

PAAS Participant Eligibility (Day 0)

Date	___/___/_____
Patient Participant ID	_____
Practitioner completing form	<input type="checkbox"/> Dentist <input type="checkbox"/> Dental Hygienist
<b>Inclusion Criteria</b>	
<i>Note: Any 'no' response in this section disqualifies the patient from study participation. The questionnaire is ended if a participant answers 'no' in this section. Please note as screen fail.</i>	
1. Potential participant is at least 40 years old; <i>Practitioner: please confirm participant's age. You will be asked to enter their date of birth before randomization to ensure the participant is 40 or older.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Potential participant has 20 or more permanent teeth excluding 3 <sup>rd</sup> molars.	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Potential participant is in good general health as evidenced by medical history (ASA Class I or II) per the practitioner.	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Potential participant needs periodontal care for Generalized Stage II-III, Grade A-C periodontitis (previously classified as moderate to severe periodontitis), and a minimum of two quadrants of SRP (CDT code 4341) in practices participating in the National Dental PBRN PAAS study, with current need for NSPT.	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Potential participant is willing to comply with all study visits and be available for the duration of the study (12-15 months).	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Potential participant is willing to provide contact information for self, including a cellular phone number for study text, and one to two emergency contacts to be reached for the follow-up visits and any other study-related matters for the duration of the study.	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Exclusion Criteria</b>	
<i>Note: Any 'yes' response in this section disqualifies the patient from study participation. The questionnaire is ended if a participant answers 'yes' in this section. Please note as screen fail.</i>	
7. Potential participant has a known drug allergy to antibiotics or anesthetics.	<input type="checkbox"/> Yes <input type="checkbox"/> No
8. Potential participant has used systemic antibiotics within the last 3 months prior to enrollment.	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. Potential participant has a medical condition which requires antibiotic prophylaxis prior to receiving dental treatments/visits.	<input type="checkbox"/> Yes <input type="checkbox"/> No
10. Potential participant currently uses medications that may cause adverse effects with Amoxicillin/Metronidazole (AMXM) such as disulfiram, warfarin, oral contraceptives.	<input type="checkbox"/> Yes <input type="checkbox"/> No
11. Potential participant has a history of receiving periodontal therapy (including SRP D4341, D4342) within the last 6 months prior to enrollment.	<input type="checkbox"/> Yes <input type="checkbox"/> No

PAAS Participant Eligibility (Day 0)

12. Potential participant is currently pregnant or lactating per self-report.	<input type="checkbox"/> Yes <input type="checkbox"/> No
13. Potential participant is considered immunocompromised, in the opinion of the practitioner (including diseases and conditions such as HIV/AIDS, immunosuppressive drug therapy and/or radiation), or has chronic mucosal lesions (e.g. pemphigus vulgaris) affecting the gingiva.	<input type="checkbox"/> Yes <input type="checkbox"/> No
14. Potential participant has Diabetes Mellitus with an HBA1c score of $\geq 10\%$ within the past 3-months as per self-report.	<input type="checkbox"/> Yes <input type="checkbox"/> No
15. Potential participant is planning to receive another type of adjunct periodontal therapy during the course of the study (the next 12 months). This includes but is not limited to laser therapy, local antibiotic, or periodontal surgery.	<input type="checkbox"/> Yes <input type="checkbox"/> No

Eligible: \_\_\_\_

**This patient is eligible for the PAAS study. Please proceed to the consent form.**

**Pass the tablet to the participant after you click the Submit button below.**

Not Eligible: \_\_\_\_

**This patient does not qualify for the PAAS study. Please click submit below.**

PAAS Baseline Visit Checklist (Day 0)

Date	___/___/___
Patient Participant ID	_____
Which practitioner is completing the form?	<input type="checkbox"/> Dentist <input type="checkbox"/> Dental Hygienist
1. Has OHIP-5 form been completed by the participant?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Has patient participant been randomized?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Has medication been distributed and administered, to include medication instructions? <i>Recommended at least 30-60 minutes prior to the procedure</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Has plaque sample been collected? <i>only if patient participant consented to collection</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
5. Has local anesthetic been administered today?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "yes" to Question 5,	
5a. Which type of anesthetic was administered	<input type="checkbox"/> Local anesthetic <input type="checkbox"/> Topical anesthetic (e.g., Oraqix) <input type="checkbox"/> None <input type="checkbox"/> Other specify: _____
6. What quadrants were treatment planned to undergo SRP?	Upper Right (UR) <input type="checkbox"/> Yes <input type="checkbox"/> No Upper Left (UL) <input type="checkbox"/> Yes <input type="checkbox"/> No Lower Left (LL) <input type="checkbox"/> Yes <input type="checkbox"/> No Lower Right (LR) <input type="checkbox"/> Yes <input type="checkbox"/> No
7. What quadrants received SRP today?	Upper Right (UR) <input type="checkbox"/> Yes

PAAS Baseline Visit Checklist (Day 0)

	<input type="checkbox"/> No Upper Left (UL) <input type="checkbox"/> Yes <input type="checkbox"/> No Lower Left (LL) <input type="checkbox"/> Yes <input type="checkbox"/> No Lower Right (LR) <input type="checkbox"/> Yes <input type="checkbox"/> No
8. Has the treatment area been verified for completion of residual calculus with an ODU 11/12 explorer (included in patient participant package)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. Has patient participant reported an Adverse Event?	<input type="checkbox"/> Yes <input type="checkbox"/> No
10. Has practitioner reviewed and provided patient participant with the post-op oral hygiene instructions at this visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
11. Does a second appointment for scaling and root planing need to be made to complete this procedure?	<input type="checkbox"/> Yes <input type="checkbox"/> No
11a. If yes, enter date	-----
11b. If no, please answer question 12.	
12. Has practitioner uploaded the periodontal chart image? <b><i>Please ensure PD, BoP, and GR are captured</i></b>	<input type="checkbox"/> Yes <input type="checkbox"/> No

PAAS Optional Second Baseline Visit Checklist – if necessary(Day 2-10)

Date	___/___/___
Patient Participant ID	___
Which Practitioner is completing the form?	<input type="checkbox"/> Dentist <input type="checkbox"/> Dental Hygienist
Days since first Baseline visit	___
1. Has local anesthetic been administered today?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If “yes” to Question 1, 1a. Which type of anesthetic was administered	<input type="checkbox"/> Local anesthetic <input type="checkbox"/> Topical anesthetic (e.g., Oraqix) <input type="checkbox"/> None <input type="checkbox"/> Other specify: _____
2. What quadrants received SRP today?	Upper Right (UR) <input type="checkbox"/> Yes <input type="checkbox"/> No Upper Left (UL) <input type="checkbox"/> Yes <input type="checkbox"/> No Lower Left (LL) <input type="checkbox"/> Yes <input type="checkbox"/> No Lower Right (LR) <input type="checkbox"/> Yes <input type="checkbox"/> No
3. Has the treatment area been verified for completion of residual calculus with an ODU 11/12 explorer (included in patient participant package)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Has patient participant been provided oral hygiene instructions at this visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Has patient participant reported an adverse event?	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Has practitioner uploaded the periodontal chart image? <b><i>Please ensure PD, BoP and GR have been captured</i></b>	<input type="checkbox"/> Yes <input type="checkbox"/> No

## PAAS Medication Compliance Form

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Patient Participant ID: \_\_\_\_

1. Please count the number of capsules you have left in the vials of medications that were given to you at your research study visit and record below.

Vial A: \_\_\_\_ capsules

Vial B: \_\_\_\_ capsules

PAAS Re-Eval Visit Checklist (6 weeks +3 weeks)

Date	___/___/___
Patient Participant ID	___
Which practitioner is completing the form?	<input type="checkbox"/> Dentist <input type="checkbox"/> Dental Hygienist
1. Has OHIP-5 form been completed by the patient participant?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Has plaque sample been collected? <i>only if patient participant consented to collection</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3. Did patient participant previously report any Adverse Events?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "yes" to Question 3,	
3a. Were all open AEs reviewed with patient participant?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Did patient participant report any new adverse events?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "yes" to Question 4,	
4a. Were the new AEs recorded on the AE log?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Has patient participant received any subsequent antibiotics for a newly diagnosed condition?	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Has the periodontal maintenance interval been established?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "yes" to Question 5,	
5a. How frequently should the patient participant return for periodontal maintenance?	<input type="checkbox"/> Every 3 months <input type="checkbox"/> Every 4 months
7. Has patient participant been provided oral hygiene instructions at this visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8. Has practitioner uploaded the periodontal chart image? <b><i>Please ensure PD, BoP and GR have been captured</i></b>	<input type="checkbox"/> Yes <input type="checkbox"/> No

PAAS Re-Eval Visit Checklist (6 weeks +3 weeks)

Date	___/___/___
Patient Participant ID	___
Which practitioner is completing the form?	<input type="checkbox"/> Dentist <input type="checkbox"/> Dental Hygienist
1. Has OHIP-5 form been completed by the patient participant?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Has plaque sample been collected? <i>only if patient participant consented to collection</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
3. Did patient participant previously report any Adverse Events?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "yes" to Question 3,	
3a. Were all open AEs reviewed with patient participant?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Did patient participant report any new adverse events?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "yes" to Question 4,	
4a. Were the new AEs recorded on the AE log?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Has patient participant received any subsequent antibiotics for a newly diagnosed condition?	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Has the periodontal maintenance interval been established?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If "yes" to Question 5,	
5a. How frequently should the patient participant return for periodontal maintenance?	<input type="checkbox"/> Every 3 months <input type="checkbox"/> Every 4 months
7. Has patient participant been provided oral hygiene instructions at this visit?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8. Has practitioner uploaded the periodontal chart image? <b><i>Please ensure PD, BoP and GR have been captured</i></b>	<input type="checkbox"/> Yes <input type="checkbox"/> No



## PAAS Adverse Events Form

Instructions for adverse event follow up: *Below are the unresolved adverse events previously reported by the participant. Review these adverse events with the participant and update the instance if anything has changed. The data is populated with the answers you entered the last time you submitted a report on this adverse event. Be sure to update the report type, Visit # and current status at a minimum.*

*If the event continues to be unresolved, you will follow up with the participant at the next visit.*

*After reviewing all unresolved adverse events, answer the question about any new adverse events the participant needs to report. If new adverse events are reported, you will complete a new adverse event instance for each new symptom.*

*Question at Baseline visit: Has the participant reported any adverse events at this visit? Yes/No*

*Question at all other visits: Has the participant experienced any NEW adverse events since their last visit? Yes/No*

Participant ID:  Report date: This is the date you are filling out the report  •	Visit #: Select the visit number below. This should be the visit where this event is being reported OR the closest visit that has already occurred if reporting between visits. <ul style="list-style-type: none"><li>• Baseline (V1)</li><li>• Optional Baseline (V1b)</li><li>• Re-evaluation (V2)</li><li>• Final (V3)</li><li>• Between visits</li></ul>
1. Description of event <i>Describe the symptom/event in detail. Only include one symptom per report.</i>	
2. Date of event <i>This is the date the event happened. The date may be today or may be a date in the past.</i>	
3. According to study personnel, was this event expected or unexpected? <i>Expected events are as follows (you will be asked to select the appropriate expected symptom in the next question if expected is marked):</i> <ul style="list-style-type: none"><li>• Post procedural tooth sensitivity</li><li>• Post procedural pain</li><li>• Nausea</li><li>• Allergic reaction: rash or itching</li><li>• Allergic reaction: difficulties breathing</li><li>• Periodontal abscess</li><li>• Diarrhea</li></ul>	<ul style="list-style-type: none"><li>• Expected</li><li>• Unexpected</li></ul>
a. If expected, please select the expected symptom:	<ul style="list-style-type: none"><li>• Post procedural tooth sensitivity</li><li>• Post procedural pain</li><li>• Nausea</li></ul>

	<ul style="list-style-type: none"> <li>• Allergic reaction: rash or itching</li> <li>• Allergic reaction: difficulties breathing</li> <li>• Periodontal abscess</li> <li>• Diarrhea</li> </ul>
<p>4. Did the event result in any of the following actions or could it be classified as:  <i>Checking any option except "None" makes this a serious adverse event. If the event is classified as serious, your Node Coordinator will reach out to collect additional information about the event.</i></p>	<ul style="list-style-type: none"> <li>• A life-threatening event</li> <li>• A hospitalization (initial or prolonged) that required at least one night in the hospital</li> <li>• A disability or permanent damage that resulted in a substantial disruption to their ability to conduct normal life functions</li> <li>• A pregnancy resulting in a congenital abnormality or birth defect</li> <li>• Other serious important medical event that may require medical or surgical intervention to prevent one of the other outcomes listed above</li> <li>• None of the above</li> </ul>
<p>5. How would you rate the severity of this event?  <i>In the opinion of the practitioner</i></p>	<ul style="list-style-type: none"> <li>• Mild</li> <li>• Moderate</li> <li>• Severe</li> </ul>
<p>6. Was this event study drug related? <i>In the opinion of the practitioner</i></p>	<ul style="list-style-type: none"> <li>• Definitely</li> <li>• Probably</li> <li>• Possibly</li> <li>• Remotely</li> <li>• Definitely not</li> <li>• Unknown</li> </ul>
<p>7. What is the current status of the event?</p> <p><b><i>Additional reporting will be required at future study visits for conditions that are improving, present and unchanged and deteriorating.</i></b></p> <p><b><i>If a death is being reported, additional reporting is required as a serious adverse event. Your Node Coordinator will reach out to gather additional details</i></b></p>	<ul style="list-style-type: none"> <li>• Completely recovered</li> <li>• Recovered with some residual problems</li> <li>• Condition improving</li> <li>• Condition present and unchanged</li> <li>• Condition deteriorating</li> <li>• Death (skip to 7b)</li> </ul>
a. On what date was this event resolved?	MM/DD/YYYY
b. Date of death?	MM/DD/YYYY
Per the protocol, the study PI should review the report and confirm the following information:	
<p>8. <b><i>PI complete this field only:</i></b> In the PI's view, was this event expected or unexpected? <i>Expected events are as follows (you will be asked to select the appropriate expected symptom in the next question)</i></p>	<ul style="list-style-type: none"> <li>• Expected</li> <li>• Unexpected</li> </ul>

<ul style="list-style-type: none"> <li>• <i>Post procedural tooth sensitivity</i></li> <li>• <i>Post procedural pain</i></li> <li>• <i>Nausea</i></li> <li>• <i>Allergic reaction: rash or itching</i></li> <li>• <i>Allergic reaction: difficulties breathing</i></li> <li>• <i>Periodontal abscess</i></li> <li>• <i>Diarrhea</i></li> </ul>	
a.If expected, please select the expected symptom:	<ul style="list-style-type: none"> <li>• Post procedural tooth sensitivity</li> <li>• Post procedural pain</li> <li>• Nausea</li> <li>• Allergic reaction: rash or itching</li> <li>• Allergic reaction: difficulties breathing</li> <li>• Periodontal abscess</li> <li>• Diarrhea</li> </ul>
9. <b>PI complete this field only:</b> In the PI's view, was this event study drug related?	<ul style="list-style-type: none"> <li>• Definitely</li> <li>• Probably</li> <li>• Possibly</li> <li>• Unlikely</li> <li>• Not related</li> </ul>
10. <b>PI complete this field only:</b> Does the PI agree with the classification of serious or not serious in question 4 above?	<ul style="list-style-type: none"> <li>• A life-threatening event</li> <li>• A hospitalization (initial or prolonged) that required at least one night in the hospital</li> <li>• A disability or permanent damage that resulted in a substantial disruption to their ability to conduct normal life functions</li> <li>• A pregnancy resulting in a congenital abnormality or birth defect</li> <li>• Other serious important medical event that may require medical or surgical intervention to prevent one of the other outcomes listed above</li> <li>• None of the above</li> </ul>
<b><i>If no to question 10: You indicated you do not agree with the practitioner's assessment of seriousness. Contact the NCC as soon as possible to resolve this issue.</i></b>	
11. <b>PI Complete this field only:</b> In the PI's view, does this event suggest that research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized).	<ul style="list-style-type: none"> <li>• Yes</li> <li>• No</li> </ul>
PI attests they have reviewed this adverse event, submitted their evaluation and verified that all	<ul style="list-style-type: none"> <li>• Yes</li> <li>• No</li> </ul>

information is complete	MM/DD/YYYY
-------------------------	------------