

-----**Proposers Day 1**-----

Q1: This is the first Institute with a biomedical theme. Will there be other FOA's in the biomedicine space?

A1: We do not know whether there will be any other biomedicine manufacturing institutes

Q2: How much is the focus of the proposal to be on development of "tools/materials/equipping the processes vs. producing tissue/cell-based products to be ready to implant in people, such as organs, blood vessel networks, etc.?

A2: The specific focus is on the manufacturing and testing technologies that will advance the industry in support of making tissues or tissue-based products. The overall goal is to develop cross-cutting technologies and solutions to help advance many tissue and tissue-related products, however, if the technology roadmap identifies a specific product then that can be considered.

Q3: Please address intellectual property challenges associated with industrial collaborations with academic institutions. Are any special provisions included as part of ATB-MII to facilitate these collaborations while protecting industrial sensitive IP? (Experiences / challenges that have come up in other MIIs)

A3: Please reference Appendix C (Guidance on Intellectual Property Rights for the National Network for Manufacturing Innovation (NNMI)). Each institute will need to carefully address IP within their proposal. This may also be a negotiable term within the TIA, individual MII membership agreements, and at the project level. Sensitive or already established IP will have to be negotiated between the awardee and its sub-awardees as to how IP will be shared.

Q4: Any instruction about format and page limit?

A4: Reference submission instructions in proposal (pages 14-19).

Q5: Is it possible for a for-profit company to lead the ATB-MII?

A5: No, the lead must be a non-profit per the FOA.

Q6: Can we receive a copy of the slide presentations?

A6: Slide presentations will be posted on www.manufacturing.gov

Q7: The government has awarded a Cooperative Agreement for other Manufacturing Innovation Institutes (MIIs) but the ATB-MII is proposing a Technology Investment Agreement. Is this based on lessons learned from prior Institutes or is the TIA decision based on the Bio-fab technology?

A7: The decision to only offer a TIA is based on lessons learned and discussions with the ACC APG RTP contracting office on the optimum assistant instrument for MII acquisitions. The Cooperative Agreements in place for 5 of the 6 DoD MIIs are also acceptable and workable, but TIAs provide additional flexibility that should prove beneficial to an MII.

Q8: What are the performance based metrics for existing Institutes (besides cost share) and how are they leveraged with the federal funds provided?

A8: These metrics are defined by each institute, but could include number of members, type of income, amount of sales, transition plans signed, licensing agreements, etc.

Q9: Will DoD provide lessons learned from other MIIs so that offerors may incorporate appropriate mitigation strategies?

A9: Lessons learned from the previous MIIs are reflected in this FOA and will be accessible to the final awardee. All prospective lead organizations are encouraged to reach out to existing MIIs and ask questions.

Q10: Is there an expectation for a certain # of MRL technologies to be in development with 1st year?

A10: Expectations are not defined for a particular quantity of technology areas to be undertaken in year one. However, the target range is between MRL 4-7 and the mix should not be completely lopsided.

Q11: Are there additional measures of success expected besides sustainability after 7 years?

A11: The Institution will develop its own measures of success.

Q12: There is a perception that lobbying is an important component of these proposals. Can the decision process on the proposals (by the ManTech office) influenced by politicians?

A12: No, all proposals are evaluated fairly against the FOA. The selection team will be insulated from any letters from Mayors, Governors, Congress, etc.

Q13: Is one allowed to participate in two proposals?

A13: Yes, but only as a team member. An organization may be the lead on only one proposal.

Q14: What is the best concept to win this award?

A14: Proposers should read and meet the FOA to the best of their ability with what they perceive to be the best concept(s).

Q15: What is the best models for example from the past 8 MII centers?

A15: There is no one best model.

Q16: How does DoD evaluate the MIIs?

A16: The ATB-MII proposals are evaluated against the evaluation criteria in the FOA. The MIIs in existence are evaluated based on a number of measures mutually developed between the awardee and the government, post-award.

Q17: Who are the panelists to review the proposals?

A17: Panel consists of Government personnel only. Actual names are not releasable.

Q18: When will we hear the award decisions?

A18: Reference timeline in FOA; award is expected in mid-December. This is an estimate only.

Q19: Is the \$75 million awarded at one time (in place) or is provided year by year depending on performance?

A19 (g): Reference funding profile in FOA (page 3 and 10). The government is anticipating \$80M in federal funding, not \$75M.

Q20: It was said that the proposal should be written by industry. Can you please comment on this?

A20: The Government does not direct applicants as to who should write the proposal. While industry largely helps drive the technical work, it is the applicant's decision as to how the proposal is written.

Q21: The released RFP (or FOA) listed four technical application included in the proposal. Is that four big applications consisting of multiple small proposals? Or only four focused areas DoD is looking for?

A21: The four thrust areas are not a call for four separate concept papers or proposals. Within those four technical thrust areas (or more, if proposed), a number of individual projects will be executed within each area, informed by technology gaps and common manufacturing problems identified in the roadmapping phase (post award).

Q22: Can you explain the format of the concept papers?

A22: Reference the submission instructions in the FOA (pages 13-16). These instructions include the format required for submitting a concept paper.

Q23: Do letters of support from political representatives add any value to a proposal?

A23: No. Evaluations are conducted solely on the proposals and the evaluation criteria.

Q24: Where can our political representatives add value to this proposal process and mission?

A24: Evaluations are conducted solely on the proposals and the evaluation criteria. Political representatives will have no bearing on evaluations. Political representatives can add value to the mission of the MII and technology space, post award.

Q25: If our organization is part of a team whose concept paper is not selected for a proposal – would we be restricted from joining another team that is invited to submit a full proposal?

A25: No, you would not be restricted from joining another team. The Government strongly encourages this.

Q26: TIA: according to DoDGARS 3%-profit goes back to the government until contract close out. Would industry partners be subject to this stipulation for this award as well?

A26: Answer to be provided following Chicago Proposer's Day.

Q27: Can existing, ongoing, or new NIH or NSF funding be used to satisfy the cost match the requirements?

A27: No. Other federal funding may not be used as cost share.

Q28: Who submits a concept paper – every institution or only the leader of the team (It's not clear what the concept paper is supposed to cover)?

A28: Only the team leads may submit a concept paper. The concept paper should address the FOA in accordance with the submission instructions.

Q29: How many concept papers do you anticipate inviting to submit a full proposal?

A29: We do not know. All concept papers considered strong enough to have a chance to win the award will be invited to submit a proposal.

Q30: Is any feedback given on the concept papers when full proposal invites are made?

A30: Yes, those concept papers selected to submit a proposal will receive feedback. Those not selected will not receive feedback (reference FOA, page 13).

Q31: How does the MII contract for scale-up projects with consortium members? Does it use federal contract vehicles or its own approved contract process?

A31: In general, the MII will not use federal contract vehicles for project awards. They will use their own process specified by the lead non-profit and endorsed by the MII governance body. The ATB-MII award recipient is to orchestrate specific projects within the consortium. Individual scale-up projects, per se, are not envisioned as this institute is meant to reduce barriers through cross-cutting technologies. However, if the project meets the mission and goals of the MII then the MII should consider the option.

Q32: Will the selected awardee be expected to include a means of evaluating the technologies that were included in unsuccessful proposals for the purpose of pulling out and incorporating 'cannot leave behind' partners? If so, should this be included in the proposals?

A32: No, the ATB-MII award recipient will not be provided access (by the federal government) to any competing proposals. However, the awardee will have to develop a technology roadmap shortly after award. The roadmap is developed with input from all stakeholders. The technology roadmap will guide the institute's technical activities and may include aspects that were not part of the awardee's original proposal.

Q33: When can we expect to be able to see the FOA?

A33: FOA is already available on www.fedbizopps.gov and www.grants.gov

Q34: Can you clarify at what point can FFRDCs engage in ATB-MII process?

A34: In general, post-award. However, the Government welcomes any description of a vision that includes FFRDC participation in the innovation ecosystem as part of the concept paper/proposal.

Q35: The FOA talks a lot about Induced Pluripotent Stem Cells (IPSC), which are mostly used for in-vitro applications in organs-on-a-chip (very few chemical trials with in-vivo applications). Does DoD envision using IPSCs for fabrication of tissues that are implanted as part of this MII? Or will tissue replacements be derived from patient cells (like bone marrow, cord, or adipose)?

A35: IPSC cells are listed as an example. It is up to the proposing team to address a strategy for cell sourcing. Primary cells, mesenchymal stem cells, dendritic cells, IPSC's, etc should all be considered.

Q36: A university is a not-for-profit. The NNMI Preliminary Design Document (PDD) precludes a university from leading an Institute unless it stands up a separate not-for-profit. The explanation in the FOA of who may lead implies a university may lead. Please clarify

A36: Universities may lead, despite the NNMI PDD's language. Please see the definition of a non-profit on pages 2-3 in the FOA.

Q37: What restrictions are there on cost sharing and participation from foreign companies/sister universities?

A37: Cost share among foreign companies and (foreign) sister universities are allowed. Participation by foreign companies should comply with page 12 of the FOA.

Q38: Can an organization participate on more than one proposal team? At concept paper stage? At full proposal stage?

A38: Yes, but only as a team member, not a team lead.

Q39: Do certain in-kind contributions, such as the commitment of a "faculty line" on bio-printing, have more lasting impact even than cash?

A39: There must be an effective balance of cash and third party, in-kind resources. It is the responsibility of the applicant to articulate how all cost sharing will be utilized. (Reference the DoDGARS and OMB circular for allowable cost-sharing methods)

Q40: While focusing on TRL 4-7, can the government funds be used to perform TRL 3 technology R&D?

A40: Yes, but more on an exception basis. The circumstance would have to fill a critical gap or opportunity in the technology roadmap. Such R&D must be critical, require minimum investment, and is aligned with the mission and goals of the MII.

Q41: Are the example projects proposed in the concept and/or proposal binding? i.e. are these 4 projects required to be executed within the ATB-MII?

A41: These are example projects, however, the quick start project could be approved to provide the new MII some early momentum and assist in the stand-up phase. While not required to be executed the example projects required in the FOA will be a means for the Government evaluators to assess capability and integration of the applicant's team.

Q42: Does the award (\$80M) include direct and indirect (costs)?

A42: Yes, the \$80M ceiling is inclusive of all direct and indirect costs associated with performing work consistent with the terms of the TIA.

-----Proposers Day 2-----

Q43: Please describe how the educational component is built into the Institute?

A43: Page 31 of the FOA Evaluation Criteria under Factor 3, Education and Workforce Development Plan, explains how the quality and degree of integration of educational and workforce/professional development and training will be evaluated. It will be up to the applicant to describe the details of this integration within the MII.

Q44: Do you provide copies of all slides?

A44: Yes. The slides will be posted on Manufacturing.gov for both Proposers Days.

Q45: Is the non-profit required to be established before submission of the full proposal?

A45: The non-profit must be established prior to award. The proposal must provide evidence to support a reasonable expectation that establishment of the non-profit can be accomplished by the leading non-profit prior to award.

Q46: Can a university outside of the U.S. be a partner on this MII?

A46: Participation by foreign companies should comply with page 12 of the FOA.

Q47: The FOA calls for consideration of "geographic concentration" in establishing an innovation ecosystem. It also acknowledges the geographic dispersion of the assets available on "day one." What factors should be considered in assessing geographic concentration factors?

A47: Page 25 of the FOA Evaluation Criteria under Factor 1 (Business Plan), Paragraph C, Physical Infrastructure states in part; "Applicants must describe relevant physical infrastructure to include the sufficiency of geographic concentration to support the overall ATB-MII processes, including the manufacturing hub and other needed nodes."

Q48: The TIA selection as an assistance instrument implies it is a vehicle requiring for-profit entity engagement to facilitate a DoD mission. How do you envision DoD participation in the institute operations in the first 5 years? The sixth and seventh years? Beyond year 7?

A48: A: The FOA requires a non-profit entity to lead the institute (Page 1, FOA Title, and Page 2 under FOA Request). Throughout the duration of the TIA, the federal government is funding the establishment of the MII and may also be a customer. After the TIA concludes, the federal government may remain as a customer of the MII, assuming the MII sustains itself beyond the length of the TIA.

Q49: Tissue biofabrication is a relatively new field – how strict is the MRL 4-7 requirement for this MII?

A49: The primary technical focus areas need to primarily address common manufacturing challenges in the MRL 4-7 range. Lower MRL level projects can be addressed on a case by case basis, but are subject to approval within the governance structure of the MII. (Also see Q40 from Proposers Day 1: The circumstance would have to fill a critical gap or opportunity in the technical roadmap. Such R&D must be critical, require minimum investment and be aligned to the mission of MII and identified as a gap in the ATB-MII technology roadmap.)

Q50: The tissue engineering industrial base is fractured and mostly consist of small companies. Cost share, especially cash, will be an issue for these companies. What is the goal 1:1 cost share or greater?

A50: Please see Page 26 of the FOA Evaluation Criteria under Factor 1 (Business Plan), Paragraph D, Cost Share, which states in part: “A minimum 1:1 cost share against federal dollars is required, and greater cost share is encouraged.” It is understood that cash can be an issue for small companies. In-kind or other non-cash contributions from a proposed ATB-MII can count toward the minimum 1:1 cost share requirements.

Q51: How will the manufacturing focus be integrated with the clinical development component of product development?

A51: This MII is focused on creating manufacturing and testing technologies which cannot be accomplished without the intended product development target in mind. The specifics on integration with the clinical development component of product development will have to be determined and developed by the MII, consistent with the ATB-MII mission and vision.

Q52: TIAs permit greater flexibility in Intellectual Property (IP) provisions. The National Network for Manufacturing Innovation (NNMI's) IP plans also set some expectations. What guidance can you provide on what IP constructs may be expected for this TIA? How would they differ from a cooperative agreement?

A52: Intellectual Property is covered on Page 26-27 of the FOA and Appendix C provides general best practices on handling IP rights for the NNMI. The government expects proposals to indicate how the MII will handle IP amongst team members. There is more flexibility to negotiate the rights within the TIA construct than the cooperative agreement.

Q53: Page 12) Section “E. Existing Manufacturing Innovation Institutes” it states “one of the existing six (6) MIIs are eligible to receive an award under this FOA.” Does this mean we could expand the capabilities of an existing MII into Biofabrication where we bring the members, expertise, capabilities, etc. and use their infrastructure? If not what do you envision?

A53: While a lead non-profit from any of the DoD Institutes is not excluded from proposing against this solicitation, this is a new MII and will not be an expansion of a current MII.

Q54: How will NIH, NSF, NASA (and other partners/sponsors) be involved, besides DoD? (Maybe new funding lines from them?)

A54: Many civilian agencies have provided subject matter expertise to this solicitation and will continue to be engaged post-award. They will be involved with the Institute as SMEs for technical advisors for projects and government representatives. Any funding provided to ATB-MII for execution of civilian agency – directed projects will be up to those agencies to decide.

Q55: DOC (NIST) has just announced that robotics topic MII applications invited for full proposal will no longer be considered given the DoD call for a robotics MII topic. NIST is also considering bio-pharmaceutical MII applications. How does DoD see these concepts interacting?

A55: DoD is working closely with NIST to coordinate the selection of topics for MIIs and ensure duplicate topics are not awarded as MIIs. Should NIST award a bio-pharmaceutical topic as an MII, this coordination would continue to ensure a complimentary interaction between the two MII's post-award.

Q56: Tissue therapies will require breakthrough innovations in GMP production processes, process controls, sensing, and product packaging. How should we consider the ATB-MII role in guiding and supporting breakthrough technology development at levels below TRL 7?

A56: This MII is an opportunity to shape and guide innovations in GMP manufacturing. Such breakthrough technology development should be discussed in terms of the Factor 2 Evaluation Criteria "Innovations Beyond Current Practice."

Q57: Will a non-profit high-education organization (e.g. a public state university) be eligible to lead the team?

A57: Yes. Per 32 CFR §37.1315, a non-profit organization is defined as: Any corporation, trust, association, cooperative or other organization that: (1) Is operated primarily for scientific, educational, service, or similar purposes in the public interest; (2) Is not organized primarily for profit; and (3) Uses its net proceeds to maintain, improve, or expand the operations of the organization. The definition includes any nonprofit institution of higher education.

Q58: RE: Technology Investment Agreement (TIA): Can you provide specific examples of where a TIA was used and Industry or Academic partners retained IP rights to technology developed within a MII? Is there a lessons learned document or white paper on successful IP frameworks developed using this funding mechanism based on other NNMI's?

A58: IP management is covered on Page 26 of the FOA. Appendix C of the FOA, "Guidance on Intellectual Property Rights for the National Network of Manufacturing Innovation," should also be consulted. An example TIA will be provided to those applicant who are invited to submit a Full Proposal.

Q59: Evaluation criteria has focus on historical viability of the lead NFP [not-for-profit], but also points to sustainability. Is there a preference for the MII to be a division of existing NFP or established at the outset as a separate and distinct organization with separate tax ID?

A59: No. There is no preference.

Q60: Format requirements state 12 point font size. Would the government all [allow] 10 point for graphics and tables?

A60: Format requirements for graphics and tables are not specified. Smaller fonts are allowed for graphics and tables, but must be legible to be evaluated.

Q61: When will the slides for the Proposers' Day be available? The slides from the previous Proposers' Day is still not available.

A61: The slides for both proposers' days are identical. These slides were recently uploaded to manufacturing.gov .

Q62: Regarding Figure 2. of FOA vs. presentation. The degree of federal investment priorities in the presentation does not match the FOA. Is this intentional or an aberration arising from progression?

A62: Appendix A, Figure 2 is a conceptual view of the ATB-MII manufacturing innovation ecosystem. The estimated level of federal funding is meant to communicate two things: (1) where the federal government believes relative overall levels of investment are needed in the ATB-MII; and (2) that portion of the needed investment that would come from federal funding (vice cost share). The FOA takes precedence over any other medium.

Q63: Many of the technologies in this space are not yet clinically proven and require significant TRL advancement. How do you anticipate synchronizing the MRL maturation with TRL progress? Will TRL advances be in-scope for this institute?

A63: This is part of the overall challenge for the ATB-MII, and applicants can address this in their proposal.

Q64: How does the ATB-MII fit in with other Government initiatives, such as AMTech and MTECH?

A64: AMTech is a DOC (NIST)-sponsored program that supports roadmapping only within an advanced technology area. MTECH is a DOD program that is in this general space but with more of a clinical trial/product development focus.