Collaborative Research Study Protocol Template

[Protocol Cover Page]

PROTOCOL TITLE:

TREATMENT ATTRIBUTE SATISFACTION WITH (RYALTRIS®) INTRANASAL NASAL SPRAY FOR ALLERGIC RHINITIS

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1. RELEVANT CONTACT INFORMATION

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2. LIST OF ABBREVIATIONS

ACIP	*Advisory Committee on Immunization Practices*
AE	*Adverse Event*
AMSRS	*Australian Market and Social Research Society*
AR	*Allergic Rhinitis*
BWS	*Best-Worst Scaling*
CaPPRe	*Community and Patient Preference Research*
EC	*Ethics Committee*
HCP	*Health Care Professional*
HREC	*Human Research Ethics Committee*
ICH	*International Committee on Harmonisation*
PAR	*Perennial Allergic Rhinitis*
SAE	*Serious Adverse Event*
SAR	*Seasonal Allergic Rhinitis*

3. INTRODUCTION

Allergic rhinitis (AR) is a highly prevalent disease, affecting more than 4.6 million Australians (Australian Institute of Health and Welfare, 2019). Intranasal corticosteroids (INCS) +/- intranasal antihistamines (INAH) are recommended as first-line therapy for AR [ASCIA AR Clinical Update (allergy.org.au)]. Patients may often differentiate intranasal treatments based on sensory attributes (Meltzer et al., 2008). Application of patient preferences when selecting INCSs could improve adherence to treatment (Meltzer et al., 2005).

4. BACKGROUND

Olopatadine hydrochloride and mometasone furoate monohydrate (RYALTRIS®) is a fixed dose combination nasal spray containing an isotonic aqueous white homogenous suspension in a metered dose manual spray unit. It is indicated for the treatment of symptoms associated with allergic rhinitis and rhinoconjunctivitis in patients 12 years of age and older and marketed in Australia by Seqirus. Allergic rhinitis will be described to participants as "allergic rhinitis (hay fever or other year-round allergies)" in the studies below as stated according to the RYALTRIS® Consumer Medication Information (CMI).

There is currently no patient satisfaction data for RYALTRIS® nasal spray. To address this knowledge, this research seeks to examine patients' satisfaction and importance of treatment attributes for AR nasal sprays from two brands (RYALTRIS® vs. DYMISTA®). The research objectives are outlined below.

5. *INVESTIGATIONAL PRODUCT*

Olopatadine hydrochloride and mometasonefuroate monohydrate (RYALTRIS®) is a fixed dose combination nasal spray containing an isotonic aqueous white homogenous suspension in a metered dose manual spray unit. It is indicated for the treatment of symptoms associated with allergic rhinitis and rhinoconjunctivitis in patients 12 years of age and older and marketed in Australia by Seqirus.

No investigational product is being supplied.

6. STUDY SETTING

Data will be collected through an online survey platform, Forsta Plus.

The site location is:
Community and Patient Preference Research (CaPPRe)
Level 20, 25 Bligh Street, Sydney NSW 2000

7. STUDY: PATIENT SATISFACTION AND SENSORY ATTRIBUTES OF NASAL SPRAY TREATMENTS FOR ALLERGIC RHINITIS

A. Objectives

To understand AR patients' level of satisfaction with RYALTRIS® compared to DYMISTA® nasal spray based on various treatment attributes. In addition, CaPPRe recommends exploring the importance of each sensory attribute to AR patients, thus enabling a much more comprehensive evaluation of true satisfaction with treatments.

The key objectives of this research are:

- To understand patient satisfaction and importance with various treatment attributes of the RYALTRIS® nasal spray
- To compare overall satisfaction for various treatment attributes of RYALTRIS® with the DYMISTA® nasal spray

B. Study Design

To directly compare patient satisfaction with 2 different AR nasal sprays, an observational, non-interventional, cross-sectional study design with 2 independent samples was chosen. Participants will complete an online survey involving a Best-Worst scaling (BWS) task to determine satisfaction and importance index for sensory attributes.

The suggested treatment attributes are informed by a range of previous studies, including those conducted by Meltzer et al 2005 and Price et al 2020, and methodology from CaPPRe's own work in developing indices for importance and satisfaction of treatment attributes using BWS.

C. Study Population

1. Description of study population

The primary population will be patients with moderate to severe SAR or PAR with or without conjunctivitis in Australia who have been initiated on RYALTRIS® or DYMISTA® in that last 12 months.

The expected sample size is between 200 to 400 patients. 100-200 patients initiated on RYALTRIS® and 100-200 patients initiated on DYMISTA® nasal spray in the last 12 months.

2. Recruitment of subjects

The main recruitment channel will be through the engagement of online panel companies that specialise in patient population and healthcare provider samples. Online panel companies will contact their list of panel members via email to invite them to participate in the study. Convenience sampling will be used to recruit participants into the study; participants will opt-in after hearing about the study. Interested panel members will be directed to the survey link where they will answer a number of screening questions that will determine their eligibility before the main survey (e.g., Prescribed treatment by doctor for AR and identifying treatment with a fixed dose combination (Ryaltris or Dymista)). Recruitment of 100-200 patients

initiated on RYALTRIS®, and 100-200 patients initiated on DYMISTA® nasal spray in the last 12 months will take approximately 2 weeks to complete.

Upon commencing the survey, participants will be provided a study information sheet and consent form before continuing to the rest of the survey. The study information sheet will contain contact details of the CaPPRe project manager to assist participants with any queries or provide additional information. Participants will have the option of saving/printing the participant information sheet and consent form to retain a copy for their records. Participants will read the Participant Information Sheet and the Consent Form online and check a box to indicate they have read the information and agree to participate.

3. Inclusion criteria

AR patients (moderate-to-severe SAR or PAR) with or without conjunctivitis who meet the following criteria will be offered the opportunity to participate in the study:

- Patients above 18 years old
- Fluent in English
- Patients initiated on RYALTRIS® or DYMISTA® nasal spray in the last 12 months and currently using treatment
- Willing and able to provide consent to participate

4. Exclusion criteria

Potential participants will be excluded if they:

- Have reported a loss of taste and/or smell related to COVID-19 (or other medical condition)
- Are employed by a pharmaceutical company (to avoid conflict of interest)
- Are employed by a vaccine company (to avoid conflict of interest)
- Do not have access to the internet (to ensure validity of the data)
- Are unable to read and understand English (to ensure validity of the data)

D. Study Procedure

1. Study treatment/intervention

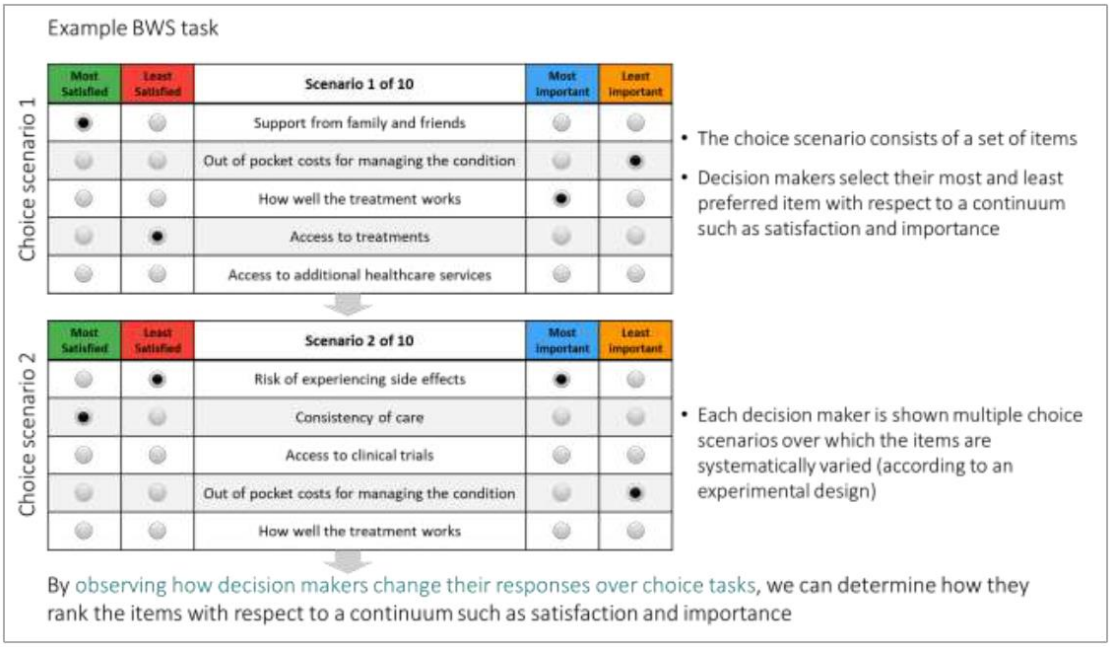
Participants would have already initiated treatment on a RYALTRIS® or DYMISTA® AR nasal spray in the last 12 months before completing the survey and currently be using treatment.

2. Satisfaction and importance of treatment attributes measurement

Treatment attribute satisfaction and importance will be assessed using Best Worst Scaling (BWS). Importance of the items will also be measured to create an overall satisfaction index between 0-100 (satisfaction weighted by importance).

The BWS exercise involves showing participants a series of scenarios that include a subset of attributes from a master list (in this case, treatment attributes of AR nasal sprays). Patients will be asked to review scenarios and choose what is most satisfied and least satisfied, and most important and least important to them in each. An example of a BWS choice task is shown below in Figure 1.

Figure 1. Example of a BWS choice task from a survey
(NOTE: this is an example only and does not reflect the final choice task)



BWS is a survey technique developed in the 1980s by Professor Jordan Louviere to overcome measurement issues with traditional scale-based research. BWS takes advantage of an individual's ability to reliably identify extremes ('best' and 'worst') in a set of three or more items, with respect to a continuum, such as satisfaction (Louviere et al., 2015). BWS studies are routinely used in health to identify patient preferences and prioritisation (Mühlbacher et al., 2016)

BWS is preferred over traditional methods, including rating scales, ranking, and paired comparisons, due to the following reasons:

- Simple and intuitive for participants to complete
- No scale biases
- Ability to handle a large number of items
- Scores demonstrate greater discrimination among items and between groups of respondents than traditional scale methods
- Scores can be estimated for individual respondents

The Directors of CaPPRe have all worked directly with Professor Louviere over many years at the Centre for the Study of Choice (CenSoC) and The Institute for Choice (I4C) and understand the advantages and disadvantages of BWS very well. BWS measures all items on a common scale which can be used to evaluate the relative hierarchy of any domain versus another domain.

BWS scores are a relative measure and cannot be used to build an index for comparison between individuals without an absolute anchoring point. Our research implements an anchoring process to rescale scores so they can be directly compared – we refer to this as anchored best-worst scaling (ABWS).

The questionnaire below (see Figure 2) was developed by Melzer et al 2005 to measure patient preferences for intranasal corticosteroids in patients with AR. This questionnaire has been adapted for use to determine satisfaction with and importance of treatment attributes of AR nasal sprays.

Figure 2. Questionnaire measuring patient preferences for intranasal corticosteroids (Melzer et al.)

Satisfaction

1. Thinking about the nasal medication that you **just tried**, how satisfied or dissatisfied are you with each of the following? (circle one response on each line)

	Very Satisfied	Moderately Satisfied	Somewhat Satisfied	Neither Satisfied or Dissatisfied	Somewhat Dissatisfied	Moderately Dissatisfied	Very Dissatisfied
a. Immediate taste of the medication	1	2	3	4	5	6	7
b. Aftertaste of the medication	1	2	3	4	5	6	7
c. Smell of the medication	1	2	3	4	5	6	7
d. Irritation to your nose	1	2	3	4	5	6	7
e. Urge to Sneeze	1	2	3	4	5	6	7
f. Dripping out your nose	1	2	3	4	5	6	7
g. Dripping down your throat	1	2	3	4	5	6	7
h. Moistness of your nose or throat	1	2	3	4	5	6	7
i. Overall satisfaction	1	2	3	4	5	6	7

3. Assessment of safety

There are no specific safety assessments, however, all respondents will be made aware at the start of the survey that their responses may potentially raise adverse events requiring reporting. Any AEs received spontaneously should be reported directly to Seqirus at AE.Reporting@Seqirus.com. They will be asked to consent to being contacted by Seqirus in this instance and to provide their personal email address to facilitate this contact. All personal contact details will only be used for the purposes specified and will kept separate from the survey data. All observed adverse events related to, Seqirus products (Adverse Drug Reactions, Serious Adverse Drug Reactions, product complaints, and other safety findings, pregnancy, lactation) in routine clinical practice will be documented in accordance with Seqirus requirement documents (e.g., Standard Operating Procedures [SOPs]).

Adverse reactions will be reported according to the Seqirus requirements. Patients will be advised about reportable events and provide consent (example survey text below):

Reportable Events

You are about to enter an online research survey. Different patients sometimes respond in different ways to the same products, and some side effects may not be discovered until many people have used a product over a period of time. For this reason, we are now required to pass on to (INSERT NAME), who is a manufacturer of medicines, details of any reportable events (side effects, situations that could affect the safety of a medicine, or product complaints) related to their own products that are mentioned during the course of market research. Although this is an online research

survey and how you respond will, of course, be treated in confidence, should you raise a reportable event, where you, or someone you know, experienced a reportable event or became ill after using one of (INSERT NAME) products, we will need to report this, so that they can keep the knowledge of the safety profile of their medicines up to date. You may be contacted to provide further information about this side effect. However, you have the choice to remain anonymous and choose not to be contacted if you so wish. You will be asked to provide your preference on this further below.

4. Duration

The online survey including the BWS exercise will take approximately 20 minutes to complete.

5. Subject withdrawal

Participants may withdraw at any time they wish, including prior to commencement of the survey or during survey completion. All data generated up to the time of voluntary discontinuation (withdrawal of consent) and the reason(s) for discontinuation, if available, will be recorded. Patients who choose to withdraw consent will no longer be contacted for follow up information.

6. Investigational Product Accountability

Any identified AEs will be reported in line with Seqirus requirements.

7. Compliance/adherence

Ongoing internal monitoring to ensure compliance of the study will be conducted by the principle and co-investigators. The progress of the study (sample achieved) will be monitored regularly (at least twice a week).

All adverse reactions related to Seqirus products (Adverse Drug Reactions, Serious Adverse Drug Reactions, product complaints and other safety findings, pregnancy, lactation) in routine clinical practice will be documented in accordance with Seqirus requirement documents (e.g., Standard Operating Procedures [SOPs]).

Adverse reactions will be reported according to the Seqirus requirements. Patients will be advised about reportable events and provide consent.

E. Endpoints

1. Primary endpoint

The primary study endpoint is the overall index score from the BWS exercise, to reflect satisfaction and importance of treatment attributes of the RYALTRIS® and DYMISTA® nasal spray.

2. Secondary endpoints

Secondary study endpoints are the domain scores from the BWS exercise (i.e., relative ranking scores for each of the domains; satisfaction and importance).

F. Data Collection and Monitoring

1. Data collection

Participants can complete the online survey by accessing a survey link online via mobile, desktop computer, laptop or standard sized tablet. At the beginning of the survey, participants will be asked to review the study participant information sheet and provide consent.

The 20-minute online survey will include:

- Patient demographics (e.g., Age, Gender, Location)
- Symptoms (mild, severe, moderate)
- Brief diagnosis and treatment history (SAR/PAR with or without conjunctivitis)
- Current treatment
    a) Duration
    b) Initiation: Doctor or self-managed

- A Best-Worst scaling task to determine the overall satisfaction index for treatment attributes

2. Data monitoring

Ongoing internal monitoring to ensure compliance of the study will be conducted by the principle and co-investigators. The progress of the study (sample achieved) will be monitored regularly.

All adverse events related to observed Seqirus products (Adverse Drug Reactions, Serious Adverse Drug Reactions, product complaints, and other safety findings, pregnancy, lactation) in routine clinical practice will be documented in accordance with Seqirus requirement documents (e.g., Standard Operating Procedures [SOPs]).

Adverse events will be reported according to the Seqirus requirements. Patients will be advised about reportable events and provide consent.

Statistical Methods and Analysis

1. Sample size and statistical power

The expected sample size is 100-200 moderate to severe SAR/PAR patients initiated on RYALTRIS® nasal spray in the last 12 months and 100-200 patients initiated on DYMISTA® AR nasal spray in the last 12 months. Traditional power calculations are not applicable to the design of BWS studies. The experimental designs used (BIBD and Youden designs) allow for individual level estimation of scores. A sample size of 100-200 patients per treatment provides appropriate precision, balanced against recruitment constraints.

2. Statistical methods

The data from the quantitative survey will be cleaned and restructured for analysis using R statistical software

Best Worst Scaling analysis

Standard BWS scores cannot be used to build an index that is comparable between groups of participants because the scores represent a relative ranking. CaPPRe have developed a new method to convert these scores from relative to absolute measures which can be combined to form an index An index will be built to measure the overall satisfaction with the sensory attributes. The index is a combined score of the BWS domains, accounting for both satisfaction and importance, and ranges from 0 to 100. Index scores will be compared using an analysis of variance (ANOVA).

The BWS exercise yields scores reflecting the relative hierarchy of each domain vs another domain (e.g., cost versus efficacy). The BWS scores for each item are calculated by finding the difference between the number of times it was chosen as most satisfied / important and least satisfied / important, and then dividing it by the total number of times it appeared throughout the exercise.

$$BWS\ score = \frac{most\ -least}{times\ appeared}$$

Furthermore, the BWS scores are mapped onto a scale ranging from 0 ("*Not satisfied at all"/"Not important at all*") to 10 ("*Completely satisfied"/"extremely important*") describing the level of satisfaction and importance. These rescaled scores allow direct inference of how satisfied/important each individual domain is, rather than just their relative ranking.

Best-Worst Scaling (BWS) scores range from -1 to 1 and represent the relative ranking (ordering) of the domains.
• A negative score indicates the domain was chosen as worst more often than best
• A positive score indicates the domain was chosen as best more often than worst
• A zero score indicates the domain was chosen as best and worst an equal number of times OR
was never chosen.

Rescaled scores range from 0 to 10 and represent the individual level of satisfaction and importance experienced. The scale was labelled at each extreme as follows:
• 0 = "Not satisfied at all"/"Not important at all"
• 10 = "Completely satisfied"/"Extremely important"

In analysing the BWS results, consideration will be given as to whether there are any respondent specific characteristics that might influence preferences, such as whether demographic factors or previous experience with treatments impacts on preferences. Rescaled scores for each domain will be compared using a multivariate analysis of variance (MANOVA).

<u>Treatment background and demographic questions</u>

Descriptive statistics will be provided for the demographic component of the survey. The analysis and reporting of the data will be conducted at a total sample or segment level with participant anonymity protected.
- the mean, median, standard deviation, minimum and maximum will be reported for numeric variables, and
- the frequency and percentage will be reported for categorical variables.

Where deemed appropriate, the results for some variables will be displayed visually through a suitable graph. Any missing data resulting from a participant selecting "prefer not to answer" will be treated as a separate category within each variable. The level of significance used will be 5% ($p < .05$).

3. Deviations including missing data

No deviation from the protocol will be implemented without the prior review and

approval of the HREC except where it may be necessary to eliminate an immediate hazard to a study subject. In such case, the deviation will be reported to the HREC as soon as possible. Any protocol deviation will be reviewed and dealt with as an amendment to the current protocol where necessary.

Each participant's response will be individually assessed to determine the validity and sincerity of their responses based on the cohesion of their open text responses and the overall time they took to complete the survey. Any responses found to fail the assessment process will be excluded from the analysis.

8. PROTECTION OF HUMAN SUBJECTS

Ethics approval for this study is being sought via the Bellberry Human Ethics Committee, Australia. The review and approval ensure the study will be conducted according to the non-interventional design and to protect the rights of the participants including data protection, participant privacy, sponsor's interest.

All ethical considerations as outlined in Chapter 4 of the National Statement on Ethical Conduct in Human Research have been considered and will be applied to the conduct of the research, as outlined in the Participant Information Sheet and Participant Consent Form.

It is important to note that this is a research project, not an interventional clinical trial. The researchers from CaPPRe, in conducting this study, will act in accordance with the procedures as set out in the ethics approval. Researchers conducting this study also comply with the Australian Market and Social Research Society (AMSRS) Code of Professional Behaviour and Medicines Australia Code. These Codes have been developed to protect the interests of people who agree to participate in research studies. In addition, individual members of the AMSRS are bound by a Code which covers both the ethical requirements and standard conditions of conducting and reporting market and social research.

The research will also adhere to the relevant Australian standards on scientific credibility (including but not limited to related standards and processes for pharmacovigilance), as applicable and their regulatory standards providing assurance that the rights, safety, and wellbeing of people participating in market research studies are protected and that the study data are credible and responsibly reported. This market research study protocol has not been submitted to any other ethics committees.

CaPPRe considers this research to be a low-risk survey-based project. The project is expected to take approximately 8 months from start of fieldwork to final completion. Ongoing internal monitoring to ensure compliance of the study will be conducted by the principle and co-investigators. The progress of the study (sample achieved) will be monitored regularly (at least twice a week).

If the study takes longer than 8 months, a progress report will be submitted to Bellberry via e-protocol detailing compliance of the study with the approved protocol, consent procedures and documentation, outcome of the research, and security of records. A final report detailing the above with also be submitted at study completion. Any protocol deviations will be reported to Bellberry within 14 days of the event.

In relation to maintenance and security of records, all data is stored in a secure encrypted environment that can only be accessed by CaPPRe personnel.

Confidentiality

CaPPRe respects and understands participant privacy. By providing consent, the participant agrees to us collecting and using personal and health information they have provided for the research study. Any information obtained in connection with the research project that can identify the participant will remain confidential. Participant personal details will not be forwarded to any other parties, nor will they be contacted by CaPPRe for anything other than the research study unless they choose to do so. Participant information will only be used for the purpose of this research project and it will only be disclosed with their permission, except as required by law.

Data de-identification

The data collected in this research will be de-identified by segmenting the dataset into two, one containing participants' names and contact information (stored in Excel) and the other containing the data to be used for analysis (using R software) and reporting with a de-identified participant ID. The first dataset containing participant personal information will be held securely by CaPPRe only and stored in Australia. The personal details of participants will not be forwarded to any other parties, nor will they be contacted by CaPPRe for anything other than this research project unless they choose to be. All responses are treated with the strictest confidentiality. CaPPRe alone will know which people have participated and their responses. No individual data will be available to anyone other than CaPPRe. Seqirus will be provided with a report of the findings containing only combined de-identified data. The research data will be kept for a period of five years.

Data storage and access

All responses collected by CaPPRe are treated with the strictest confidentiality. The data will be stored in a secure encrypted environment in the cloud that only CaPPRe can access. Any data collected will be used for the purpose of this research study only.

A. Informed Consent

Participants will be provided with both a Participant Information Sheet and Consent Form for the survey prior to participating in this study. In addition, CaPPRe is available at any time to answer any questions prior to or during the study.

9. ADVERSE REACTION MANAGEMENT

All respondents will be made aware at the start of the survey that their responses may potentially raise adverse reactions and will be asked for their consent for their doctor to be contacted by Seqirus in this instance as well as for their personal email address to facilitate this contact. All personal contact details will only be used for the purposes specified and kept separate from the survey data.

All adverse reactions related to observed Seqirus products (Adverse Drug Reactions, Serious Adverse Drug Reactions, product complaints, and other safety findings, pregnancy, lactation) in routine clinical practice will be documented in accordance with Seqirus requirement documents (e.g., Standard Operating Procedures [SOPs]).

Adverse reactions will be reported according to the Seqirus requirements. Patients will be advised about reportable events and provide consent (example survey text below):

You are about to enter an online research survey. Different patients sometimes respond in different ways to the same products, and some side effects may not be discovered until many people have used a product over a period of time. For this reason, we are now required to pass on to (INSERT NAME), who is a manufacturer of medicines, details of any reportable events (side effects, situations that could affect the safety of a medicine, or product complaints) related to their own products that are mentioned during the course of market research. Although this is an online research survey and how you respond will, of course, be treated in confidence, should you raise a reportable event, where you, or someone you know, experienced a reportable event or became ill after using one of (INSERT NAME) products, we will need to report this, so that they can keep the knowledge of the safety profile of their medicines up to date. You may be contacted to provide further information about this side effect. However, you have the choice to remain anonymous and choose not to be contacted if you so wish. You will be asked to provide your preference on this further below.

10. STATEMENT OF CONFORMANCE

This study will be conducted in compliance with the protocol approved by the Bellberry Human Ethics Committee, Australia. No deviation from the protocol will be implemented without the prior review and approval of the HREC except where it may be necessary to eliminate an immediate hazard to a study subject. In such case, the deviation will be reported to the HREC as soon as possible.

11. DISSEMINATING AND COMMUNICATION OF RESULTS

A. Publication Plans

The results will be disseminated through articles submitted for publication in peer reviewed international journals, as well as oral and poster presentations at national and/or international conferences. Publication or presentation of the overall research study results requires prior written or verbal approval of CaPPRe.

The project will have a dedicated research project manager and technical lead as well as access to

methodological and strategic expertise. All technical aspects, including the BWS experimental design, programming of the survey, development of the BWS model and statistical analysis are managed in-house directly by CaPPRe staff.

Community and Patient Preference Research (CaPPRe) is a consultancy group committed to meaningful research, leading to better engagement and understanding of community and health consumer needs. CaPPRe is an independent company committed to high quality choice modelling. CaPPRe will have full responsibility for designing all materials for this study which will be reviewed and approved by Seqirus prior to fieldwork commencing.

Key CaPPRe research staff (and their responsibilities) are shown in the table below.

Table 2: Research staff and their responsibilities

Research Staff	**Main Roles and Responsibilities**

Dr Simon Fifer	- Project Oversight
	- Technical lead
	  o Experimental Design
	  o Scripting and programming
	  o BWS modelling and analysis
	- Report and dashboard review
	- Journal paper development

Lili Toh	- Project Management - Survey design - Statistical analyses - Dashboard development - Journal paper development

The project will take approximately 8 months to complete. Based on the estimated timeframe and pending ethics approval the research fieldwork is anticipated to commence in September 2021 with completion of the project estimated around December 2021.

Table 3. Project timeline

Milestone	**Planned date**
Start study preparation	August 2021
Start of data collection - Quantitative research component	September 2021
End of data collection	December 2021
Finish analysis modelling, report and dashboard preparation	January 2022
Journal publication preparation	February 2022

12. REFERENCES

Australian Institute of Health and Welfare 2019. Allergic rhinitis ('hay fever'). Cat. no. PHE 257. Canberra: AIHW. Viewed 01 May 2020, https://www.aihw.gov.au/reports/chronic-respiratory-conditions/allergic-rhinitis-hay-fever/contents/allergic-rhinitis

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