of risk related to breast implants. The outputs in conjunction with existing evidence may inform regulatory decision making on the use of breast implants on the UK market.

There is a need to conduct research due to a rise in reported cases of Breast Implant Associated Anaplastic Large Cell Lymphoma known as BIA-ALCL and other symptoms related to breast implants. Currently, there are no plans to publish or widely disseminate the final report/findings (in its entirety or extracts), but this may change.

The aim of the research is to gauge public perception of acceptable levels of risk amongst specific subject groups:

1. General members of the Public – no experience of breast implants, not on a treatment pathway.
2. Reconstructive surgery (including mastectomy with reconstruction using an implant)
3. Cosmetic augmentation
4. Revision surgery

In all cases, we are interested in people who are pre and post-surgery. We want to determine how attitudes to risk may vary amongst different groups and at various different stages in their journey.

We require a research organisation/Supplier to manage and deliver these research services, taking responsibility for (not an exhaustive list): participant recruitment including the payment of any incentive payments; sampling; questionnaire and script/topic guide design; fieldwork; analysis; and producing the reporting and data outputs as stated in section 7. We consider a range of research methodologies could be effective in this delivery. The appointed Supplier should be experienced in handling research projects on sensitive subjects (especially in the healthcare sector) and with potentially hard-to-recruit participants.

This research shall commence late November 2021, with some initial outputs required by the end of the financial year, end of March 2022.

Section 3. Background to the issue

The MHRA is responsible for the regulation of medicines, medical devices, and blood components for transfusion in the UK. Breast implants are regulated as medical devices. Manufacturers of medical devices must comply with the Medical Devices Regulations and one of its obligations is to report adverse events from medical devices to the MHRA so that we can identify safety issues which might not have been previously known about. The MHRA will review the issue and if necessary, take action to minimise risk and maximise benefit to the patients.

Further information can be found here:

MHRA webpages: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

MHRA Devices regulation: https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety

Breast implants are used for cosmetic enhancement, and reconstruction. For women with a risk of developing breast cancer or those with confirmed breast cancer, who undergo mastectomy, breast reconstruction using breast implants offers improved psychological and cosmetic outcomes. It's estimated that to date, over 1 million implants have been sold in the UK for both aesthetic and reconstructive purposes.

Breast implants differ in size, shape, filling material and surface characteristics. They may be filled with saline (sterile saltwater), with silicone gel or a combination of both. The surface of the implant may be smooth or textured (macro- or micro-textured), or coated with polyurethane, and different implants may vary in the amount of irregularity of the texture.

There is increasing evidence of an association between breast implants and an uncommon sub-type of anaplastic large cell lymphoma (ALCL), a form of non-Hodgkin's lymphoma, called breast implant associated - anaplastic large cell lymphoma (BIA-ALCL), which grows around a breast implant.

Issues associated with breast implants have been of media and political interest over the years, and the MHRA has received feedback from consumers indicating a non-uniform spectrum of risk appreciation.

BIA-ALCL background

ALCL accounts for less than 1% of all breast malignancies. Not all ALCL in people with breast implants is BIA-ALCL; to be diagnosed as BIA-ALCL it must meet the specific World Health Organisation (WHO) diagnostic criteria (including CD30+ and ALK- markers) defined in 2016. While it is a type of malignancy that can occur in the breast, it is not breast cancer, and there has been confusion about this among the media and patients.

Research is yet to provide a definitive answer as to how BIA-ALCL develops although there are several competing theories. One suggested theory is that surface texture of implants may play a role in how some patients react to having an implant in place. Whilst most cases of BIA-ALCL have been reported in patients with textured implants, it has not been proven that smooth implants are not involved in the pathogenesis of BIA-ALCL.

Research is ongoing in the UK and worldwide to better understand the cause and the mechanism for the development of BIA-ALCL.

It is estimated the rate of BIA-ALCL in the UK is around 1 in 20,000 breast implants sold. This estimate is based on all types of breast implants known to be sold in the UK and reported cases of BIA-ALCL confirmed to meet the WHO criteria until August 2020. This is only an estimate because some cases may not have been reported to the manufacturer or to MHRA during this time, and every device known to be sold in the UK may not have been implanted. There is an estimated 10-35 million women who have received breast implants world-wide, as approximated in the scientific literature, with over a million sold in the UK.

BIA-ALCL most commonly presents as a 'late' seroma (a collection of fluid) forming around the breast implant. Very rarely BIA-ALCL has been found when a lump develops next to an implant, or within a tough fibrous tissue capsule, which can build up around an implant. In most patients, it is treated successfully with surgery to remove the implant and surrounding capsule. However, if there is disease outside of the capsule then patients may require chemotherapy, radiation therapy or antibody therapy such as Brentuximab.

Although an uncommon disease, a key part of informed consent between a patient and clinician is discussing the benefits and risks before a person can decide on which treatment is best for them.

Further information can be found at this link: BIA-ALCL guidance on gov.uk

Section 4. Research objective

1. To gain insight into the public perception of the risks associated with breast implants, including BIA-ALCL.

This will include assessing:

- Public awareness of the risks associated with breast implants and opinion on known risks presented to those who have considered or have breast implants.
- Public understanding of BIA-ALCL as a disease.
- Any differences in opinion for people at different stages of the process and whether these differences extend to those having implants for cosmetic or reconstructive purposes.
- Assessing public awareness of the risk of textured and smooth surface implants and polyurethane coated breast implants, as well as sampling groups with each of these types of breast implant implanted.

Section 5. Target participant group

The sample would have to include a general population view as a comparator, and patients at all stages in the process (with each surface texture of breast implant) and in the categories of those having implants for cosmetic and reconstructive purposes.

- No specific gender requirements.
- Includes adults over the age of 18.
- There are no specific geographical requirements, the MHRA operate UK-wide.

The subject groups to be included:

1. General members of the Public – no experience of breast implants, not on a treatment pathway (for the quantitative research only).
2. Reconstructive surgery (including mastectomy with reconstruction using an implant)
3. Cosmetic augmentation
4. Revision surgery

We expect a target sample size of around 2,000 participants for the quantitative survey, to cover the groups listed above. The final sample across the subject groups shall be agreed with the appointed Supplier, but participant recruitment should be maximised (noting our budget) to ensure we meet our research objective and have robust findings. We would like a minimum of 8 participants for each of the three subject groups to be included in the qualitative research.

The MHRA cannot assist the appointed Supplier with participant details.

Section 6. Suggested approach and analysis

We consider a range and/or combination of qualitative and quantitative research methodologies could be effective in this delivery, such as face-to-face, telephone, and online approaches including panels, tripod interviews, focus groups, and depth interviews. Research organisations/tenderers are requested to provide details of appropriate methodologies/approaches that ensure that the research aims and objectives are met.

The MHRA will assess the methodology proposals in our evaluation stage.

Research organisations/tenderers should indicate how they propose to recruit and sample a representative audience across the subject groups based on the project/research objective. We are interested in how a specialist audience will be identified and recruited. We would like to see a minimum of 8 participants for each of subject groups 2 - 4 included in the qualitative research. We are open to the research organisation/tenderer making recommendation(s) for how best to conduct the qualitative

research and would like to see a range of methods such as tripod interviews, focus groups and 1:1 in depth interviews considered in the proposal.

Research organisations/tenderers should consider and indicate how they will conduct fieldwork, and how they intend to manage sensitive subject matter in group or individual qualitative research.

The appointed Supplier shall perform the research using all reasonable skill and diligence and in accordance with good industry practice. Robust data handling and processing procedures must be observed by the appointed Supplier in delivering the research - safeguarding confidentiality and the integrity of information/Personal Data.

Section 7. Outputs

We require the following outputs:

Raw qualitative data (if relevant) to be provided to MHRA in a suitable format
Presentation of research findings (in powerpoint) to be delivered to key MHRA personnel
Interim report
Final report with high level summary of findings – to be of a publishable standard to enable the MHRA to disseminate it if needed
Raw data in spreadsheet form (tables/graphs – however appropriate), in addition to the processed data
Thematic analysis
Case studies (optional)

The robust findings should be delivered as high quality and informative research outputs, which could include infographics/visual representations (as applicable) for ease of interpretation and access to wide audiences.

The MHRA shall review drafts of key outputs and may request revisions, before approving final versions. The Supplier shall also produce and deliver for our review other key documents e.g. questionnaires and scripts etc, as agreed.

The appointed Supplier shall assign the intellectual property rights/copyright in the Supplier Materials (as defined in the Call-Off Contracts terms) to the MHRA/Customer and/or to the Crown. Currently, there are no plans to publish or widely disseminate the final report/findings (in its entirety or extracts), but this may change.

Section 8. Liaison arrangements

The MHRA shall assign a Research Account Manager, Project/Contract Manager, and Subject Matter Experts as our project team. The nominations and details of roles will be confirmed in the contract with the appointed Supplier.

The Research Account Manager will be the key contact point for communication with and by the Customer and will manage the relationship with the appointed Supplier/research organisation.

The research organisation shall nominate an account manager/Project Manager as their main point of contact and for overseeing the smooth running of the research/project, including quality assurance and risk and data management.

The Customer's project team shall meet the appointed Supplier's nominated team/representatives at a virtual inception/implementation meeting, where the parties will agree the finer details of the agreed methodology and final Project Plan and discuss any challenges or other points to ensure understanding.

The relationship between the parties shall be collaborative, with regular communication and progress updates provided at regular intervals.

Section 9. Indicative Timings

The successful research organisation will be notified around 19/11/2021.
A project inception/implementation meeting will be scheduled w/c 29/11/2021.
Some initial outputs are required by the end of March 2022.
We expect the research to be completed and reported by 29/04/2022.

Section 10. Budget

There is a budget of up to £50,000 excluding VAT to complete this research project including all fees, expenses, and any incentive payments.

ANNEX B

Supplier Proposal

Technical Proposal

Extracts from the Supplier's Tender outlined below (project examples to evidence corporate and Personnel experience have been provided and details can be found in the full Tender)

Corporate summary

Revealing Reality provide detailed insight about how life is really lived through a multidisciplinary offer combining qualitative and quantitative expertise.

As a small, 100% owner-managed company, all work is held to the highest quality standards, and the most senior team are personally accountable. Our reputation for robust research means we regularly work with regulators. Revealing Reality have extensive healthcare research experience and are regularly relied upon to inform regulation and best practice on sensitive topics with hard-to-reach groups.

Relevant accreditations include membership of the Market Research Society and the Association for Qualitative Research. The majority of our work is performed in-house, but for this project we are using a quantitative panel provider for the public survey and sourcing some qualitative interviews from a specialist recruitment agency.

Revealing Reality has also confirmed that they don't believe there could be any potential/actual Conflict of Interest in their conducting this research.

Proposal Overview

Understanding risk in context

The MHRA need robust evidence of risk awareness and information provided to patients associated with breast implants and BIA-ALCL. To do this, the MHRA need to understand what risk means to the individual, which is relative to each person and their circumstances. This necessitates a method that delves beyond surface level reflections to understand the drivers and barriers to risk perception and awareness of BIA-ALCL.

Capturing details across groups and journeys

This detail will be captured through a mixed method approach. Researchers will explore the 'why' behind perceptions of risk through depth interviews with those who have recently undergone (or are undergoing) breast implants surgery. Each interview will generate a detailed journey map, including context around the surgery and the information provided to them at each stage. An additional survey with breast implants patients will seek to add scale to qualitative findings, while a nationally representative survey (n=2,000) will provide an understanding of BIA-ALCL awareness among the general public. Qualitative and quantitative data will be compared across groups, based on the type of surgery and implant, as well as relevant personal characteristics of interest (e.g. age).

This will provide MHRA with a robust understanding of BIA-ALCL information provision and how people interpret it along the surgery pathway. This insight will show how information sources and context influence people's decisions about 'acceptable risk', and what best practice and policy should look like to best enable people to make informed decisions.

Research Methodology and Approach

Aims & objectives:

There is increasing evidence linking breast implants to BIA-ALCL and MHRA has noticed that there is a spectrum of risk appreciation in the population concerning breast implant associated risks. To properly regulate breast implants as a medical product, MHRA need to understand the populations' perception and awareness of potential risks. As a trusted regulator, MHRA requires an agency who can provide data and insight that stands up to the highest levels of public scrutiny. This project will provide a robust and in-depth understanding of:

- What risk related information patients receive (especially BIA-ALCL) throughout the surgery pathway
- How and if patients process and use this information
- The range of competing priorities and influences on awareness and conceptualisation of risks
- Any differences in perception and awareness between sample groups and throughout the journey.

Key considerations

#1 Providing robust insight to inform regulation

The MHRA need reliable data to inform potential regulation and policy. Measures in our proposal to ensure an incredibly high level of rigour include:

- In-depth desk research (free of charge) to gain a detailed understanding of the wider context around BIA-ALCL. Revealing Reality will ensure the sensitive nature of the issue (in media coverage, social media discourse etc) is embedded into reporting
- All key project personnel have direct experience working with regulatory bodies and will uphold the level of rigour required in research and analysis
- Extensive experience producing reports of publishable quality for regulators which we will utilise in the delivery of this project.
- Our method is collaborative, with key touchpoints with the MHRA team in regular meetings and dedicated analysis session(s). This will ensure that the reporting highlights issues of current concern and interest to MHRA.

#2 Reaching the right people in a very low incidence group

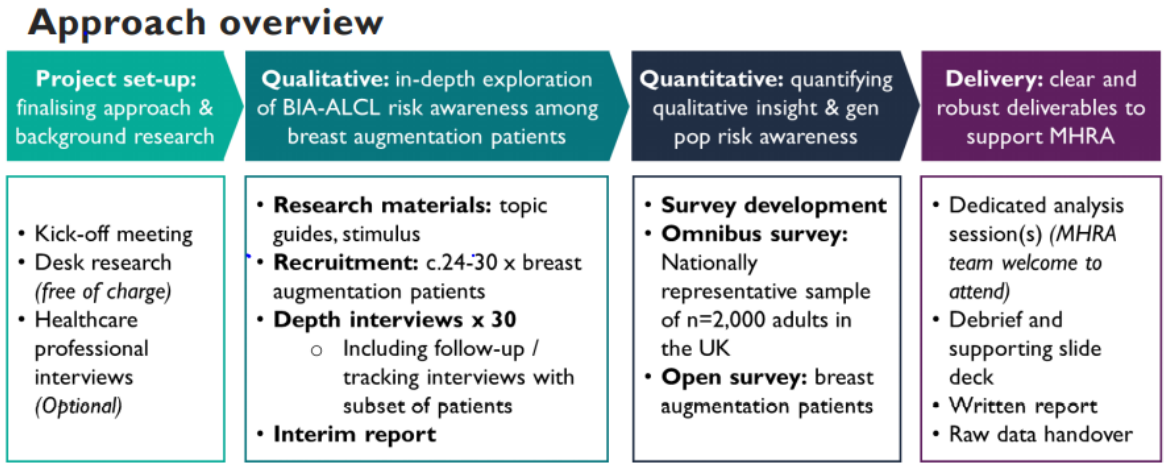
Talking to those who have recently gone through surgery is essential to understanding current BIA-ALCL information provision. Reaching the right people will prove challenging due to the decline in number of surgeries in recent years. BAAPS data shows a decline in surgeries since 2013, and even fewer due to COVID meaning only ~20,000 people have had this operation in the past three years. Therefore, this group will be unreachable through commercial survey panels or recruitment companies. Revealing Reality will mitigate this challenge by using:

- **Multi-method recruitment**: in-house, researcher-led recruitment, utilising organisations, pre-existing networks and online recruitment methods - an approach that has enabled our team to recruit extremely hard-to-reach audiences
- **An open survey** not limited to existing research panellists

#3 Understanding BIA-ALCL risk awareness in context

Overcoming this complex context requires systematic and detailed mapping of people's surgery journeys. Revealing Reality will achieve this by understanding a range of factors through a carefully designed research methodology.

Contextual factors to consider include:		
'Acceptable risk' Understanding how risks, such as BIA-ALCL, compare and factor into the context of patient's lives is essential. From extensive healthcare research we have seen people weigh up 'acceptable' levels of risk, e.g. cancer patients.	**Information provision** The content, when and how information is presented all affect decision making. Especially considering that there is no definitive evidence for why BIA-ALCL develops, leaving room for confusion and irregularity.	**Personal circumstance** Another consideration is the individuals' frame of mind when receiving information. We have seen that when going through a stressful time risk information and awareness may not be fully comprehended.
Research design mitigations include:		
Exploring personal context through depth and tracking interviews to provide necessary time to investigate context **Pathway mapping** to identify and understand information provision and decision-making points **Tracking interviews** to capture experiences in real time along the surgery pathway **Risk information mapping** around current discourse (e.g. narratives reported across social media, online guidance from surgeries)		



Project set-up

Kick off meeting: opportunity for the Revealing Reality and MHRA teams to meet and confirm approach; agree sample specification and timelines; and discuss existing research/ data and hypotheses.

To ensure researchers are aware of existing discourse and information that patients might have received, ahead of starting qualitative fieldwork the team will conduct background research (free of charge):

- Reviewing information sources around breast implants surgery process and risks (e.g. NHS advice, literature, online support)
- Existing research and testimony from patients
- Current discourse around breast implants (e.g. trends online, on social media)

(Optional) Redacted under FOIA Section 43 (2) Commercial interests

[redacted]

Redacted under FOIA Section 43 (2) Commercial interests

Qualitative phase

24-30 people who have had, or are expecting to have, breast implants surgery will be recruited for remote interviews. The proposed budget allows Redacted under FOIA Section 43 (2) Commercial interests depending on length, with the intention that a small number of participants who are currently going through consultation and surgery will be interviewed multiple times in longitudinal tracking.

Remote interviews (telephone or video call):
The aim of the interviews is to build as detailed a picture as possible of each person's surgery pathway to understand where information about BIA-ALCL risks were raised (if at all) and how this - and competing factors - influenced their decisions.

For many people the interviews will be retrospective, so techniques to assist in accurate recollection will be crucial to getting the most out of each interview. Stimulus and materials used in the interviews—which will be developed in collaboration with MHRA - will include:

- **Journey map(s)** – data capture tools to ensure systematic collection of data related to each part of the surgery pathway. This allows researchers to ensure patient recollections of experiences, attitudes, perceptions of BIA-ALCL risk are captured in clear chronological order.
- **Example information sources** – websites, leaflets, social media pages can all be used to stimulate discussion and trigger memories for respondents around information they received or conversations they had (or did not) about BIA-ALCL.
- **Patient 'artifacts'** – collecting information provided to patients at different stages of their surgery journey such as emails, leaflets or online info they accessed, particularly sources mentioning BIA-ALCL. Respondents will be asked to share this with researchers and will be used to stimulate discussion.
- **Detailed topic guides**, covering areas such as:
    - Relevant personal medical history (especially for reconstructive surgery patients); other cosmetic surgeries
    - Information provided at different stages of the pathway
    - Respondent awareness and attitude to risk (unprompted and prompted)

Why remote interviews?

Revealing Reality have proposed remote interviews as a flexible way to reach a large number of people. Many respondents, particularly those who are going through a medical journey, will find the flexibility and ease of remote interviews beneficial. Having conducted hundreds of telephone and video interviews, the team are extremely experienced at getting the most out of these interactions. Splitting interviews into smaller chunks to avoid video call fatigue; sharing stimulus on screen; checking tech setup in advance etc. are all techniques researchers employ.

Respondents will receive an incentive as a thank you for their time. This has been factored into the project costs and will be administered by our researchers.

Additional 'tracking' interviews:
For some patients we will aim to capture data in real-time as they go through the surgery pathway. This will provide data that is as objective as possible, rather than relying on recall.

These respondents will have several shorter interviews and will also be asked to upload non-sensitive communications and information they receive to our secure data sharing platform, Connect. This will provide a bank of up-to-date resources showing how BIA-ALCL risk is communicated.

Interviews will be timed to coincide with key moments in the respondents' journey. For example, for cosmetic patients we would aim to speak pre-consultation; at the beginning and end of the post-consultation 'cooling off' period; and pre and post-surgery.

Why depth interviews rather than groups?

Groups provide a useful environment in which to test ideas and creative concepts and capture people's immediate reactions or perceptions. A group environment can also foster useful discussion between participants.

However, they do not allow for detailed exploration of any one person's experience, which is vital for this work. For instance, a 2-hour group with 8 participants provides a maximum of 15 minutes of engagement with each participant. Groups enable collection of surface-level reflections on what information people remember engaging with. Understanding the contextual factors via in-depth exploration in interviews enables us to interpret these reflections much more accurately (i.e. identifying the most important drivers behind someone's decision-making).

The topic we are going to be exploring can also be very sensitive, suited to a one-to-one conversation where respondents have the time and space to recall their experiences in a comfortable environment.

Qualitative sample specification:
The sample specification below represents our intended target sample. The primary consideration informing this is reaching an equal number of people from each of the surgery-type categories.

Revealing Reality would work with the MHRA team to finalise this specification ahead of recruitment. We will also update the MHRA team regularly with recruitment progress.

Surgery stage:	**Pre**	**Post**	Factors to account for by surgery type:
Reconstructive	4	4	Single or double mastectomy; immediate or delayed reconstruction
Cosmetic	4	4	
Revision	4	4	Original surgery type; enlargement or reduction
Factors to account for across sample:	Implant type/material (smooth, textured, polyurethane-coated); Region; Age		

Recruitment:
Recruitment is one of the biggest challenges for this project. The hard-to-reach nature of the audience also means it is important to avoid, where possible, the most vocal (i.e. people who have had a particular bad experience) and explore the 'normal' experience.

A multi-method approach to recruitment, utilising different sources to reach as wide a group as possible will enable us to reach a diverse sample. The methods we will use are:

- **Professional recruiters.** Specialist recruiters are likely to have some people who have had breast implants surgery in their existing networks but cannot be relied upon for the full sample.
- **Researcher-led recruitment**. For hard-to-reach groups this is often the only way to effectively recruit people into research and has proved highly effective on a range of other challenging recruits.
- Organisations and partners to reach out to for each sample group include:
    - Charities, [redacted] Foundation
    - Healthcare professionals, including private practice cosmetic surgeons and NHS HCPs through pre-existing in-house networks
- Other routes we've used previously:
    - Social media pages and groups, as well as online forums for relevant interests (e.g. cosmetic surgery advice, condition-specific support and experience groups etc.)
    - Advertising for participants online (e.g. gumtree)

Quantitative phase

There are two aims of the quantitative phase:

1. Understand awareness of the BIA-ALCL risk among the general public
2. Scale up findings from the qualitative research with a larger number of people who have had, or are expecting, breast implants surgery

We propose running the quantitative phase after the qualitative phase so that insight from interviews can inform the development of the questions we ask.

Survey among nationally representative sample of UK adults (n=2000)

An omnibus survey allows us to ask questions to a nationally representative—based on age, gender and region - sample of UK adults in a cost-effective way. We propose asking 10 questions, providing space to ask about awareness of BIA-ALCL and important background:

- Whether they or a close relative or friend has experience of breast implants surgery and type
- Un-prompted awareness of associated risks with breast implants surgery
- Perception of risk in comparison to other interventions (e.g. other cosmetic or reconstructive surgeries)
- Prompted awareness of associated risks (specifically BIA-ALCL)
- Influences on personal awareness and assessment of risk

It also provides an opportunity to capture data from people who are considering breast implants but not on the surgery pathway - a group who are not technically in scope but among whom it may be useful to understand awareness of risks.

Open survey among people who have had or are expecting to have breast implants surgery

Due to the low incidence of people who have been or are on the surgery pathway in the UK, commercial panels are unable to guarantee certain numbers of people who meet our criteria, especially those with a recent experience (e.g. past three years).

An open survey sent out to partners, networks and organisations we engage during recruitment provides an opportunity to hear from a larger number of our target audience and to quantify some findings and hypotheses.

We have used similar approaches in previous work with audiences who are too low - incidence to reach through traditional methods. We are not able to guarantee a minimum sample size so would discuss the pros and cons in detail with the MHRA team.

The content of this questionnaire will focus on unprompted and prompted awareness BIA-ALCL and related information provided during the surgery pathway. It also provides an opportunity to test key insights from the qualitative interviews - e.g. the extent to which different priorities play a role in decision-making. Detailed profiling and surgery-specific information (e.g. type of surgery, type of implant) will ensure we are not conflating issues.

Project outputs

Outputs from the project will be designed in collaboration with the MHRA team. Feedback on detailed plans and full drafts of each deliverable will ensure outputs are developed to meet specific needs - from communicating key findings to senior stakeholders through to delivery of detailed qualitative and quantitative data for teams who need in-depth data on patient journeys.

Outputs will include:

- Written interim report
- Debrief presentation and supporting PowerPoint deck
- Final written report to publishable standard
- Raw data as required by MHRA team – raw survey data and tables, qualitative analysis grids, stimulus and example information collected throughout the project

As part of key deliverables we will include visual outputs including case studies and journey maps of research respondents for no additional charge, although we are happy to provide costs for professionally designed case studies as an additional output.

Understanding of the Health Sector

As an agency Revealing Reality have conducted a huge number of projects exploring people's interactions with the healthcare system and relationship with public health, at both a national and regional level across the UK.

Besides numerous projects exploring the needs of people with a wide variety of long-term health conditions (e.g. multimorbidity, cancer, physical disability), we also work extensively on health literacy issues and understanding people's relationships with public health.

Through all this healthcare work Revealing Reality see first-hand how information provision and empowering people to make choices and be in control of their medical interactions is a significant challenge for the whole health sector.

We have also worked with MHRA in the past and understand the requirements on the organisation to be able to confidently fulfil its remit with respect to the regulation of medicines and medical products. In many cases - including breast implants - patient's perceptions and decision-making are a critical element of what counts as an 'acceptable' level of risk for MHRA. For MHRA to make these decisions they have to be confident in their knowledge about what people experience, how they perceive risk and how they make these decisions.

Capability

Revealing Reality have nearly 20 years' experience conducting research in the healthcare sector. We're relied upon by central government departments, local authorities, healthcare organisations and charities to understand people's experience of the healthcare system, informing policy and service innovation and improvement - especially among hard to reach or vulnerable audiences.

The experience of the proposed project team spans a huge range of issues and projects, but there are several specific areas particularly relevant to this project:

Extensive health sector experience
Understanding how people engage with and interpret healthcare-related risks and benefits is critical to interpreting how individuals treat information about BIA-ALCL risks. We have conducted a huge amount of research in the healthcare sector, with a focus on the experiences of patients as they navigate the healthcare system.

Due to the expertise in this area, we are regularly requested to conduct research on difficult and sensitive subjects, and with those who are hard to reach.

We also have extensive experience researching people on a cancer treatment journey, as well as people who are terminally ill. In all cases we have seen how the context and headspace individuals are in are key factors to influencing their interpretation of a 'risk' and subsequent behaviours are individual to each person - something the method proposed here is focusing on understanding.

A trusted partner to regulators
We work as trusted partners to a range of regulators. In all cases, the need for clear, robustly evidenced findings that withstand the highest levels of scrutiny (including legal review) and command the attention of senior stakeholders both internally and across government and industry is paramount. We regularly provide qualitative and quantitative data and insight that is used to inform regulation and support regulator's positions in legal proceedings and under public scrutiny. In the past, our data has been used in judicial reviews, and we have provided raw data sets for public access (e.g. accessible via FOIA).

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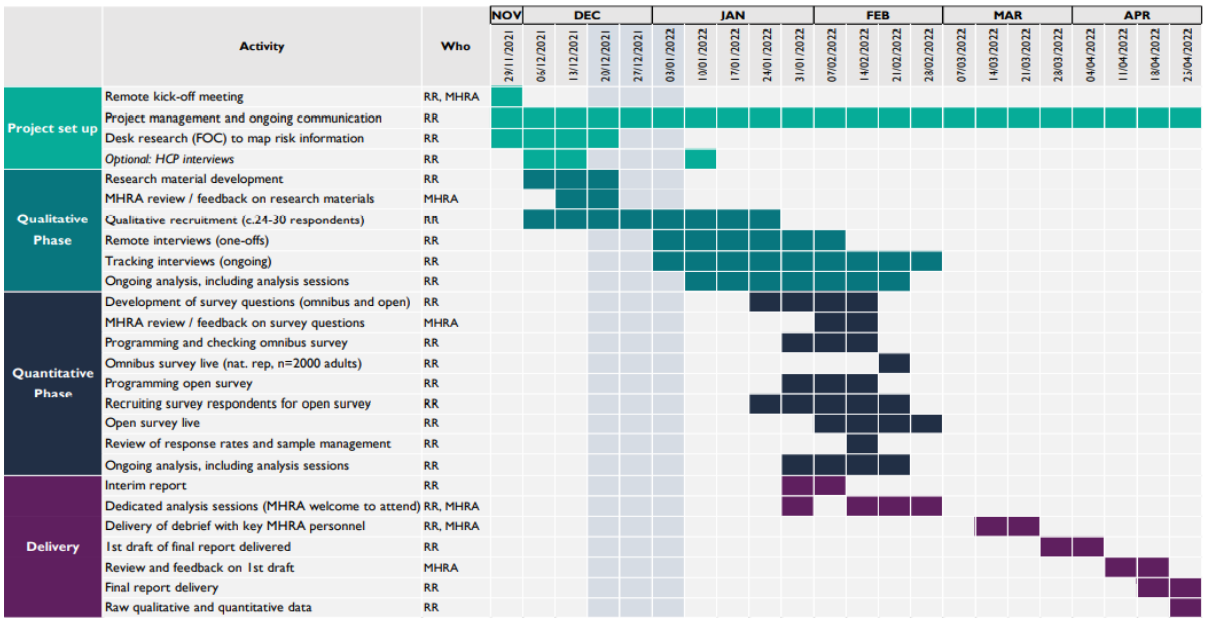
Project Plan

Revealing Reality can guarantee the proposed delivery timelines as stated in the proposal and have planned mitigation to ensure this. We are aware of the busy Christmas period and have planned for this to ensure the recruitment period is long enough to reach sample across all groups. The qualitative and quantitative phases will be staggered so findings from interviews can inform our survey questions. The interim report is planned for the middle of fieldwork to provide the MHRA with emerging findings and enable the MHRA to review and input on the direction of the project. In the spirit of collaboration, we have planned for reviews and feedback at all stages to ensure the MHRA have ample time to input on materials and deliverables.



Management

Robust project management techniques

To ensure the project runs smoothly we have tried and tested processes in place:

- The Project Manager is the dedicated first point of contact for MHRA who will respond promptly to all queries MHRA may have. The team will regularly report to MHRA to review progress (frequency to be agreed at kick-off) and respond to emerging priorities or adjust approach elements if needed.
- Timings and risk registers are regularly reviewed and updated, with any concerns being communicated to MHRA
- Consistency of staff is preserved through our resourcing system, which is monitored daily by the Resourcing Manager to ensure work will be completed on time
- We built our own qualitative data management platform, Connect, to allow us to collect a wealth of detailed data and organise it in robust, systematic way through tagging and board-building functionalities
- Secure remote project and file management tools are in place, to ensure the continued smooth running of the contract in the event of staff absence / illness
- The senior team meet weekly to monitor project progress who will identify resourcing needs and continuous improvement opportunities

High quality work

Senior involvement throughout. Key project personnel all have a wealth of expertise working on similar projects. If the Project Manager is unavailable for whatever reason the Research Lead will assume management of the project. The leadership team will be involved from the start to the finish of the project, supported by expertise of the wider senior team to ensure the project benefits from the variety of skills and expertise in our multi-disciplinary agency. All analysis sessions are led by the Project Director and Quantitative Lead. [redacted] will be involved in the report writing stage to ensure the publishable standard of work. No deliverables are sent without the approval of the Project Director.

Collaboration. The team will agree the structure of the deliverables with MHRA before we write them so MHRA have input on the structure and direction. MHRA will review drafts of key outputs before approving final versions. MHRA are welcome to attend all our analysis session as we believe client

benefit from analysing the data in person and throughout the project timeline, not just at the deliverables stage.

A Risk management initial log can be found in the full Tender proposal (to be updated throughout project).

Data Protection & Confidentiality

Revealing Reality regards access to personal information for research purposes as an important privilege, so we have rigorous processes in place to ensure the ongoing confidentiality, integrity, availability and resilience of our systems and services to keep data safe. Our Data Protection Policy adopts the fundamental principles of the UK-GDPR and the Data Protection Act 2018 as the minimum standard to which Revealing Reality, its employees and suppliers must adhere. Staff receive training once starting at Revealing Reality and we hold regular, whole-company refreshers on data security and sign a non-discuses agreement. We are registered with the Information Commissioner's Offices as a Data Controller[redacted] and we are Cyber Essentials Certified (Certificate Number: [redacted] and have annual Penetration Tests conducted by an external supplier to ensure that our networks are secure.

Measures in place for this project to ensure the security of data include:

- Never storing respondent data for longer than is necessary
- Respondents are always told how their data will be used and what they have consented to
- All participants' identities will be anonymised and only referred to by pseudonyms
- All documents containing Personally Identifiable Information (PII) relating to respondents will be password-protected and only stored on secure storage with access limited to core team members
- There will be no printed copies of documents containing respondent PII
- Any particularly sensitive data will be encrypted
- All our computer terminals and servers are protected by a professional-grade firewall and anti-virus software
- All project information will be shared only with the project team, and all members of the team will be required to read and adhere to our overarching NDA
- No personal data will be transferred outside the United Kingdom.

As well as ensuring our approach to data protection and confidentiality is rigorous, Revealing Reality's approach to ethics is also uncompromising. We regularly go through ethics reviews for projects on sensitive subjects. Due to the sensitive nature of this topic we will employ the following principles:
Ongoing consent: we obtain both 'informed' and 'ongoing' consent, ensuring participants make fully informed decisions about participation and feel able to withdraw consent any time.
Safeguarding: All researchers have up-to-date Enhanced DBS checks for working with children and vulnerable adults obtained or updated within the last two years.

Ethics Policy is available upon request.

Personnel/Team

The team have all be chosen based on their prior experiences across similar projects and key capabilities. We have pre-emptively set aside resource to ensure that all key personnel will be made available for the complete project duration. Combined, the team hold extensive expertise across the following areas that will be key to this projects' successful delivery:

- Informing regulation
- Healthcare systems and services
- Sensitive healthcare research
- Hard to engage groups

Key Personnel CVs

Project Director: [redacted]

Roles and responsibilities: [redacted]

Project Manager: [redacted]

Roles and responsibilities [redacted]

Project Advisor: [redacted]

Roles and responsibilities: [redacted]

Quantitative Lead: [redacted]

Role and responsibilities: [redacted]

Wider Research Team: [redacted]

Roles and responsibilities [redacted]

Commercial Proposal [redacted]

Key Activity	Activities / tasks	Researcher and Project Manager	Senior Researcher	Associate Director	Project Director	Outcosts	Total fees/ costs per task
Project management	Kick-off meeting	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
	Ongoing project management	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
	Desk research *(free of charge)*	-	-	-	-	-	-
Sub-total		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Qualitative interviews	Recruitment of [redacted] x respondents [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
	External recruitment support [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
	Qualitative research material development (topic guides, stimulus etc.)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
	[redacted] qualitative depth interview (remote - tel/video call), including write-up	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
Qualitative analysis	[redacted] interview incentives [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
	Ongoing and dedicated analysis sessions	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
Sub-total		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Quantitative fieldwork - omnibus survey with n=2000 general public	Questionnaire design	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
	[redacted] questions on omnibus	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
	QA - checking scripts and data	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]

	Data analysis	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
Quantitative fieldwork - open survey with breast implants patients	Questionnaire programming (bespoke open survey)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
	Recruiting survey participants / survey distribution	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
	Data processing and analysis	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
Sub-total		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Deliverables	Creation of PowerPoint debrief	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
	Delivery of debrief	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
	Final report in MS Word	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
	Interim update (e.g. 2-pager summary report)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	£ [redacted]
Sub-total		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
						TOTAL (EXCLUDING VAT)	**£** [redacted]

Variability Note:

Redacted under FOIA Section 43 (2) Commercial interests

[redacted]

Contract Terms

See separate attached document with completed Contract Terms and Conditions template.