Section		
1.0	**General Information**	
1.1	**Study Title:**	QUICKly eradicate Hepatitis C in patients Undergoing REnal Transplant with 4 weeks of Glecaprevir/Pibrentasvir (QUICK-CURE)
1.2	**1.2 Institution Name:**	Massachusetts General Hospital, Boston, MA 02114
1.3	**Investigator Contact Information:**	Nahel Elias Transplant Surgery, Massachusetts General Hospital 55 Fruit Street Boston, MA, 02114 Phone: 617-726-5277 E-mail: Elias.Nahel@mgh.harvard.edu Raymond T. Chung Gastrointestinal Unit, Massachusetts General Hospital 55 Fruit Street Boston, MA, 02114 Phone: 617-643-2257 Mobile: [redacted] E-mail: chung.raymond@mgh.harvard.edu Meghan Sise, MD, MS Division of Nephrology, Massachusetts General Hospital 165 Cambridge St. Suite 302 Boston, MA 02114 Phone: 617-643-3948 Mobile: [redacted] Email: msise@partners.org
2.0	**Background Information**	
2.1	**Rationale & Background Information**	Nearly 95,000 people in the United States are waiting for a kidney transplant. Increasing kidney transplantation is an important component of the Advancing American Kidney Health Initiative, and identifying ways to decrease discard of potentially viable kidneys is an important priority. Over the last five years, the number of deceased organ donors with hepatitis C virus (HCV) infection has increased substantially, largely due to the opioid epidemic. Since HCV-infected donors are typically younger and their kidneys are predicted to have robust allograft function, there has been tremendous interest in increasing utilization of kidneys from these donors by allowing recipients who do not have HCV to accept offers from HCV-infected donors, and then begin treatment with direct-acting antiviral therapies (DAAs). These strategies are only possible because DAAs are highly effective at curing HCV with relatively short courses and are well tolerated with very few side effects. Single center clinical trials investigating whether transplantation from actively viremic HCV-infected donors to HCV-naïve recipients have demonstrated 100% cure rates using a 12-week course of DAAs begun in the peri-transplant period. However, other single-center retrospective studies have delayed starting DAA therapy for weeks to months after kidney transplant due in part to difficulties in insurance approval. These studies reported higher rates of complications, including virologic relapses, episodes of acute rejection, cytomegalovirus infection, polyoma virus infection, and even cases of fibrosing cholestatic hepatitis. We recently completed enrollment for the MYTHIC trial, a multicenter, prospective, open-label study to evaluate the safety, efficacy, and viral kinetics when glecaprevir and pibrentasvir (G/P), a fixed-dose

		combination antiviral regimen, was administered on post-operative day three and continued for eight weeks after transplantation from an HCV-viremic donor to an HCV-naïve recipient. Because of the efficacy of G/P and the low viral loads observed after kidney transplant, many have wondered whether shorter courses of G/P could be effective, particularly if G/P is begun in the immediate post-transplant period, before HCV infection can become established. Pilot studies have examined four-week courses of G/P and demonstrated so far 100% cure rates however numbers are very small. The American Society of Transplantation Consensus Conference on the Use of HCV Donors in Solid Organ Transplantation has highlighted the urgent need for more prospective investigation into the risks and benefits of using organs from HCV-infected donors. Indeed, more prospective studies will be needed to determine the safety of these approaches. However, we believe that starting G/P in the peri-transplant period compared to waiting until viremia is established in the recipient will minimize post-transplant complications and be highly cost effective.
3.0	**Core Protocol**	
3.1	**Study Objectives and Purpose**	Primary Study Objective Determine if the administration of G/P for 4 weeks beginning in the immediate peri-transplant period prevents establishment of HCV infection in HCV negative recipients receiving transplanted kidneys from HCV RNA positive donors Secondary Objectives 1. Evaluate the safety and tolerability of G/P in patients undergoing kidney transplantation by evaluating study-participation related (either related to G/P or HCV-viremia) severe and non-severe events from transplant until one-year post-transplant. Post-transplant allograft function outcomes: mean eGFR over time through the 1-year study period. We will also determine the rate of the following clinical outcomes related to safety: death, graft failure, acute allograft rejection, delayed graft function, ALT elevations > 5x ULN that occur within the 1-year study period 2. Capture patient reported outcomes 1 year after transplant or 1 year after consent (for those who remain on the waiting list) using the Functional Assessment of Chronic Illness Therapy Fatigue Subscale (FACIT-F) and compare results among patients who receive a kidney from a HCV-viremic donor and those who do not. Hypothesis We hypothesize that the administration of G/P (300mg/120mg) once daily for 4 weeks beginning within 24 hours of kidney transplant (either on-call to the operating room or within 24 hours of transplant) will prevent detectable HCV RNA in HCV RNA negative recipients receiving transplanted kidneys from HCV RNA positive donors during and after treatment completion.

3.2	**Study Design**	This study is an open label, single-center, interventional, uncontrolled, pragmatic clinical trial for the donation of HCV positive kidneys to HCV negative patients with ESRD. It is a single arm study; all HCV-uninfected recipients of an HCV-viremic kidney transplant will begin G/P for 4 weeks beginning in the peri-transplant period (either on-call to the operating room or within 24 hours of transplant). Forty subjects will be enrolled (transplanted and dosed with G/P), with up to 80 total consented to determine eligibility. The target population is patients with ESRD who are at least 18 years old, do not have history of HCV infection, and are listed for transplant at the MGH Transplant Center. Primary Endpoints SVR12 - sustained virologic response 12 weeks after completing G/P (16 weeks post-kidney transplant). Secondary Endpoints • Severe and non-severe adverse events attributed to study drug • Severe and non-severe adverse events attributed to HCV-viremia • Assessment of HCV RNA viral load at on-treatment visits (week 2 and 4) • Post-transplant allograft function outcomes: mean eGFR over time through the 1-year study period. • The rate of the following clinical safety outcomes: death, graft failure, acute allograft rejection, delayed graft function, ALT elevations > 5x ULN that occur within the 1-year study period. We will classify which of these events are related to G/P or HCV-Viremia and those which are not related.
3.3	**Inclusion Criteria**	Donor Inclusion Criteria: a. Detectable HCV NAT test b. KDPI score is less than ≤ 0.850 c. Traditional Donor Selection Criteria Met - acceptable for transplantation per usual evaluation Recipient Inclusion Criteria: a. Met MGH Transplant Center criteria and already listed for kidney transplant with stage 5 CKD / ESRD (eGFR <15 ml/min/1.73m^2 or on renal replacement therapy) b. Must agree to birth control. Women must agree to use birth control in accordance with Mycophenolate Risk Evaluation and Mitigation Strategy and at least one barrier method c. No evidence of clinically significant liver disease at the time of transplant readiness as determined by the clinical team d. Able to sign informed consent

3.4	**Exclusion Criteria**	Donor Exclusion Criteria: a. Confirmed HIV b. Confirmed HBV positive (surface antigen or HBV DNA positive) c. Any standard contra-indication to donation noted in donor (significant malignancy, unusual infection, kidney anatomical damage or significant pathology) Recipient Exclusion Criteria: a. Pregnant or nursing (lactating) women b. HBV positivity (Ag or DNA) c. Any contra-indication to kidney transplantation per MGH transplant center protocol d. Any signs or symptoms of clinically significant chronic liver disease per transplant center physician e. Inability to discontinue any medication with a known drug-drug interaction as listed in the G/P package insert
3.5	**Study Flowchart**	

Visit	AEs	Con Meds	G/P adherence	Vitals & PE	Dispense G/P	CMP	CBC & diff	HCV RNA	HCV Ab	HCG	DAA resistance	PROMs
Screening		x		x		x	x	x	x	x		
Peri-transplant visit	x	x		x		x	x					
Day 1 post-KT	x	x		x	x	x	x	x				
Week 2 post-KT	x	x	X	x		x	x	x				
Week 4 post-KT	x	x	x	x		x	x	x				
End of G/P	x	x	x									
Post-treatment Week 4	x	x		x		x	x	x				
Post-treatment Week 12	x	x				x	x	x				
Post-treatment 1 Year	x	x		x		x	x	x	x			x
G/P treatment failure	x							x			x	
Premature discontinuation	x			x		x	x	x				
1 year from consent (if not transplanted)												x

3.6	**Study Procedures**	The study will be a single-arm, open-label, pragmatic trial to evaluate the efficacy and safety of fixed-dose combination tablets of glecaprevir/pibrentasvir (G/P) for four weeks in HCV-negative subjects who consent to receive a kidney transplant from an HCV RNA-positive deceased kidney donor. Patient reported outcomes will be performed 1 year after transplant or 1 year after consent for those who do not undergo transplant. <u>Screening Period</u> Potential subjects will be contacted by a member of the research staff to provide information about the study and to gauge interest. Interested individuals will be provided educational materials on HCV infection and transplantation. After this, potential subjects will be eligible for screening (there should be at least 24 hours between the educational visit and the screening visit, though special cases may allow these visits to occur on the same day as educational materials were provided). At the screening visit, the potential subject will review the informed consent again with the PI and sign if still interested in participating. Upon signing consent, the individual will receive a unique subject number. Both in-person and remote written informed consent will be conducted in accordance with institutional policy. Remote consent can be performed by a physician investigator in lieu of in person consent. During the consent process, the consenting physician will explain the scope of the study, potential risks and benefits. When the subject fully understands the scope of study participation, their consent will be obtained. Consents will be signed by the patient and mailed back to the study site, at which time the consenting physician will sign the consent. The rest of the screening visit will include a physical exam, vital signs, blood tests, and review of medical history and concomitant medications. The study investigators and research team will then review the potential subject's information to determine whether the patient is eligible to participate or not. Patients who are on contraindicated medications will need to be able to cease the contraindicated medication or switch to an alternative, allowed co-medication to be deemed eligible. Up to 80 subjects will be consented for trial participation, of whom 40 subjects will receive an HCV RNA-positive kidney and open-label G/P for 4 weeks post-transplant. <u>Waitlist Period</u> Subjects who have been enrolled in the study and are listed for kidney transplant at MGH Transplant Center will be placed in the waitlist group until being called for a transplant. While on the waitlist, subjects will be monitored by the transplant team for changes to health status, and changes in transplant waitlist status as per standard of care. <u>Baseline Period</u> Upon matching to a donor, the study subject will come into the hospital, following kidney transplantation standard-of-care procedures. The first dose of G/P will be given as early as "on call" to the operating room and no later than 24 hours after the transplant operation begins. The patient will be provided with a month supply of drug upon discharge from hospital. Treatment with G/P will then continue once daily for four weeks. Physical exam, vital signs, CMP, CBC & differential and pregnancy test will occur at baseline per standard of care. <u>On-treatment Period</u> Subjects will be followed per standard of care throughout the on-treatment period. Data will be recorded on day 1, week 2, and week 4 post-transplant: adverse events (including graft survival, mortality, allograft rejection, and potential hepatic and extrahepatic manifestations of HCV infection), concomitant medications, adherence to G/P dosing, vitals, physical exam, CMP, CBC & differential, HCV RNA will take place at these visits. Counseling regarding contraception and

		pregnancy testing will occur per standard of care. Follow-up Period Subjects will be followed per standard of care throughout the post-treatment period up to one-year post-transplant. Data will be recorded on week 4 and week 12 post-treatment and week 52 post-transplant: adverse events (including graft survival, mortality, allograft rejection, and potential hepatic and extrahepatic manifestations of HCV infection), concomitant medications, adherence to G/P dosing, vitals, physical exam, CMP, CBC & differential, HCV RNA and pregnancy test, as per standard of care. Recipients of RNA-positive kidneys will be assessed for SVR12 at the week12 post-treatment visit. HCV Ab will be tested at screening and 1 year after transplant. Subjects treated with G/P who experience virologic failure will be evaluated for the emergence/persistence of direct-acting antiviral agent (DAA)-resistant viral variants, and suitable retreatment will be offered to study participants directed by Dr. Chung or Dr. Sise. Patients will receive a standard of care kidney transplant care including induction and maintenance immunosuppression as directed by their treating transplant team. Subject Withdrawal Criteria Pre-transplant patients (still on the waiting list) will be withdrawn if he or she has not achieved MGH Transplant Center criteria (per inclusion criteria). The patient will be removed from the study and will not be followed-up any longer. Study subjects have the right to withdraw from the study at any time. Additionally, the investigator may decide to withdraw a subject from the study at any time, if the investigator considers it necessary for any reason (including adverse event or failure to comply with protocol). If the subject withdraws from the study post-transplant while on treatment with G/P, an Early Discontinuation visit should occur as soon as possible. At this visit, the following procedures will occur: physical exam, vital signs, CMP, CBC & differential, and HCV RNA. The subject will be treated according to the principal investigator's best clinical judgment. The last dose of the study drug and reason for discontinuation will be recorded in the medical record and submitted to the sponsor and IRB for review. The subject should then be followed for up to 24 weeks post-transplant to monitor for HCV RNA. If the subject withdraws from the study with an ongoing adverse event or an unresolved laboratory result that is significantly outside of the reference range, the investigator will attempt to provide follow-up until a satisfactory clinical resolution of the laboratory result or adverse event is achieved. Study subjects with treatment failure, as defined below, will be provided a regimen chosen at the discretion of study's principal investigator (Raymond Chung, MD or Meghan Sise, MD). The retreatment of the subject will then be followed per standard of care. Retreatment will be handled outside of this protocol, at the discretion of the treating physician, coordinating with best practices recommendations from the principal investigator. The treating team will apply for coverage of the second-line DAAs through insurance since at that point the infection will be established. Hospital funds have been made available to cover any case where insurance fails to approve DAAs after transplant or an uninsured patient does not meet the institution's criteria for indigent status, so if the patient's insurance does not cover second-line DAA or an uninsured patient does not meet the institution's criteria for indigent status we will use the hospital funds to assure retreatment. Study Record Retention

		Study records will be maintained at the study site for a minimum of 7 years after the study has completed (LSLV)
3.7	**Statistical Analysis and Sample Size Justification**	Sample Size Justification Power/Sample Size: This study is designed to generate preliminary data related to cure rates (defined as SVR12) from treating donor-derived HCV infection post kidney transplantation using 4 weeks of G/P. For this reason, the sample size was not determined with reference to power to detect differences between groups for the primary objective. The lower bound of a one-sided 95% confidence interval will be performed using the Clopper pearson exact method. This is a pilot study with the goal to complete enrollment in 18 months. 40 patients will be dosed with medication. With 40 patients, if 40/40 are cured the lower bound of the confidence interval will be > 92%. Statistical Analysis Plans Include statistical methods for analysis of all primary and secondary endpoints *Variables/Time Points of Interest.* The primary variable of interest will be HCV RNA at the multiple time-points assessed during and after treatment. The primary efficacy outcome "Prevention of HCV Transmission" will be determined by a negative HCV RNA test at 12 weeks after completing G/P. A summary of reasons for SVR12 non-response (e.g., establishment of infection, loss to follow-up, or other) will be provided. We will use an intention to treat analysis to determine, but will also modified intention to treat which only evaluates virologic failures. The safety outcomes include summation of treatment related-severe and non-severe adverse events. We will only collect data on adverse events deemed to be at possibly related to study participation (either from the study treatment G/P or from HCV viremia itself). An adverse event will be considered treatment-emergent if it begins or worsens in severity after initiation of study drug through 30 days post-study drug dosing. Related adverse events are those considered at least possibly related to study. The number and percentage of subjects with the following clinical outcomes and data post-transplant as applicable: death, graft failure, acute allograft rejection, delayed graft function, ALT elevations > 5x ULN, and SAEs. Statistical Methods Patient characteristics for this transplanted cohort (N=40) will be presented with summary statistics for baseline demographics and clinical variables. The SVR12 rate will be presented and 95% CI constructed with the exact test. Mean and standard deviation for on-treatment laboratory values will be presented to analyze safety. Power/Sample Size: This study is designed to generate preliminary data related to cure rates (defined as SVR12) from treating donor-derived HCV infection post kidney transplantation using 4 weeks of G/P. For this reason, the sample size was not determined with reference to power to detect differences between groups for the primary objective. The lower bound of a one-sided 95% confidence interval will be performed using the Wilson's score method.

		The primary efficacy endpoint is sustained virologic response 12 weeks post dosing (SVR12), defined as HCV RNA < LLOQ 12 weeks after the last actual dose of G/P. The SVR12 rate will be determined from all enrolled subjects who received an HCV RNA-positive kidney and received at least one dose of G/P study drug along with a two-sided 95% confidence interval. The confidence interval for the SVR 12 rate will be calculated using Clopper pearson exact method. As an exploratory secondary outcome, we will compare FACIT-F scores among three groups 1. HCV-viremic donor kidney transplant recipients 2. Standard of care kidney transplant recipients 3. Patients remaining on the kidney transplant waiting list. Means will be compared using ANOVA testing. Investigators will be responsible for analyzing data with statistical support.
3.8	**Specific Drug Supply Requirements**	The investigator and research team will keep accurate records of the study drug (G/P 100 mg/40 mg). The study drug will be stored at 15° to 25°C (59° to 77°F) in the Clinical Trials Research Pharmacy (CTP) at MGH. It will be maintained under adequate security and stored under the conditions specified on the label until dispensed for subject use, destroyed on-site, or returned to AbbVie (or designee) as per ICH/GCP Guidelines, local regulations and MGH institutional policies. The investigator and research team will also maintain a current disposition record of study drug (inventoried and dispensed) at the study site, including: • amount received and placed in storage area • amount currently in storage area • label identification number or batch number • amount dispensed to and returned by each subject, including unique subject identifiers • amount destroyed at study site, if applicable • amount returned to AbbVie, if applicable • dates and initials of person responsible for Investigational Product dispensing/ accountability, as per the Delegation of Authority Form
3.9	**Safety Reporting**	Subjects will be monitored throughout the study period for clinical and laboratory evidence of adverse events, according to standard medical practice, AASLD HCV guidelines, and kidney transplant protocols. An adverse event is defined as any untoward medical occurrence associated with the protocol procedures, whether or not drug or procedure related. This is considered to be any sign, symptom, illness, or experience that develops or worsens during the course of the study. Every adverse event will be reviewed by the principal investigator for adjudication on relatedness to study protocol. Only adverse events that are related to study participation will be reported. We consider study participation to be related to G/P or receiving an HCV + kidney transplant. Not those related to kidney transplant, immunosuppression, underlying disease process etc. Adverse event logs will be kept for each subject enrolled in the study and provided to the sponsor and IRB for review. A Data Safety Monitoring Committee (DSMC) will be established to review subject data after every 10 transplants and on an ad hoc basis. The DSMC is comprised of three physicians who have expertise in transplantation, infectious diseases, and hepatology. The DSMC will review all safety data including adverse events and make determinations regarding the conduct and continuation of the study.

If an adverse event meets the following criteria, it will be reported to the sponsor (AbbVie) as a serious adverse event (SAE) within 24 hours of learning of the event, regardless of relationship to study drug or procedures:

- Death of subject
- Life threatening: per investigator, an event that would have resulted in immediate fatality had medical intervention not been taken
- Hospitalization or prolongation of hospitalization (does not include emergency room visit or admission to outpatient facility)
- Persistent or significant disability/incapacity: event that results in condition that significantly interferes with daily activities of subject
- Important medical event requiring medical or surgical intervention to prevent serious outcome: per investigator, an event that may lead to one of the outcomes listed above and therefore requires medical or surgical intervention
- Pregnancy that has resulted in congenital anomaly: An anomaly detected at or after birth, or any anomaly that results in fetal loss."

SAEs will be categorized as pre-transplant or post-transplant, and pre-treatment, on-treatment, or post-treatment. The following information will be reported to the sponsor and to the IRB:

- Admission and discharge notes
- Consults with vitals and physical exam, as available
- All labs
- Imaging and procedure reports
- Medication administration record

All SAE correspondence with AbbVie will be sent to: *PPDINDPharmacovigilance@abbvie.com*

For events that meet the IND safety reporting criteria, the investigator will also copy AbbVie on submission of SAE report to FDA.

Adverse event severity

Per investigator, adverse events will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) using the following definitions:

1. **Mild:** Adverse events and/or symptoms recorded in the medical record where no therapy was given to treat the event or where an over-the-counter medication/intervention ONLY was given to treat the event.
2. **Moderate:** Adverse events and/or symptoms recorded in the medical record requiring prescription medication treatment.
3. **Severe:** Adverse events and/or symptoms requiring any study drug discontinuation will be defined and coded as severe. ANEMIA events requiring blood transfusion will be coded as severe.

Adverse event relatedness to study drug

Per investigator, adverse events will be assessed for relatedness to study drug according to the following definitions:

- **Reasonable possibility ("associated"):** An adverse event where there is evidence to suggest a causal relationship between the study drug and the adverse event
- **No reasonable possibility ("not associated"):** An adverse event where there is no evidence to suggest a causal relationship between the study drug and the adverse event.

Pregnancy

		Pregnancy should be avoided starting from screening through 30 days after completion of study drug. If a pregnancy occurs, it should be reported to the sponsor within 24 hours of the site learning of the event. The administration of DAAs to that subject may be continued at site investigators discretion and in consultation with the study's principal investigator after discussion with the subject, if the benefit of continuing DAAs is felt to outweigh the potential risk. Toxicity Abnormal laboratory values that occur during the study period will be evaluated by the investigator. Those that are deemed "clinically significant" by the investigator, or require intervention will be classified as adverse events and will be managed and followed until clinical resolution. • **Management of ALT elevations while on study drug:** if subject experiences a post-baseline increase in ALT > 5x ULN and > 2x baseline value, a repeat ALT measurement will be performed – if confirmed, the following procedures will be done: o Evaluation for alternate etiology o Management as medically appropriate o Repetition of liver chemistries within one week, and until resolution o Discontinuation of study drug if a) ALT level > 8x ULN in absence of alternate etiology, or b) increasing direct bilirubin or INR or onset of hepatitis signs or symptoms Acute rejection or graft failure If at any time a patient experiences either presumed or biopsy proven rejection, this will be reported as an adverse event. Graft failure will also be reported as an adverse event. Product complaint A product complaint is defined as any written, electronic, or oral communication that alleges deficiencies related to the physical characteristics, identity, quality, purity, potency, durability, reliability, safety, effectiveness, or performance of a product after it is released for distribution. Product complaints must be reported to AbbVie within 24 hours of the time it is observed. Principal Investigator will report product complaints that involve to AbbVie products to: RD_PQC_QS@abbvie.com
3.10	**References**	United States Renal Data System. 2019 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018. Hart, A., J.M. Smith, M.A. Skeans, et al., OPTN/SRTR 2017 Annual Data Report: Kidney. Am J Transplant, 2019. 19 Suppl 2: p. 19-123 Reese, P.P., P.L. Abt, E.A. Blumberg, and D.S. Goldberg, Transplanting Hepatitis C-Positive Kidneys. N Engl J Med, 2015. 373(4): p. 303-5 Chute, D.F. and M.E. Sise, Effect of the Opioid Crisis on the Donor Pool for Kidney Transplantation: An Analysis of National Kidney Deceased Donor Trends from 2010-2016. Am J Nephrol, 2018. 47(2): p. 84-93 Chute, D.F., R.T. Chung, and M.E. Sise, Direct-acting antiviral therapy for hepatitis C virus infection in the kidney transplant recipient. Kidney international, 2018. 93(3): p. 560-567 Durand, C.M., M.G. Bowring, D.M. Brown, et al., Direct-Acting Antiviral Prophylaxis in Kidney Transplantation From Hepatitis C Virus-Infected Donors to Noninfected Recipients: An Open-Label Nonrandomized Trial. Annals of internal medicine, 2018. 168(8): p. 533-540

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<tr><td></td><td></td><td>Potluri, V.S., D.S. Goldberg, S. Mohan, et al., National Trends in Utilization and 1-Year Outcomes with Transplantation of HCV-Viremic Kidneys. Journal of the American Society of Nephrology : JASN, 2019. 30(10): p. 1939-1951
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Kapila, N., K.V.N. Menon, K. Al-Khalloufi, et al., HCV NAT positive solid organ allografts transplanted into HCV negative recipients: A real-world experience. Hepatology (Baltimore, Md.), 2019: p. 10.1002/hep.31011
Molnar, M.Z., S. Nair, O. Cseprekal, et al., Transplantation of kidneys from hepatitis C-infected donors to hepatitis C-negative recipients: Single center experience. American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons, 2019. 19(11): p. 3046-3057</td></tr>
<tr><td>3.11</td><td>Study Timelines</td><td>Provide the estimated study timelines below:

<table>
<tr><th>Milestone</th><th>Est. Date (Month/Year)</th></tr>
<tr><td>Duration*</td><td>18 months</td></tr>
<tr><td>First Subject First Visit (FSFV)</td><td>May 2021</td></tr>
<tr><td>Last Subject Last Visit (LSLV)</td><td>December 2024</td></tr>
<tr><td>Final Report (e.g., manuscript/ publication)</td><td>August 2025</td></tr>
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*Duration is defined as FSFV to LSLV in months.</td></tr>
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