

NC TraCS Clinical & Translational Science (CTS) Pilot Awards Request for Applications (RFA)- Deadline: July 8, 2025

I. Key Dates for Cycle 5

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| • FOA Release Date | March 1, 2025 |
| • FAQ Sessions | Apr 24 th register here /Apr 29 th register here |
| • *Applicants meet w/CTS Pilot Program staff | March - June 2025 |
| • **Meetings held with TraCS service reps | March - June 2025 |
| • Application Due Date | July 8, 2025 |
| • Anticipated Funding Announcement | October 2025 |
| • Regulatory/NCATS Prior Approval Deadline | February 1 – March 1, 2026 |
| • Funding Period | April 1, 2026-March 31, 2027 |
- * To ensure optimal responsiveness to the FOA, all applicants are **required** to consult with TraCS pilot program staff prior to submitting a proposal (see “**IV.A. Consultation with NC TraCS Pilot Program Staff**” below).
- ** Applicants proposing to use TraCS services are **required** to meet with and obtain approval from service representatives prior to submitting a proposal (see “**IV.B. Use of NC TraCS Research Services**” below).

II. Purpose of RFA/Examples of appropriate projects

The North Carolina Translational and Clinical Sciences Institute (NC TraCS) is the academic home of the National Institutes of Health Clinical and Translational Science Award (CTSA) at UNC Chapel Hill.

The CTS pilot award program is intended to support Clinical and Translational Science (CTS), the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational *process*. Whereas translational research focuses on the specific case of a target or disease, **translational science focuses on the general case that can be applied to research on any target or disease.**

Submitted pilot projects must be focused on translational science, i.e., focused on (i) understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research, or (ii) addressing a broadly encountered roadblock in the process of translational research. Translational **research** projects, i.e., projects focused on crossing a particular step of the translational process for a particular target or disease, are generally not allowed. However, the proposed research may use a specific translational research use case to test a CTS hypothesis, *as long as the CTS relevance of the work is clearly described.*

Types of CTS Pilot activities that may be supported include (this list is not exclusive):

- Development of new research methodologies and/or new technologies/tools/resources that will advance the efficiency and effectiveness of research
- Improve recruitment of patients into clinical trials
- Early-stage development of new therapies/technologies with *generalizable* application to an identified translational roadblock
- Demonstration, in a particular use case(s), that the new methodology or technology advances translational science by successfully making one or more steps of the translational process more

- effective or efficient
- Dissemination of effective tools, methods, processes, and training paradigms

III. Funding & Eligibility

A. PI/Co-I Eligibility

- Principal Investigator applicants should hold a faculty appointment or a permanent non-faculty appointment like “research scientist” or other position typically held by investigators from research institutes and centers who are eligible to apply for investigator-initiated awards and NIH R01/R21 funding. For specific questions regarding eligibility, please contact pilots@unc.edu
- Only eligible investigators from one of the NC TraCS academic partner institutions (UNC-CH, NC A&T or NC State) can serve as the project PI.
- Multiple-PI teams are allowed, with the understanding that (i) all PIs share equal responsibility for the conduct and direction of the project, and (ii) all co-PIs individually fulfill the PI eligibility requirements described above. However, one PI - designated as the “Contact PI” - will serve as the primary contact between the research team and CTS Pilot Program administration.
- Co-Investigators (co-Is) must be (i) from one of the TraCS partner institutions, and (ii) a postdoctoral fellow or higher (eg, Research Associate, permanent research staff or faculty).

B. PI/Co-I Support

PIs must include between 1-5% salary effort (up to the NIH salary cap). Other faculty (e.g., Co-Is) who are significant contributors to the project must also budget effort commensurate with their role in the project, with a minimum of 1% salary effort per contributor. Budget guidelines are detailed in [VII. Budget Guidelines](#) below.

C. Award size, Cost Sharing

TraCS CTS Pilot Awards offer \$25,000 - \$50,000 in direct costs. However, please note that:

1. Cost sharing is not allowed. Pilot projects must be supported solely with CTS Pilot Award funds, and no other funding sources may be budgeted for these projects (See [VII. Budget Guidelines](#) below for more information).
2. Pilot grant awardees may avail themselves of TraCS services if such assistance will strengthen their projects, although the level of TraCS assistance to be provided *must* be discussed and agreed upon before grant submission (see *Section IV.B “Use of NC TraCS Research Services” below*). To maximize the value of the pilot award, these TraCS services are available to Pilot grant awardees at significantly reduced rates (see below).

IV. Pre-Application Consultations with TraCS

A. Mandatory consultation with NC TraCS Pilot Program Staff

To ensure that the proposed work is as responsive as possible to the goals of the CTS Pilot Program, prospective applicants are required to meet with Pilot Program staff to discuss their project prior to submission. Staff can advise on how to best present the translational science problem to be addressed, the general methodological approach, and whether any TraCS services might be useful. Applicants can request a Pilot Program consult through the “Start a Request” link on the [TraCS home page](#). Select “Pilot Program” from the “TraCS Programs” drop-down menu.

B. Use of NC TraCS Research Services

If the applicant proposes to use [TraCS services](#), for example, Biostatistics or Recruitment & Retention, ***the applicant must meet with service representatives and obtain a written estimate and approval from each relevant service prior to submission.*** This should be done after the initial meeting with the Pilot Program staff.

While TraCS services are available to pilot awardees, this assistance is not unlimited and is dependent on service capacity. The extent of assistance available to the applicant must be determined and agreed upon prior to submission, and this must be described in the grant application (see [Section V.9](#) below) using a [TraCS Service Agreement form](#), and itemized in the grant Budget and Budget Justification. Bear in mind that, depending on their workload, service consultations may not be immediately available. Therefore, please consult with service representatives as early as possible, so that the extent of TraCS assistance can be discussed and agreed upon before the submission deadline.

TraCS will alleviate the cost of services to awardees by providing a 1:1 match to cover the cost of these services. *This match applies to TraCS services only, and to no other budget item.* This match will result in a 50% reduction in the hourly service rate effective at the start of the funding period. Complete a Service Agreement Form for each TraCS service you need, save the document(s) as PDFs and combine them into a single PDF to be uploaded with the application.

We strongly recommend that applicants initiate discussions with TraCS services at least three weeks before the submission deadline, to ensure that the TraCS service requested can be reviewed and agreed upon, and the requisite Service Agreement completed, before grant submission.

Applications that do not include the requisite TraCS Service Agreement(s), describing the TraCS assistance to be provided, and approved by appropriate service representatives, will be considered incomplete and will not be reviewed.

Applicants can request a service consultation through the “Start a Request” link on the [TraCS home page](#). Select the relevant TraCS program from the “TraCS Programs” drop-down menu

V. Proposal Submission

Applications are submitted using the NC TraCS [online pilot submission system](#). Applications are due by 5:00 p.m. on Tuesday **July 8, 2025**. Applicants will be notified by email in **October 2025** whether or not their application has been selected for funding. Proposal sections (except the Abstract and Impact Statement) are uploaded as individual PDF files. The application sections are:

- 1) **Scientific Abstract:** Summary of the proposal (*online 1500 character limit, ~250 words*).
- 2) **Impact Statement:** Briefly describe the likelihood for your project to exert a sustained, powerful influence on the research field(s) involved (*online 300 character limit, ~50 words*).
- 3) **Discussion of the CTS problem to be addressed:** This section of the application should clearly:
 - Outline the CTS problem the work will address and the overarching hypothesis that underlies the proposed CTS project
 - Explain how addressing this problem will have broad applicability
 - Explain the relevance of any proposed Clinical and Translational Research (CTR) use case to the broader CTS problem (*if applicable*)
 - Detail how, if the project is successful, the results or lessons learned will impact other realms of translational research – please provide specific examples if possible(*PDF, 2-page limit, 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round*).

- 4) **Research Team:** Briefly describe the research team, highlighting the skills and experience that speak to the feasibility of the proposed work and what specific role each will play in the project (*PDF, 1-page limit, 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round*).
- 5) **Response to Previous Review:** If you previously submitted the application to the TraCS CTS Pilot Program, outline how the revised application addresses reviewer critiques. (*PDF, 2-page limit, 1.5 line spacing, font no smaller than Arial 11 and 0.5-inch margins all round*).
- 6) **Research Plan:** The Research Plan should include Specific Aims, Innovation, and Approach. Include, where applicable, clear evidence of how the proposal meets the review criteria and how the project will be generalizable. (*PDF, 5-page limit, including tables and figures. 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round. Cited references do not count towards the 5-page limit.*)
- 7) **Cited References:** (*PDF, no page limit*)
- 8) **Plan for Future Funding:** Describe in as much specific detail as possible how the data generated during the pilot project will support subsequent application(s) for external grant support (*PDF, 1-page limit, 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round*).
- 9) **Use of TraCS services (if applicable).** A [TraCS Service Agreement form](#) be filled out for each TraCS service to be utilized. Those forms should then be converted to PDF, combined and uploaded into the application.
- 10) **Timeline:** Outline the proposed activities for the funding period, including timeline and milestones (up to 12 months). It is important that the proposed work (i) be ready to start April 1, 2026, and (ii) be completed by March 31, 2027, as no-cost extensions are not permitted. Therefore, the applicant should address plans for (i) obtaining institutional (IACUC/IRB) and NCATS approvals in preparation for an April 1, 2026, project start, and (ii) spending grant funds within the one-year funding period. Include specific factors (eg, submitted/approved IACUC/IRB protocols, including protocol ID numbers if available, availability of an established study cohort, etc.) that speak to the feasibility of commencing the study April 1, 2026 and completing the work within 1 year (*PDF, 2-page limit, including graphics, 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round*).
- 11) **Budget:** Use [PHS 398 Form Page 4](#) (see also Section VII “Budget Guidelines” below). The total direct project budget should not exceed \$50,000. The time period for the budget is April 1, 2026 to March 31, 2027. Apply a 50% cost reduction to the quoted amount provided by TraCS services for the purposes of the budget.
- 12) **Budget Justification:** Include sufficient detail for reviewers to assess whether appropriate resources, including TraCS services, have been requested. For projects involving more than one institution, institution-specific budgets and budget justifications must be included, combined into a single PDF (*PDF, no page limit, 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round*).
- 13) **Protection of Human and/or Animal Subjects:** Although Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) approval is not required prior to submission; briefly describe any human or animal subject involvement. If human subjects, samples, or data are involved in the research, provide a description of their involvement and characteristics, specific risks to subjects who participate, and protection against those risks. Describe the sources of materials that will be obtained from human subjects as part of their study participation. *Do not use this space to include experimental detail that should be described in the research plan.* Note that no funds will be disbursed until required NCATS, IRB or IACUC approval is received (See Section VIII below) (*PDF, No page limit, 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round*).

- 14) **Biosketches:** [NIH-format](#). Provide for team members at the PI or Co-I level only. (*Combined into a single PDF, no page limit*).
- 15) **Letter(s) if applicable:** Letters may be included if (i) they outline work that will be done for the project by a consultant (**do not** include letters from co-PIs, co-investigators or NC TraCS collaborators) or (ii) clearly state a commitment of resources required for the project's success.
- 16) **External Funding Agency Review (if applicable):** If the proposal references a prior review from an external funding agency (eg., NIH), include the agency reviewer comments (*PDF, no page limit*). If the purpose of the pilot project is to respond to specific reviewer concerns, the relevant section of the review should be indicated by highlighting or other means.

VI. Review Criteria

It is the applicant's responsibility to present the proposal in a clear and logical fashion, to make a convincing case for the significance of the work and to present the proposed methods in sufficient detail so that an adequate evaluation of the proposal can be made. All applicants – funded or not – will receive written feedback from the reviewers.

The following criteria will be considered during review of the proposal:

- 1) CTS Significance of the translational work – its likelihood to **advance clinical & translational science methods and processes**.
- 2) Novelty/Innovation
- 3) Multidisciplinary team in place that is integral to the conduct of the research
- 4) Potential for the project to lead to future external funding or to a commercialization opportunity
- 5) Soundness of the proposed methods
- 6) Feasibility of (i) starting the project April 1, 2026, and (ii) accomplishing the stated project goals within the one-year project period
- 7) Level of community engagement (if applicable)

VII. Budget Guidelines

- 1) NC TraCS CTS pilot grant budgets cover expenditures for a 12-month period. The funding period for this cycle will commence **April 1, 2026**, so it is important that applicable regulatory (NCATS/IRB/IACUC) documentation is received by NC TraCS and that the PI indicates that everything is in place for the project to begin by that date. The expectation is that all funds will be expended by the end of the grant period, *as no-cost extensions are not permitted*.
- 2) Per NCATS rules for CTS Pilot Awards, *voluntary cost share is not permitted*. The proposed work must be supported *solely* by the CTS pilot award. Pilot Program staff will work with awardees to ensure that their project budget conforms with NCATS guidelines.
- 3) Mandatory, allowable and non-allowable budget items:

What must be budgeted for:	What cannot be budgeted for:
- PI, co-PI(s), other significant contributors (eg, co-I) salary support - Research support personnel, including RAs/GRAs, technicians and other research staff	- Office supplies or communication costs - Meals (except for focus groups) - Travel, except as required to collect data - Conference travel, registration or attendance

• Equipment, research supplies and core lab costs • Travel necessary to perform the research • Other purposes deemed necessary for the successful completion of the proposed project • Any proposed TraCS services at the pre-agreed hourly rate (see Section IV.B above)	• Professional training or education • Manuscript preparation, submission or other publishing costs • Costs outside the US (eg, foreign individuals, foreign entities)
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- 4) **All** personnel effort **must** be included in the budget, and no personnel effort, including faculty, may be listed as “in kind”. Include at least 1% per PI, with no more than a total of 5% salary effort across multiple PIs (at the NIH salary cap). Co-Is who are significant contributors to the project may also budget effort of up to 5% each (at the NIH salary cap). These % FTE guidelines apply only to members of the project leadership (PIs and co-Is), but do *not* apply to non-faculty technical staff or RAs or GRAs, who should be budgeted with whatever % FTE is required for the project.
- 5) CTS Pilot funds can be expended only in (i) participating partner institutions (UNC, NC A&T, NC State) or (ii) outside commercial entities providing a service unavailable from one of the partner institutions. This includes **Consultants** who provide a specific service otherwise unavailable to the research team, for example, producing a video. Private individuals in the role of consultant must be registered as a UNC-approved vendor or as an “Independent Contractor”. Researchers from outside institutions cannot serve as consultants. Where an applicant is proposing to use a consultant, the application must include an adequate justification of the proposed expenditure in the Budget Justification.
- 6) Where the proposed work involves investigators from more than one institution, separate institution-specific budgets and budget justifications should be included. While an equitable distribution of funds between institutions is encouraged, the proposed work will determine the optimal distribution of effort and funds between team members and institutions, and unequal distribution of funds between institutions is acceptable if adequately justified. Indirect costs will be paid based on grant funds spent at NC A&T or NC State, but these are additional to the award and should **not** be itemized in the Budget.

VIII. Regulatory and Reporting Information

- 1) Please remember that NC TraCS Pilot grants are funded through a CTSA grant from the National Center for Advancing Translational Sciences (NCATS) and therefore carry similar regulatory and reporting obligations as any other NIH grant.
- 2) We anticipate completing review and notifying successful applicants by **October 2025**. The grant funding period will commence no earlier than **April 1, 2026**, and is strictly limited to 1 year. It is very important, therefore, that teams be ready to start their work on April 1, 2026. Prior to receiving funds, research involving human subjects and/or vertebrate animals must have appropriate approvals from the UNC-CH IRB. Applicants are strongly encouraged to start preparing IRB paperwork as soon as possible. Either an IRB approval letter or an IRB response to a “Determination Whether Research or Similar Activities Require IRB Approval” must be submitted to NC TraCS prior to funds being released. Human subjects research must be reviewed in accordance with the University’s general assurances and HIPAA. In addition, if the research involves human subjects, all personnel named on the budget page must have the requisite certification of training in the protection of human subjects prior to the start of the grant period.

- 3) NCATS reviews and approves all NC TraCS pilot grants involving human and animal subjects research prior to funds being released. If a funded application involves human or animal subjects research, NC TraCS will require additional documentation to send to NCATS. *NCATS review can only commence after institutional approvals (IRB/IACUC) have been received.* NCATS reviews may be subject to a 30-day prior approval period, however grants determined to be “minimal risk” are usually approved within a few days.
- 4) NC TraCS staff will work closely with funded projects throughout the grant period to monitor progress and provide assistance. In the period between notification of application success and commencement of the funding period, Pilot Program staff will work with awardees to assist with regulatory documentation and to liaise with other TraCS services to ensure that required services will be available to the research team. We envisage an arrangement closer to a cooperative agreement than a standard research grant, so that Pilot Program staff and Navigators will work closely with investigators, meeting regularly to discuss progress, troubleshoot unforeseen obstacles and plan future research- and funding directions. A 6-month interim progress report and a final progress report will be required. NC TraCS expects the project PI/Contact PI to report over the lifetime of the work the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations and patents.
- 5) If the project involves human subjects, samples, or data: inclusion enrollment reporting is required to be completed. Unless determined to be IRB Exempt Category 4, you are required to report race, ethnicity, gender, and age of individual research participants at regular intervals.
- 6) If an awardee plans to leave their position before the end of the award period, they should contact NC TraCS **prior** to departure to discuss next steps.

IX. Tips for writing an effective proposal

- 1) Remember that the reviewers, while scientifically literate, are unlikely to be experts in your field. When explaining the technical detail of your proposed work, avoid jargon and “inside” references – it’s critical that the reviewers understand what you propose to do, but it’s your job to pitch your narrative at a level that the non-expert will understand.
- 2) This grant mechanism focuses on Clinical and Translational *Science* – identifying broadly encountered roadblocks and barriers to the conduct of translational research, so that addressing these roadblocks will accelerate a range of translational research endeavors. Therefore, it is very important to clearly identify the broader translational barrier. This is arguably the most important. If you’re proposing to use a more focused translational research use case to address the translational science question, ensure that these two components of the project – the broader translational science question and the more narrowly focused translational research project that will address this – are clearly distinct, while explaining how the use case will address the broader question.
- 3) Consider what will happen to your research after the CTS Pilot funding period is over. What are your plans for future research directions and funding?
- 4) When describing your research team, ensure that the specific roles of your team members are clearly described, and that team expertise is appropriate and adequate for the proposed work.

CTS Pilot Frequently Asked Questions (FAQs)

1. I submitted an application to the CTS Pilot program, but I wasn’t funded. Can I resubmit?

Yes, you can resubmit one time (two applications total). We recommend that you meet with Program staff to discuss how best to address the reviewers’ critiques and include a 2-page “Response to Previous

Review” document in your application, outlining how you have updated your project and grant application in response to reviewer input. We *strongly* suggest that you don’t simply respond in the “Response to Previous Review” doc and leave the Research Plan unchanged – update the entire application as appropriate. Applicants can request a Pilot Program consult through the “Start a Request” link on the [TraCS home page](#).

2. Are investigators/institutions from outside the TraCS partnership allowed?

No. No award funds, in the form of a subcontract or any other mechanism, can be paid to institutions outside the TraCS partnership. Since NIH regulations require that *all* personnel effort must be included in the budget, and no personnel effort, including faculty, may be listed as “in kind”, this precludes the inclusion of outside research personnel in the team.

3. Do I have to include TraCS services in my budget?

Awardees may incorporate TraCS service assistance into their projects. The cost of these services, determined through discussion with the relevant TraCS program reps, should be included in the grant budget. Remember that the nature and extent of assistance to be provided *must* be discussed with the appropriate TraCS service rep(s) and agreed upon prior to grant submission. This agreement must be documented in one or more [TraCS Service Agreement forms](#) included in the grant application. Pilot Program staff can assist applicants in navigating this process. The cost of TraCS services will be supplemented by TraCS through a 1:1 match, resulting in an effective 50% reduction in the budget cost of TraCS services.

4. What about international partners or research?

Pilot funds cannot be used to support research outside of the US. However, data previously generated through international research can be used in pilot projects, as long as data analysis etc. is conducted domestically.

5. What can awardees expect in terms of TraCS input and assistance post-award?

TraCS envisages these awards as more like cooperative agreements than simple grants, so that TraCS will provide ongoing input into the conduct and direction of the work. This will involve the convening of a TraCS support team, comprising a TraCS Navigator, faculty content experts and potentially TraCS service reps, who will meet regularly with the research team to evaluate progress, identify roadblocks and discuss workarounds, and discuss next steps, such as research directions and potential funding opportunities.

6. Can any funds be spent outside the TraCS partnership institutions?

Yes, but *only* under specific circumstances, such as engagement of a consultant to provide a specific service otherwise unavailable to the research team. While we encourage awardees to spend grant funds on “on-campus” university services such as sequencing cores, if a specific service is unavailable, an appropriate outside service can be paid for using grant funds, as long as this is addressed in the Budget Justification (see [VII. Budget Guidelines](#), section 5) above).

7. Does the number of institutions involved in the project affect the total award amount?

No. Pilot award budgets will be between \$25k and \$50k, regardless of the number of institutions involved, and the total grant amount will be distributed between institutions, based on the scope of work proposed at each institution. While multi-institution applications must include individual institution-specific budgets and budget justifications, the sum of these budgets will not exceed the \$50k grant limit.

8. Can CTS pilot grant funds be used to pay consultants?

Yes, as long as the necessity of using a consultant and a description of the skills/services they provide are described in the Budget Justification and detailed in a Consultant’s Letter. Since PIs and Co-Is can

only receive limited salary support (see 9 below), a consultant cannot also serve as a PI/Co-I, and *vice versa*. Since funds cannot be transferred to outside institutions, researchers at such institutions cannot serve as consultants (see [VII. Budget Guidelines](#), section 5) above).

9. Can CTS pilot grant funds be used to support PI or Co-I salary?

PI and co-PI efforts **must** be budgeted at between 1-5% effort each (at NIH salary cap). No personnel, including faculty, may be listed as “in kind”. Other faculty who are significant contributors (eg, Co-Is) to the project must also budget effort (at least 1% effort each, at the NIH salary cap). Salary support can also be budgeted for research support personnel, including GRAs, technicians and other research staff.

10. Are there any limitations to equipment purchases?

Equipment can be budgeted if its necessity for the proposed work is justified in the Budget Justification. Plans to purchase a large piece of equipment or to spend a significant portion of the budget on equipment should be discussed with Pilot Program staff prior to submission.

11. Should I budget for indirect costs?

Indirect costs will be paid based on grant funds spent at NC A&T or NC State, but these are additional to the award and should **not** be itemized in the Budget.

12. When should I start preparing my IACUC/IRB paperwork?

We recommend that you start preparing your regulatory paperwork as early as possible – preferably as soon as you receive a funding notification. Because these grants use NIH funds, they require NCATS regulatory approval, which can only be applied for *after* institutional (IRB/IACUC) approval has been received. This extra step can add up to 4-5 weeks to the regulatory approval process. We recommend that applicants endeavor to have their institutional approvals in place as soon as possible after award notification and no later than mid- to late February.

13. Two pages are allowed to discuss the CTS problem that my proposed work will address and to describe how my work fits into this CTS context. Can I use this space for other purposes (e.g., my Research Plan)?

No – your Research Plan must be described within the five-page Research Plan doc. Even if you don’t use all of the available pages to discuss the CTS relevance of your proposed work, this space should *not* be used for any other purpose. Reviewers will not be obliged to consider any extraneous research detail included in this section.

14. The FOA talks about a 4/1/26 project start date. If I have all my IRB/IACUC approvals in place, can I start my project earlier?

No – the pilot funding period is synced to our NIH funding, and therefore pilot grant funding can start *no earlier than 4/1/26*. Bear in mind, also, that the one-year funding period ends 3/31/27, regardless of whether you start on 4/1/26 or later. Starting your project later than 4/1/26 will result in a shorter funding period, so we strongly encourage awardees to complete their regulatory requirements in a timely manner and be prepared to start on 4/1/26.