An Exploratory Study of Detection of Endometrial and Ovarian Cancers in Vaginal Samples Retrieved by the Ellele Sampling Device

Sponsor	Ellele Health Ltd.
Protocol author	Dr Neil Ryan, Dr Dominic Blake, Sue Spencer, Ann Doust, Megan Sands
Chief Investigator	Professor Andrew Horne
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This study will be conducted in accordance with the clinical study protocol, the latest version of the Declaration of Helsinki (2013), guidelines for good clinical practice, EN ISO 14155:2020 (Clinical investigation of medical devices for human subjects - good clinical practice) and current regulations. Incorporating the respective reviews of the clinical study protocol approved by the Sponsor and the relevant Ethics Committee.

CONFIDENTIAL INFORMATION

This protocol describes the overall device investigation from the clinical performance requirements (e.g, reliability of results, kit failure, clinical utility and safety) and governs the activities at the site of the device investigation. The protocol describes the study details, interactions and records to be generated throughout the study. This document serves as the lead document and supersedes all other documents.

This Clinical Study Protocol has been approved by:

Megan Sands **CEO** Ellele Health	Signature/Date: Megan Badenhorst 12/01/2026 Megan Badenhorst (Jan 12, 2026 10:03:09 GMT)
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INVESTIGATOR SIGNATURE PAGE

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By signing below, the Investigator agrees to adhere to the protocol as outlined and agrees that any changes to this protocol must be approved in writing by the sponsor, prior to seeking approval from the Ethics Committee.

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Please submit an original copy of this page to the sponsor and file a copy in the Investigator Site File.

CONTENTS

LIST OF ABBREVIATIONS

Abbreviations	Description
AE	Adverse Event
ADE	Adverse Device Event
BMI	Body Mass Index
CI	Chief Investigator
CMO	Chief Medical Officer
eCRF	Electronic Case Record Form
CSO	Chief Scientific Officer
CSM	Clinical Study Manager
DD	Device Deficiency
DM	Data Manager
DNA	Deoxyribonucleic Acid
cfDNA	Cell-Free Deoxyribonucleic Acid
EDC	Electronic Data Capture
REC	Regional Ethics Committee
EU	European Union
FFPE	Formalin-Fixed Paraffin-Embedded
GP	General Practitioner
GCP	Good Clinical Practice
HIV	Human Immunodeficiency Virus
HRA	Health Research Authority
HPV	Human Papilloma Virus
HTLV-II	Human T-lymphotropic virus 2
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
ICMJE	International Committee of Medical Journal Editors
ISF	Investigative Site File
IVD	In Vitro Diagnostics
MHRA	Medications and Healthcare products Regulatory Agency
NGS	Next Generation Sequencing
PPI	Patient & Public Involvement
PCR	Polymerase Chain Reaction
PI	Principal Investigator
PIS	Patient Information Sheet
PMB	Post-Menopausal Bleeding
SAE	Serious Adverse Event
SADE	Serious Adverse Device Event
USADE	Unexpected Serious Adverse Device Event
TMF	Trial Master File
eTMF	Electronic Trial Master File
GMC	General Medical Council

1 INTRODUCTION

1.1 BACKGROUND – sort references

Endometrial Cancer: A Growing Challenge

Endometrial cancer is a significant and growing health concern globally [1,2]. Rising obesity rates, ageing populations, and increased use of hormone replacement therapy (HRT) have contributed to the rising incidence of this cancer [1, 3-6]. Post-menopausal bleeding, a common symptom of endometrial cancer, frequently leads to urgent investigations [1,7]. However, the current diagnostic pathway relies on invasive procedures, such as hysteroscopy or endometrial biopsy, which are painful, costly, and require specialist expertise in secondary care [8,9]. These limitations often result in delayed diagnoses, putting women at greater risk of progression to advanced disease and worse outcomes [3]. There is an urgent need for a diagnostic tool that is accurate, non-invasive, and accessible in primary care to address these challenges [3].

Ovarian Cancer: The Silent Killer

Ovarian cancer presents another critical issue in women's health. Known as the "silent killer," its early symptoms are vague and non-specific [10,11], leading to the majority of cases being diagnosed at advanced stages when survival rates are poor [12]. Current diagnostic methods are highly invasive, involving transvaginal ultrasounds, surgical biopsies, or laparoscopy, all of which require specialist intervention and further delay treatment. The lack of a reliable, non-invasive diagnostic test for ovarian cancer compounds the problem, making early detection and intervention difficult [10,13,14]. Early diagnosis is key to improving survival rates, as women diagnosed at an early stage have a far better prognosis [12, 15]. A non-invasive alternative that can be performed in primary care would revolutionise the diagnostic pathway for ovarian cancer.

Why the Ellele Sampling Device is Promising?

The Ellele Sampling Device is an innovative tool designed to address the shortcomings of current diagnostic methods for both endometrial and ovarian cancers. In Ellele01, our feasibility study, the Ellele Sampling device proved to collect vaginal mucus samples rich in both human and microbial DNA [16, 17]. This indicates the ability of the device to collect both human and microbial cells, suggesting the potential to provide not only DNA but also other key biomarkers, such as RNA and proteins. These molecules, shed by cancerous and surrounding cells, along with alterations in the vaginal microbiome, offer additional avenues for detection. By capturing this diverse range of biomarkers, the Ellele Sampling Device holds promise for enhancing early and accurate cancer diagnostics [16].

From the Ellele01 study we know the device is acceptable to women, easy to use, and has demonstrated the ability to yield high-quality DNA suitable for sequencing methods, making it a feasible alternative to invasive diagnostic methods.

There is strong evidence supporting the potential of this approach. Studies have shown that endometrial cancer cells and DNA are present in the vagina and can be used as a means for non-invasive testing [18, 19]. This provides a sound biological basis for the Ellele device's ability to collect material containing biomarkers indicative of endometrial cancer.

Ovarian cancer also holds promise for detection via this approach. Research indicates that ovarian cancer often originates in the fallopian tubes [20], which are anatomically continuous with the uterus.

This continuity means cancer-related DNA is likely to be present in the uterine cavity and subsequently in the vagina. Studies have further confirmed the presence of ovarian cancer-related DNA in uterine samples [19, 21], reinforcing the feasibility of detecting ovarian cancer through a vaginal sample collected with the Ellele device.

Our approach: Ellele02 Study

The Ellele02 study aims to evaluate the feasibility of vaginal mucus samples collected using the Ellele Sampling Device, to identify biomarkers associated with endometrial and ovarian cancer. This study will assess the potential of this novel sample type, in combination with multiomic analysis, to assess biomarkers that may be associated for the early detection of endometrial and ovarian cancer.

Conclusion

The increasing global incidence of endometrial and ovarian cancers, combined with the limitations of invasive diagnostic procedures, underscores the critical need for innovative detection methods. The Ellele Sampling Device presents a promising, non-invasive, and patient-preferred alternative to conventional sampling techniques.

The Ellele02 study is an exploratory study on biomarkers associated with endometrial and ovarian cancer through a multiomic approach, utilising an enhanced sample type collected with the Ellele Sampling Device.

1.2 STUDY OBJECTIVES

1.2.1 Primary Objective

- Determine the ability to stratify controls from cases on vaginal samples collected using the Ellele Sampling Device.

1.2.2 Secondary Objective

1. Validate the DNA extraction and enrichment methodology established in Ellele-01, particularly across different disease cohorts.
2. Assess compatibility of multiomic approaches with vaginal mucus samples.
3. Evaluate the potential of single omic biomarker categories for stratifying clinical groups.
4. Determine cross-reference genomic features identified in vaginal samples.
5. Investigate sample quality in relation to participant characteristics
6. Investigate sample quality in relation to logistical characteristics
7. Assess study feasibility.
8. Assess patient-reported discomfort associated with the Ellele Sampling Device

1.3 ENDPOINTS

1.3.1 Primary Endpoint

- Exploratory analysis of biomarkers associated with endometrial and ovarian cancer through a multiomic approach, from a vaginal sample collected with the Ellele Sampling Device

1.3.2 Secondary Endpoint

1. Calculate DNA extraction QC pass/failure rates, as defined in Ellele-01, to verify technology compatibility across disease cohorts (e.g. ovarian cancer, endometrial cancer) and

participants where no cancer has been identified (e.g. benign ovarian cysts and post-menopausal bleeding).
2. By using laboratory and data QC metrics for each 'omic assessed (e.g transcriptomics, methylation analysis etc) to calculate pass/failure rates, for assessment of technology compatibility.
3. Stratification by statistical, bioinformatic and data scientific analysis of each 'omic (e.g microbiome) on vaginal mucus derived biomarkers in disease
4. Use pairwise concordance analysis of 'omic signatures between vaginal mucus samples and appropriate available matched samples (e.g. ascitic fluid, tumour blocks) where feasible.
5. Correlations between defined sample quality metrics and available clinical meta data (e.g. BMI, age, stage of disease)
6. Correlations between defined sample quality metrics and available logistical meta data (e.g. time of sample to analysis, time of day of sample)
7. Calculate enrolment metrics, including numbers of participants given a PIS, consented and retained.
8. Calculate acceptability of the Ellele device using a standard visual analogue scale (where 1 represents no discomfort, 2-4 mild discomfort, 5-7 moderate discomfort, and 8-10 severe discomfort) measured after use (only on patients who are not undergoing the procedure during surgery).

2 STUDY DESIGN

This case-control study is designed to explore vaginal mucosa samples collected with the Ellele Sampling device as a means of identifying biomarkers for diagnosing conditions of the female reproductive tract, with a primary focus on endometrial and ovarian cancers. The aim is to identify biomarkers that could significantly improve early detection and, in turn, lead to earlier intervention and better outcomes. By using carefully selected control groups of symptomatic patients rather than healthy individuals, the study aims to provide more clinically relevant and robust comparisons that reflect real-world diagnostic challenges.

Patient and Public Involvement (PPI)

The investigator has sought the advice of a PPI advisory group of four women with lived experience of endometrial and ovarian cancers on the acceptability of the study methodology and the information to be shared with patients with suspected or diagnosed endometrial and ovarian cancer. The feedback from the group was very positive, the women welcomed the innovation of the Ellele Sampling Device and believed it addressed a critical gap in gynaecological cancer diagnosis. The device was seen as potentially transformative, offering a less painful, more accessible alternative to current methods and that the research valuable to the population under study.

Use of Clinically Relevant Control Groups

Unlike studies that rely on healthy controls, this research will compare cancer cases to individuals with similar symptoms but different diagnoses. For endometrial cancer, control participants will be recruited from the post-menopausal bleeding (PMB) pathway, ensuring they are symptomatic and undergoing investigations. For ovarian cancer, controls will be drawn from patients suspected of having ovarian cancer but whose final diagnosis rules out malignancy. This approach reflects real-world diagnostic scenarios, making it possible to identify biomarkers that are relevant and meaningful in clinical practice.

Expanding the potential of the vaginal sample collected with the Ellele Device

The Ellele01 study demonstrated that the Ellele Sampling Device enables the collection of samples from which high-quality human and microbial DNA can be extracted, supporting the use of genomic-

based ‘omic approaches for vaginal sample analysis in diagnostics. Furthermore, these findings also indicate that the device may be capable of capturing other important biomarkers, such as proteins and RNA. To further explore this potential, we will recruit 50 participants, whose samples will be collected and processed using optimized methods to preserve these additional biomarkers. This will allow us to assess the feasibility of non-genomic ‘omic approaches for vaginal samples collected with the Ellele Sampling Device and refine the analytical methods applied to these samples.

Sample Size and Statistical Justification

The study will recruit 50 participants diagnosed with endometrial cancer and 50 controls, as well as 50 participants diagnosed with ovarian cancer and 50 controls. Additionally, 50 participants will be included for optimisation of analytical methods, making a total of 300 participants to obtain 250 analysable samples. This sample size is statistically robust for an exploratory biomarker discovery study. These findings will serve as a foundation for future, larger-scale validation studies.

Longitudinal Data Collection

In addition to collecting biological samples, the study will utilise participants’ electronic medical records for the duration of the study. This will allow the researchers to gather critical clinical data, including survival outcomes, cancer recurrence, treatment responses, and the occurrence of complications. The availability of this longitudinal data will enable a deeper understanding of the long-term implications of the identified biomarkers, including their potential to predict prognosis or guide treatment decisions. These insights will add significant depth and clinical relevance to the study’s findings.

Sample Collection

We will collect the following biological samples:

- Vaginal secretions (Ellele Sample)
- Blood (plasma and red blood cells)
- Urine (Collie Pee)
- Tissue, endometrial biopsy or biopsy taken at time of surgery (eg. peritoneal or ovarian biopsy, etc), post-surgical specimen (solid tumour or FFPE (Formalin Fixed Paraffin Embedded) block)
- Ascitic fluid (either at time of surgery or during routine clinical care)

Conclusion

This case-control study provides a robust framework for identifying clinically relevant biomarkers for endometrial and ovarian cancers. By focusing on symptomatic control groups and incorporating long-term clinical data, it ensures findings are directly applicable to real-world diagnostic challenges. The inclusion of 200 participants, combined with sound scientific evidence from previous research, offers a strong foundation for biomarker discovery. The results of this study have the potential to inform the development of non-invasive diagnostic tools that could improve early detection, reduce delays in treatment, and ultimately improve outcomes for women affected by these cancers.

3 STUDY POPULATION

3.1 NUMBER OF PARTICIPANTS

Approximately 300 patients will be enrolled to allow for 250 analysable vaginal samples.

3.2 INCLUSION CRITERIA

- Aged 18 years or over.
- Be able to give voluntary, written informed consent to participate in the study.
- Attending secondary care gynaecology services
- Can tolerate a tampon or previous speculum examination

3.3 EXCLUSION CRITERIA

- Vaginal, vulval and perineal symptoms that make a vaginal examination inappropriate.
- History of an allergic reactions to polypropylene, nylon and/or nitrile.
- Current pregnancy or suspicion of pregnancy. (A urine pregnancy test may be performed if applicable for pre-menopausal women without a reliable form of contraception).
- Has a known Hepatitis B, Hepatitis C, HIV or HTLV-II infection, or similarly classified human pathogen including prion diseases (Creutzfeldt-Jakob disease).
- Undergone pelvic radiotherapy within the last 6 weeks.
- Undergone systemic chemotherapy, immunotherapy, or received a novel pharmaceutical agent for malignancy within the last 3 weeks.
- Previously undergone a hysterectomy or do not have a uterus.
- Patients who at the clinician's discretion cannot be included for medical or social reasons.

Exclusion Criteria Justification

The following exclusion criteria have been defined based solely on the scientific requirements of the study. Individuals meeting these criteria are unlikely to provide adequate or representative reproductive tract material necessary to meet the study's objectives. While the use of the Ellele Sampling Device is considered safe and feasible in these groups, their inclusion would not yield data relevant to the study aims. Therefore, their exclusion is not based on safety concerns, but on the need to ensure scientific integrity and the collection of meaningful, analysable samples.

- Pelvic radiotherapy within the last 6 weeks
  Recent radiotherapy may alter the vaginal and endometrial environment in ways that compromise sample quality and reproducibility.
- Systemic chemotherapy, immunotherapy, or use of a novel anti-cancer agent within the last 3 weeks
  These treatments can influence cellular turnover, immune profiles, and microbial composition in ways that may confound study outcomes.
- Previous hysterectomy or absence of a uterus
  The absence of a uterus precludes collection of the target sample type central to this study's design.

In addition, the following exclusions are based on laboratory biosafety limitations and regulatory compliance:

- Known infection with Hepatitis B, Hepatitis C, HIV, HTLV-II, or similarly classified human pathogens (including prion diseases such as Creutzfeldt-Jakob disease)
  The laboratory responsible for processing biological samples collected in this study is not certified to handle these pathogens. Their inclusion would violate biosafety protocols and regulatory standards.

Finally, for precautionary reasons:

- Current pregnancy or suspected pregnancy
  The Ellele Sampling Device has not yet been evaluated for use in pregnant individuals. Until safety data are available for this population, they will be excluded to prevent unknown risks.

- History of an allergic reaction to polypropylene, nylon and/or nitrile.
  Nitrile, the material commonly used in barrier contraception, is also used in the Ellele Sampling Device, posing a risk for allergic patients.

4 PARTICIPANT SELECTION AND ENROLMENT

4.1 IDENTIFYING PARTICIPANTS

Potential participants will be identified by a member of their clinical care team. They will then be referred, with their permission, to the research team. A letter of invitation with information about the study may be sent or the patient may be approached at the time of their clinic appointment (with their permission).

Consenting patients to the study will be conducted in person by members of the clinical study team who have been trained and delegated to this task by the PI and whose details have been completed on the study's training and delegation logs.

4.2 CONSENTING PARTICIPANTS

All participants will be required to give written informed consent. Following consent, the original signed informed consent form (ICF) will be filed in the ISF and a copy of the PIS and ICF will be given to the participant. The PIS, signed ICF and consenting narrative will be uploaded to the participant's medical records. The consenting narrative should detail the following:

- Study name
- PIN & date of consent.
- Name of person taking consent
- Confirmation of eligibility
- Versions of the PIS and ICF used for consent
- Copy of the PIS and signed ICF given to the participant
- Date and details of samples taken.
- Barcode of the Ellele sampling device used

4.3 ENROLLED PARTICIPANTS

Patients who have given consent and fulfil the inclusion and exclusion criteria, will be allocated a study number and their demographic and medical history details recorded in the electronic case report form (eCRF) including but not limited to:

- Demographics (age, BMI, ethnicity)
- Clinicopathologic data
- Smoking history
- Relevant medical history
- Current medication
- Surgical history
- Obstetric history – including gravida, parity, mode of delivery (vaginal delivery +/- instrumentation, episiotomy, perineal tears, elective or emergency caesarean section)
- Menopausal status

- Date of last menstruation (if known)
- Pessaries or other products inserted into the vagina within the previous 48 hours
- Sexual activity and contraceptive usage (if applicable)
- Outcomes of all diagnostic tests with diagnosis when known

4.3.1 Withdrawal of Study Participants

Participants are free to withdraw from the study at any time without giving a reason. The sponsor will keep and analyse the collected samples, but no further samples or data will be collected from the date of withdrawal.

If a participant wishes to withdraw from the study, they shall be free to do so at any point with no detriment to their medical care.

- If a participant withdraws after providing an Ellele sample, data already collected up until the point of withdrawal will be retained and the sample stored for analysis. No further data will be collected from the date of withdrawal as described in the PIS.
- If the participant withdraws prior to providing an Ellele sample their data will not be used.
- Withdrawal of any participant will be documented on the eCRF with a reason if known.

5 STUDY ASSESSMENTS

The following assessments will be carried out (a visual representation of study participation can be found in Figure 1 in the Appendix for details):

- Obtain written informed consent
- Confirmation that the patient fulfils the inclusion and exclusion criteria
- Obtain demographic data, relevant medical & surgical history, current and recent medication usage, ECOG performance status
- Perform pregnancy test if applicable
- Obtain up to 40ml blood sample
- Obtain up to 50ml of urine
- Obtain up to 1L of ascitic fluid, if appropriate
- Obtain tumour block, if appropriate
- Ellele Sampling
- Record level of discomfort during Ellele sampling and routine clinical examination (if the patient is not under a general anaesthetic/sedated).

It is preferable that the Ellele sampling procedure occurs before any clinical investigation, as the use of a speculum or other vaginal procedures may interfere with sample quality. If the sample is taken following a procedure this must be recorded on the eCRF. The Ellele sample may be taken at the time of surgery, prior to commencing the procedure, if more convenient. For these participants a level of discomfort will not be recorded.

For participants who undergo tumour resection as part of their treatment, a tissue block will be requested. Tumour blocks will only be supplied to sponsor for analysis where surplus tissue is available following routine histopathological procedures.

Regardless of study involvement, participants will continue to receive standard care for their symptoms and treatment.

The following Assessment Table details what information and samples are collected at Clinic Visits versus At Time of Surgery:

Assessment Table

Assessments	Clinic Visit	At Time of Surgery (if applicable)
Consent to Study	X	
Check Eligibility for Study Participation	X	
Demographics	X	
Clinicopathological Details	X	
Pregnancy Test if required	X	
*Ellele Sample	X	*X - if sample has not already been taken or a second Ellele sample is being collected*
**Blood Sample (up to 40 mL)	X	*X - if not already collected*
**Urine Sample (Up to 50 mL)	X	
**Ascitic Fluid if appropriate (Up to 1 L)	X	*X - if not already collected*
Tumour Block		*X - if excess tissue is available*
Patient Assessment of Discomfort during Ellele Sampling if sample is not taken under anaesthetic	X	

***If a study participant is unable to provide a blood, urine or ascitic fluid samples for any reason, they will not be classed as a protocol deviator.*

For up to 12 months following study enrolment, data will be collected from medical notes when results become available. The following data will be collected:

- Check medical records for results of any tests
- Check medical records for pathology results following surgery (if appropriate)

5.1 LONG TERM FOLLOW UP ASSESSMENTS

Participants physical involvement in the study will end after sample collection and the relevant study assessment completion.

5.2 SAMPLE COLLECTION and STORAGE

The Ellele Sampling Device is an innovative device for collecting material from the vaginal wall. When inflated with air from the syringe, the nitrile hydrophilic membrane within the device captures material within the vagina including cells, shed cellular fragments including cfDNA and microbiome. Following membrane deflation and retraction back into the device, buffer is added, and the sample is sent to the laboratory for genetic and epigenetic analysis of the material retrieved.

Figure 2: Ellele sampling device fully inflated with syringe attached

Blood sampling

Up to 40ml blood sample will be obtained. The samples will be stored pseudo-anonymously at Ellele Health laboratory to perform DNA extraction and analysis.

Urine Collection Using the Colli-Pee Device

The Colli-Pee device is a specialized urine collection system designed to capture the first-void urine (FVU), which is particularly useful for biomarker detection, including HPV, STIs, and cancer-related markers. The device ensures standardized and efficient collection while minimizing contamination.

Collection of Ascitic Fluid for Research in Routine Clinical Ascitic Drainage

For this study, ascitic fluid will be collected during routine clinical ascitic drainage as appropriate and processed for biomarker analysis.

Collection of Solid Tumour Samples for Research

For participants who have solid tumour tissue removed as part of their routine clinical care, a portion of the excess tissue remaining after histopathological testing will be requested for analysis.

Further information relating to sampling, storage, transportation, and analysis of all biological samples is detailed in the Logistics Manual, separate to this protocol and filed in the ISF.

6 DATA COLLECTION

6.1 Source Data Documentation

The investigator must keep source data for every participant in the clinical study. In this source data, the available demographic and medical information of a participant is documented, in particular the following: name, DOB, ethnicity, sex, height, weight, medical history, concomitant diseases and medications, statement of entry into the study, study identification, date of informed consent, study visit date, predefined performed examinations and clinical findings, observed ADEs and reason(s) for withdrawal from the study, if applicable. It should be possible to identify each participant and verify the inclusion and exclusion criteria for the study from the available source data.

All clinical decisions will be made according to standard clinical practice and independently of the Ellele sample analysis. Study data will be archived by the site and sponsor in line with archiving policy.

For this study source data may be:

- eCRF completion – participant reported data
- Medical records

6.2 Case Report Forms

The sponsor will build an electronic data capture (EDC) database where each participant will be identified by a study ID number and their study data captured on Electronic Case Report Forms (eCRFs). EDC training and eCRF completion guidance will be provided by the sponsor who will be responsible for developing, validating, and maintaining the database.

Data queries can be raised by Data Managers (DMs), Clinical Study Manager (CSM) and/or delegates and will be referred to site personnel for resolution. Data entry and query resolution will be completed by site personnel trained on eCRF completion and delegated to this activity by the Principal Investigator (PI) as confirmed on the delegation log filed in the ISF.

7 DATA MANAGEMENT

7.1 Personal Data

The collected data will be pseudoanonymous and conform to and comply with the Data Protection Act 2018 and UK GDPR. All study documents and supplies will be stored securely and only accessible by study staff and authorised sponsor personnel. No personal and identifiable information will be included in the study report or subsequent publications.

7.2 Data Information Flow

A data management plan will be written by the sponsors Data Manager and filed in the electronic Trial Master File (eTMF). Sponsor Clinical Study Manager (CSM) or delegated monitor will carry out source data validation, during either on-site or remote monitoring visits at designated intervals throughout the study to ensure data recorded on the eCRFs are complete and accurate.

Programs for post-entry checks and data listings will be created and executed for validation of data. Completeness will be checked by authorised personnel of the sponsor so that there are no unexplainable empty fields in the eCRFs. A clean-file meeting will be held prior to database lock.

At the end of the study the PI will confirm data is complete and accurate by submitting a PI approval electronic form within the database. The PI has overall responsibility for the quality of the data recorded in the study database at their site.

An inspection/audit of the study may be carried out by regulatory agencies at any time during or after completion of the study. If an audit or inspection occurs, the PI, database provider and sponsor agree to allow the auditor/inspector direct access to all relevant system information and documents and to allocate their time and the time of their staff to discuss any findings or relevant issues.

7.3 Data Storage

A web-based EDC system will be used with access being restricted to site personnel who have completed the database training and been delegated to data entry by the PI. Details relating to storage will be captured in the study specific data management plan filed in the eTMF. Any data stored outside of the UK will have an appropriate transfer mechanism in place.

7.4 Data Retention

At the end of the study, the site will receive a copy of the participant data for filing in the ISF prior to archiving. The site will retain records and documents pertaining to the conduct of the study including reports of the eCRFs, source documents, signed ICFs, laboratory test results where appropriate and device accountability logs. No study records will be destroyed without prior authorisation from the sponsor.

7.5 Data Controller

A data controller is an organisation that determines the purposes for which, and the way, any personal data are processed Ellele Health, the sponsor of the study is the data controller.

8 STATISTICS AND DATA ANALYSIS

8.1 SAMPLE SIZE CALCULATION

This feasibility study aims to evaluate the quality of samples collected using the Ellele Sampling Device while also being sufficiently powered for an initial biomarker discovery phase. The study plans to enrol approximately 300 participants to allow for 250 analysable samples from 50 participants with endometrial cancer, 50 with ovarian cancer, and 50 controls for each cancer type, and 50 participants for sample analysis optimisation totalling 300 participants.

Rationale for Sample Size

The study will recruit 50 participants diagnosed with endometrial cancer and 50 controls, as well as 50 participants diagnosed with ovarian cancer and 50 controls. Additionally, 50 participants will be included for optimisation of analytical methods, making a total of 300 participants to obtain 250 analysable samples. Due to the exploratory nature of the study, sample size calculations cannot be performed. Instead, data will be generated from this study to perform sample size calculations which will inform future research. As Ellele-02 is evaluating large numbers of candidate predictor biomarkers, the analysis will build on literature research and take false discovery rates into account. This will ensure high standards of research while evaluating large numbers of candidate predictor biomarkers in an exploratory cohort.

Feasibility of Subgroup Analysis

In addition to detecting moderate effect sizes between cases and controls, the planned sample size allows for meaningful subgroup analyses if required. This flexibility ensures sufficient variability within and between the endometrial and ovarian cancer cohorts, as well as their respective control groups. Subgroup analyses could provide insights into potential differences in biomarker expression across

disease subtypes, stages, or other clinically relevant factors, further enhancing the study's exploratory potential.

Impact and Future Directions

The collection of 250 samples will generate valuable preliminary data to assess the feasibility of detecting biomarkers for endometrial and ovarian cancers using the Ellele Sampling Device. These findings will inform the design of larger-scale validation studies, ensuring that subsequent research is optimally powered and methodologically robust.

This study represents a critical step in evaluating the potential of the Ellele Sampling Device to revolutionise non-invasive diagnostic testing for gynaecological cancers. With robust statistical justification and a well-designed sample framework, it is positioned to provide meaningful insights that will guide the future of biomarker discovery and diagnostic innovation.

9 ADVERSE EVENTS & DEVICE DEFICIENCIES

Only Adverse Events (AEs) and Device Deficiencies (DDs) associated with the Ellele Sampling Device and/or the Ellele Sampling Procedure will be recorded on the eCRFs. These shall be reported to the sponsor as soon as the site becomes aware of this.

Any Adverse Event or Device Deficiency leading to a related Serous Adverse Event (SAE), Serious Adverse Device Event (SADE) or Unexpected Serious Adverse Device Event (USADE) must be reported to the sponsor within 24 hours of being made aware of issue.

Any device where a deficiency has occurred will be returned to sponsor for analysis.

All AEs and DDs will be reported to the sponsor by submitting a scanned copy of the AE or DD CRF within the required time prior to completion of the eCRF.

The definition of a DD is any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use error or inadequacy in information supplied by the manufacturer.

The responsible officer can be contacted on the following numbers:
Tel: +44 (0)1223 750490
E- mail: ellelestudy@ellelehealth.com

10 OVERSIGHT ARRANGEMENTS

10.1 INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit study related monitoring and audits on behalf of the sponsor, REC review, and regulatory inspection(s). In the event of audit or monitoring, the PI agrees to allow the representative(s) of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the PI agrees to allow inspectors direct access to all study records and source documentation.

10.2 STUDY MONITORING AND AUDIT

The monitor will be responsible for ensuring the PI and site clinical team adhere to the protocol, the requirements of the current version of ISO 14155, current ICH GCPs and the regulatory agencies or regulatory government regulations and guidelines, and any conditions of approval imposed by the reviewing EC.

The PI will permit representatives of the sponsor to inspect source data in the participant's clinic records and/or original hospital medical records, at designated intervals throughout the study, provided that participant confidentiality is maintained in accordance with local requirements. These inspections are for the purpose of verifying adherence to the protocol and the completeness and accuracy of the data being entered on the eCRFs. The sponsor's Clinical Study Manager will develop a monitoring plan for the study describing all monitoring activities. The monitoring plan will be filed in the eTMF.

Sponsor personnel or their designee may perform an audit at any time during or after completion of the clinical study. All study-related documentation will be made available to the designated auditor. In addition, study site personnel will be available to answer any questions. The PI will permit authorised representatives of the sponsor and the regulatory agencies or local health authorities to inspect facilities and records relevant to this study.

11 GOOD CLINICAL PRACTICE

11.1 ETHICAL CONDUCT

The study shall be reviewed and approved by an Ethics Committee. The relevant regulatory authorities will be notified in line with country specific requirements. The study will follow country specific data protection requirements. Patient and data confidentiality will be respected.

This study will be conducted in accordance with the Declaration of Helsinki and its updates, International Conference on Harmonisation (ICH) (E6) Good Clinical Practice (GCP) guidelines and United Kingdom Medical Devices Regulations 2002 (S.I. 2002/618).

Before the study can commence, all necessary approvals will be obtained, and any conditions of approvals will be met.

11.2 INVESTIGATOR RESPONSIBILITIES

The PI is responsible for the overall conduct of the study and compliance with the protocol and any protocol amendments Each Investigator and those delegated by the PI to study activities, will adhere to GCP, regulatory guidelines, local laws and regulations, and the protocol as detailed in this document.

The PI will obtain written approval of any changes to the protocol from the sponsor prior to seeking approval from the EC. The PI is responsible for enrolling only participants who meet protocol inclusion and exclusion criteria.

Delegated tasks for all study persons must be documented on the Delegation Log and signed by the PI prior to undertaking any study-related procedures.

11.2.1 Informed Consent

A prerequisite for participation in the study is obtaining written informed consent from the participant. The PI must ensure that the current, ethics committee-approved PIS and ICF, ensuring no changes are made without prior approval from the sponsor and ethics committee.

Participants will receive both oral and written information about the study, allowing time for questions and consideration. The PI or a delegated person will explain the study details, ensuring participants understand their rights, including the option to withdraw at any time without affecting their medical

care. Consent includes agreement for the sponsor and regulatory authorities to review the participant's medical records for data accuracy.

By consenting, participants agree to provide samples for analysis, which may be used in future ethically approved research. They will also be aware that their data will be reviewed by sponsor representatives and may be audited by external bodies.

The participant and the person conducting the consent process will sign and date the ICF before any study procedures begin. The original ICF will be kept in the investigator site file, with copies uploaded to the participant's medical records and given to the participant.

If new relevant information arises, the PIS will be updated and re-approved by the ethics committee. Participants can opt to receive a summary of the study results via email at the end of the study.

11.2.2 Study Site Staff

The site study staff must be familiar with the protocol and all study requirements. It is the responsibility of the PI to ensure that all staff assisting with the study understand the protocol and have been trained on the study related activities and their details entered on to the training and delegation logs prior to any study involvement.

11.2.3 Data Recording

The PI is responsible for the quality of the data recorded on the eCRFs.

11.2.4 Investigator Documentation

The PI will ensure that the required documentation is filed in the Investigator Site File (ISF).

11.2.5 GCP Training

All site personnel involved in the study are required to undertake GCP training to understand the principles of GCP. A current GCP certificate will be required for filing in the ISF and eTMF.

11.2.6 Data Protection Training

All site personnel involved in the study will be familiar with GDPR and adhere to their Trust GDPR policies.

11.2.7 Information Security Training

All site personnel involved in the study will be familiar with Information Security Training and adhere to their Trust IT policies.

11.2.8 Participant Confidentiality

All identifiable information obtained during the study is confidential and will not be shared with unauthorised third parties. Participants will be assigned a unique identifier number (pseudonymised) for study analysis. Once data leaves the NHS, participants will only be referred to by this number.

Data collected during the study will be processed and transmitted in line with data protection and clinical trial laws. It may be reviewed by the study team, sponsor, and authorised personnel to ensure accuracy. Only health professionals or those bound by confidentiality will handle sensitive information.

The sponsor may use study data for product development, regulatory filings, or other medical research. The PI is required to provide accurate test results and data, which may be shared with other research bodies or regulatory agencies as needed.

In compliance with ICH GCP and UK regulations, study data must be available for inspection by health authorities, the sponsor, and ethics committees. No identifiable participant data will leave the study site or be shared with anyone without legal authorisation.

All data and samples will be pseudonymised before transfer, and published results will not contain any personal identifiers. Study staff must comply with GDPR regulations regarding the handling of personal information.

11.2.9 Data Protection

Computers used to collate the data will have limited access measures via usernames and passwords.

Published results will not contain any personal data that could allow identification of individual participants.

Information obtained during the study will be collected, processed, and transmitted to the sponsor or its representatives in accordance with data protection and clinical trial laws. It may be inspected by the clinical researcher, the researcher's staff, the sponsor, and its representatives, to check, process, evaluate and use the information collected during the study. Processing, evaluation, or use of the information will be performed by a health professional for medical purposes and/or by those operating under a duty of confidentiality. Information will be transmitted and processed as the sponsor may direct, including to the sponsor and its representatives in the UK or elsewhere. Information obtained from this study may be used by the sponsor in connection with product development, including possible filing of regulatory dossiers with governmental authorities for marketing approval, and for other medical research purposes.

12 STUDY CONDUCT RESPONSIBILITIES

12.1 PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator (CI).

Proposed amendments will be submitted to the sponsor for classification, review and authorisation.

Amendments to the protocol must be submitted in writing to the appropriate REC and local R&D for approval prior to implementation and prior to participants being enrolled into the amended protocol.

12.2 MANAGEMENT OF PROTOCOL NON-COMPLIANCE

12.2.1 Protocol Deviations

The site study team are not permitted to deviate from the protocol. Deviations may occur to protect the rights, safety and well-being of the participants. Data points not collected and/or delayed in recording will be considered deviations unless otherwise specified. Only the sponsor may modify the protocol, which will be by protocol amendment, approved by the EC and regulatory authorities as appropriate. The only exception is when the PI considers a participant's safety to be compromised without immediate action.

12.2.2 Management of Deviations and Violations

Deviations and violations are non-compliance events discovered after the event has occurred. Protocol deviations will be recorded on the eCRF and on a protocol deviation log which will be sent to the PI each time the log is updated with the monitoring follow-up letter. Protocol deviations will also be reported to the EC in accordance with EC policies and/or local laws.

12.3 SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the study; or

(b) the scientific value of the study.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or any member of the site study team, the sponsor must be notified within 24 hours. It is the responsibility of the sponsor to assess the impact of the breach on the scientific value of the study, to determine whether the incident constitutes a serious breach and report to ethics committee as necessary. Data breaches will be reported to ellelestudy@ellelehealth.com.

12.4 STUDY RECORD RETENTION

On completion of data collection, all the study data will be securely stored for 10 years to allow adequate time for review and reappraisal, to enable the resolution of any queries or concerns about the results, and to facilitate further follow-up research.

No study records will be destroyed without prior authorisation from the sponsor.

12.5 END OF STUDY

End of study is defined when all data has been collected from each participant (e.g. final diagnosis). To support this patient data (from medical records) may be reviewed up to 12 months following study enrolment has been entered on to the eCRFs.

Participants can opt to receive a summary of the study results via email at the end of the study as indicated on the ICF.

The Investigator and/or the sponsor have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC, R&D Office and sponsor within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved.

A summary report of the study will be provided to the REC within 1 year of the end of the study.

12.6 CONTINUATION OF TREATMENT FOLLOWING THE END OF STUDY

All participants will continue with the standard of care.

12.7 INSURANCE AND INDEMNITY

The sponsor is responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the sponsor responsibilities:

- The site participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the site concerned. The sponsor requires the site participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.
- Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity.

13 AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the sponsor. All prospective publications and presentations must be discussed with the sponsor before submission. Authorship will be determined by use of standard criteria as applied by publication convention (ICMJE) https://www.icmje.org/recommendations/.

14 PUBLICATION POLICY AND DISCLOSURE POLICY

The sponsor intends to pursue publication of the results of the study to the terms and conditions of the clinical study agreement between the sponsor and site. Sponsor approval in writing is required for publication of any data subsets. Final authorship will be determined in accordance with the International Committee of Medical Journal Editors definition of authorship (for example, by contributions to study design, enrolment, data analysis, and/or interpretation of the results; www.icmje.org/). Participant names and other personal data relating to an identified or identifiable participant (such as photographs, audio, videotapes, or other factors specific to physical, physiological, mental, economic, cultural, or social identity), will not be disclosed in any publication without prior written authorisation from the sponsor and the participant.

This study has been registered on the publicly accessible database of clinicaltrials.gov.

Patient & Public Involvement (PPI)

The investigator has sought the advice of a patient advisory group with gynaecological disease on the merits of the study and the acceptability of the methodology. They reviewed and commented the design and we have incorporated their input.

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16 APPENDIX

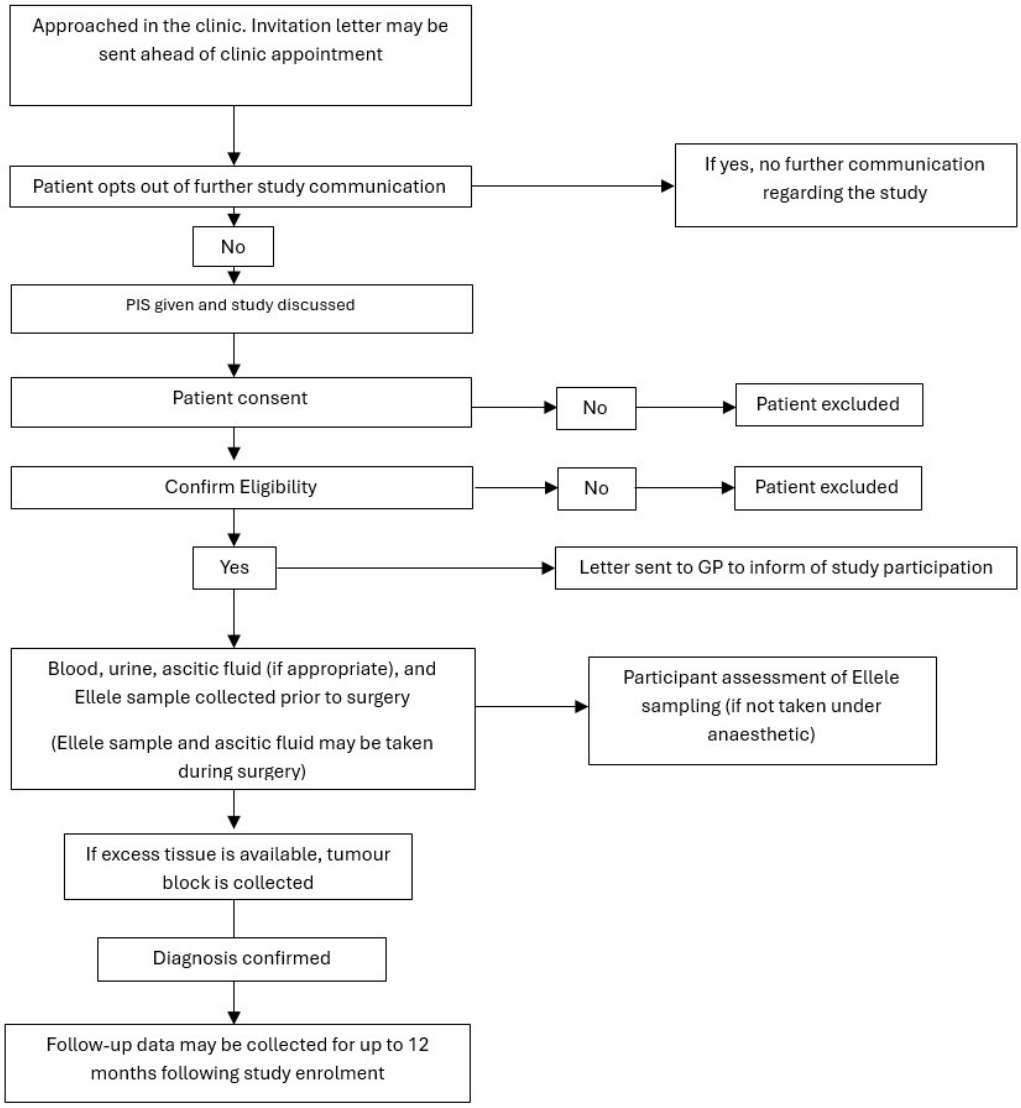

Figure 1: Study participation flowchart

EH-01-PR-01 Ellele-02 Protocol_Version 0_30 June 2025

Final Audit Report 2026-01-12

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