

Ohio Opioid Technology Challenge – Challenge Phase

OFFICIAL RULES

1. **LEGAL TERMS:** By submitting an Entry (as defined herein) to the Ohio Opioid Technology Challenge – Challenge Phase (the "Competition"), you are agreeing to be bound by the following legal terms ("Official Rules") which constitute a binding agreement between you, on one hand, and the Sponsors (defined below), on the other. The Official Rules also incorporate by reference the additional terms specified at www.opioidtechchallenge.com (the "Competition Website"). **THESE OFFICIAL RULES SUPERSEDE ANY OTHER RULES AND TERMS & CONDITIONS ON THE WEBSITE OF THE SPONSORS. THIS COMPETITION IS VOID WHERE PROHIBITED BY LAW AND NO FEE OR PURCHASE IS REQUIRED TO PARTICIPATE. SPONSORS RESERVE THE RIGHT TO MODIFY THESE RULES AT ANY TIME.**
2. **SPONSOR; ADMINISTRATOR:** The Competition is administered by NineSigma ("Administrator"), NineSigma North America Inc., Summit One, Suite 535, 4700 Rockside Rd., Independence, OH 44131 USA on behalf of Ohio Development Services Agency with a principal place of business located at 77 South High Street, Columbus, OH 43215 USA ("DSA"). Administrator NineSigma and DSA are collectively referred to as "Competition Sponsors" or "Sponsors."
3. **COMPETITION DATES:** The Challenge Phase Competition commences February 28, 2018 and ends on the date specified on the Competition Website.
4. **GENERAL INFORMATION:** Participation is subject to all federal, state and local laws and regulations in the applicable individual's or entities' country of residence, geographic location, or jurisdiction of charter or incorporation. Void where prohibited or restricted by law. Multiple Entries are permitted. Each Entry (as defined herein) will be reviewed independently. Multiple individuals or entities may collaborate to submit a single Entry, but a single individual must be designated as an official representative for each Entry. You are responsible for i) checking applicable laws and regulations in your jurisdiction before participating in the Competition to make sure that your participation is permitted under the law, ii) for abiding by your employer's policies regarding participation in the Competition, iii) for all taxes due and all reporting responsibility related to any award you may receive as part of the Competition, and iv) for complying with all third party Intellectual Property rights for the materials submitted. Sponsors expressly disclaim any and all liability or responsibility for disputes arising between you and your employer related to this Competition, any violation of law due to your participation, and any tax liability related to your award. Sponsor reserves the right to limit or exclude any person from participation in the Competition who fails to comply with the terms contained herein. All registration information is deemed to be provided and collected in the United States of America.
5. **ELIGIBILITY:** Responses from companies (small to large), academic researchers, other research institutes, consultants, venture capitalists, entrepreneurs or inventors are welcome. However, in order to be eligible to win an award under the Competition, an individual or entity must:
 1. Comply with all of the requirements in this section.
 2. Have a Principal Point of Contact that is at least 18 years old.
 3. Be registered to do business and in good standing in the State of Ohio or partnered with an In-State Entity. For purposes of the Challenge Phase, an In-State Entity is an entity that has a substantial presence in Ohio (see Ohio Revised Code Section 184.10).
 4. In the case of an individual, be incorporated or otherwise affiliated with an entity meeting the eligibility requirements of item #3 above.
 5. Not be an employee, or family member of an employee, of the Sponsors and any of their respective affiliates and subsidiaries.
 6. Not be related to or affiliated with any judge on the review panels.

You are solely responsible for all hardware, software, and internet service connections and any service fees associated with such access necessary to submit file your submission as well as all costs incurred by you or on your behalf to participate in the Competition.

6. **HOW TO ENTER:** At the Competition Website you will find further instructions and the required Response Form. All of the registration information that you provide is collectively referred to as your "Account." You must submit your completed response (hereinafter your "Entry" and referenced interchangeably as your "submission" or "response" on the Competition Website and in Response Form) using the Response Form and follow the instructions provided on the Response Form. By submitting your Entry, you formally accept these Official Rules for this Competition.

Each registrant is referred to as an "Entrant" in these Official Rules and as "Entrant" or "Respondent" on the Competition Website.

All Entries must be in English and attachments may be submitted in .pdf, .xls, .xlsx, .doc, docx, ppt, or .pptx formats. Links to publicly available online videos (e.g., YouTube) or other sites can be included in your Entry.

By submitting an Entry, you agree that all required fields have been completed and all information in your Account is correct and accurate. Your registration may be rejected or terminated and all Entries submitted by you may be disqualified if any of the information in your Account is (or the Sponsors have reasonable grounds to believe it is) incomplete, incorrect or inaccurate. You are solely responsible for your Account.

Sponsors are not responsible for (a) late, lost, stolen, damaged, garbled, incomplete, incorrect or misdirected Entries or other communication; (b) errors, omissions, interruptions, deletions, defects, or delays in the transmission of information, in each case whether arising by way of technical or other failures or malfunctions of hardware, software, communications devices, or transmission systems; or (c) data corruption, theft, destruction, unauthorized access to or alteration of Entry materials. Sponsors are not responsible for electronic communications received on social media or for emails which are undeliverable as a result of any form of active or passive filtering or insufficient space in any account to receive the electronic communication. Sponsors reserve the right to modify, remove or add data to the Competition Website. Sponsors also reserve the right to extend or modify the dates of the Competition and/or Entry submission dates. Entrants are urged to consult the Competition Website regularly during the Competition.

Sponsors shall have the right, in their sole discretion, to remove from the Competition Website any blog comment or social media posting related to the Competition, at any time and for any reason.

BY REGISTERING FOR THE COMPETITION, YOU ARE ACCEPTING THE CONDITIONS STATED IN THESE OFFICIAL RULES, AGREEING TO BE BOUND BY THE DECISIONS OF THE SPONSORS, AND WARRANTING THAT YOU ARE ELIGIBLE TO PARTICIPATE IN THE COMPETITION. IF YOU CAN NOT ACCEPT ALL OF THESE OFFICIAL RULES, PLEASE DO NOT SUBMIT AN ENTRY TO THE COMPETITION. WE RECOMMEND THAT YOU PRINT A COPY OF THESE OFFICIAL RULES FOR YOUR FUTURE REFERENCE.

7. **COMPETITION OBJECTIVE:** The State of Ohio invites submissions for technology solutions to alleviate the national opioid crisis. We are asking for solutions that address prevention, treatment, overdose avoidance, or overdose response. Your solution must use technology as a component of your approach, including:
- Sensors, diagnostics, medical devices, pharmaceuticals, and/or health information technology.
 - Software, but only if in conjunction with one of the aforementioned technologies.

8. **ENTRY CRITERIA GUIDELINES:** Entrants will submit Entries per the instructions on the Competition Website.

Minimum Requirements for all Challenge Phase Topics:

- Your solution must use technology as a component of your approach:
 - Sensors, diagnostics, medical devices, pharmaceuticals, and/or health information technology
 - Software, but only if in conjunction with one of the technologies mentioned above
- You must already be working on your approach, have proof of concept, and have compelling data to support the effectiveness of your approach.
- You must have a clear plan and path forward to get your technology ready for broad deployment or implementation.
- Your approach must be able to be implemented in the United States of America (e.g. it should be likely to receive regulatory approval and not violate any federal or state law) and you must be able to demonstrate your approach in conjunction with an Ohio-based entity.
- Your approach must align with one of the four Challenge Topics

Approaches that are Not Eligible:

- Approaches that are strictly at early concept stage of development
- Any solution that requires a change in current law, policy, or regulation
- Clinical treatment protocols not associated with a new technology development
- Predictive analytics to inform public policy
- Programs for direct delivery of social or clinical point of care services that do not have a significant technology component
- Education and public awareness programs
- Professional training programs

Key Attributes for Topic 1 DIAGNOSE:

For your Entry for Topic 1, your approach should:

- Enable identification of a person's risk of addiction
- Offer clear interpretation or signaling
- Offer concrete evidence that demonstrates efficacy
- Be effective in as short a time as possible
- Be robust
 - Have low occurrence of false events
- Be easy to implement and use (from a patient and/or clinician perspective)

Key Attributes for Topic 2 PREVENT:

For your Entry for Topic 2, your approach should:

- Reduce urges, cravings, or other symptoms of withdrawal
- Offer lasting effect/s over time
- Not pose other significant health risks
- Preferably be in a later stage of development
 - For a pharmaceutical, preferably at least be in human clinical trials
 - For a medical device, preferably have received 510 (k) clearance

Key Attributes for Topic 3 CONNECT:

For your Entry for Topic 3, your approach should:

- Enable rapid access to intervention such as:
 - Connection to trained counselors
 - Connection to locally available treatment providers
 - Connection to medical intervention administered remotely
- Enable extended access to interventions from remote locations (e.g. in rural locations without immediately available care; in locations away from hospitals; during travel by bus, train, or boat)
- Promote positive habit forming or reinforcement

Key Attributes for Topic 4 PROTECT:

For your Entry for Topic 4, your approach should:

- Prevent, minimize, or counteract exposure to opiates
- Be fast-acting (preferably in 1-60 seconds)
- Be simple to use
- Be robust for field deployment
- Require minimal space, (e.g., be portable for use in a first responder vehicle)
- Have a unit cost that enables widespread deployment
- In the case of opiate detection equipment:
 - Detects presence of legal and illicit opioids and mixtures thereof
 - Preferably able to: discriminate between several opioids, enable detection of related substances, and detect trace amounts
 - Preferably minimizes exposure of person conducting the test (e.g., by non-contact detection)
 - Is not susceptible to interference from other common agents
 - Has low occurrence of false events

Evaluation Criteria:

Responses should consider:

- How your approach aligns with Key Attributes for the Topic for which you are submitting an Entry
- Technology maturity and time to market
 - For similar approaches, preference will be given to the one that is more mature and/or that has a shorter time to market
- Potential for broad deployment or implementation
- Size/scope of audience impacted (“market size”)
- Robustness
- Effectiveness

Entries will be evaluated by an independent panel of subject matter experts using Entry Evaluation Criteria (defined herein). Prizes will be awarded for the best solutions. The Challenge Phase Competition will award up to twelve (12) US\$200,000 prizes across the four Topics. Prize Recipients of the Challenge Phase will be eligible to compete in the final Product Phase for prizes of US\$ 1 million or more.

9. **INTELLECTUAL PROPERTY RIGHTS:** By submitting an Entry and participating in this Competition, you are granting Sponsors certain limited rights under any patents or pending patent applications related to the uses and technical approaches described in your Entry as set forth in these Official Rules. Further, your Entry may be considered a public disclosure limiting your ability to subsequently file for patent protection. You are advised to seek legal counsel on this point as may be necessary. Information in your Entry which may become public information includes, but is not limited to: primary submitter name, entity name, and public summary. **BY ACCEPTING THE**

CHALLENGE PHASE AWARD, YOU THEREBY AGREE TO EXECUTE A CONFIDENTIALITY/NON-DISCLOSURE AGREEMENT DIRECTED TO ALL FUTURE DISCUSSIONS REGARDING YOUR ENTRY AS DESCRIBED BELOW.

Entrants maintain ownership of their intellectual property. Your submission of an Entry and participation in this Competition, grants Administrator certain rights. Upon submission, solely for the purposes of review, testing and/or conducting experimental proof of concept tests as may be required in Administrator's sole opinion to determine the commercial and technical feasibility of the Entry in order to determine a Prize Recipient, you agree and thereby grant to the Administrator a royalty free, non-exclusive, irrevocable license to use any information, concepts, inventions, approaches, technology, designs or drawings arising from or in your Entry materials, whether or not protected by patent or copyright or other intellectual property rights,.

By submitting an Entry, you also consent to the use, by Sponsors and their affiliates, agents and representatives, of your name, likeness, image, biographical information, award and award information (if a Prize Recipient), your company or institution name (if your Entry is from a company or institution), any personal data submitted with your Entry, and the contents in your Entry (including any created works), in connection with the Competition, in any media or format, in any and all locations worldwide, and without any payment to you or further approval from you. You agree that this consent is perpetual and cannot be revoked. For uses beyond the consent that you grant herein, you agree that Sponsors use of your personal data will be governed by the Privacy Policy posted on the Competition Website.

You agree that nothing in the Official Rules grants you the right or license to use of any intellectual property of Sponsors, including without limitation the Sponsor's trademarks or service marks. Your submission thereby grants to Sponsors the limited right to include your company name (if your Entry is from a company) as an Entrant on the Competition Website and in materials related to Sponsors promotion of the Competition. Other than for these uses, you are not granting Sponsors any rights to your trademarks.

10. **BUSINESS RELATIONSHIP:** The intent of the Competition is to uncover and accelerate the development and deployment of innovative technology solutions that address the opioid crisis. Participation in this Competition and acceptance of the cash award does not create an obligation on either your part or Sponsor's part to enter into any business relationship or to sign any commercial agreement in the future. Prior to acceptance of the cash award, you are free to discuss your Entry with other parties and you are free to contract with any third party provided you do not sign any agreement or undertake any obligations that conflict with any agreement that you have entered into or subsequently enter into with the Sponsor regarding your Entry.
11. **PRIVACY:** By entering this Competition, you acknowledge and agree that Sponsors will have access to and use of any personal data provided in connection with your Entry for purposes as described in these Official Rules and as governed by the Ohio Development Services Agency Privacy Statement posted on <https://development.ohio.gov/feat/privacy.htm>. You further agree that Sponsors may share this data in connection with your Entry with designated third parties for purposes as described in these Official Rules.
12. **CONFIDENTIALITY:** Sponsors do not wish to receive or hold any submitted materials "in confidence". It is agreed that, with respect to your Entry, no confidential relationship or obligation of secrecy is established between Sponsors and you, the company you represent or represented when submitting your Entry, or the owner of any part of your Entry or the subject matter thereof. **HOWEVER, ADMINISTRATOR WILL REQUIRE YOU TO SIGN A CONFIDENTIALITY/NON-DISCLOSURE AGREEMENT TO ENTER INTO FURTHER BUSINESS DISCUSSIONS IF YOUR ENTRY IS SELECTED AS A PRIZE RECIPIENT.**

Your Entry will not be considered confidential or have any restrictions on its publication, except as

follows: All information submitted is public information unless a statutory exception exists that exempts it from public release under the Ohio Public Records Act in Section 149.43 of the Ohio Revised Code. Trade secrets are eligible for protection from public release.

“Trade Secret”, as defined in the Ohio Revised Code 1333.61(D), means information, including the whole or any portion or phase of any scientific or technical information, design, process, procedure, formula, pattern, compilation, program, device, method, technique, or improvement, or any business information or plans, financial information, or listing of names, addresses, or telephone numbers, that satisfies both of the following:

- It derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use.
- It is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

If any information in the submission is to be protected as a trade secret from public release, the submission must identify each and every occurrence of the information within the submission with an asterisk before and after each section containing trade secret information and underline the trade secret information itself.

13. **WARRANTIES:** By submitting an Entry, you represent and warrant that all information in your Entry and all information that you submit via the Competition Website is true and complete to the best of your knowledge, that you have the right and authority to submit the Entry and disclose the information therein on your own behalf or on behalf of the persons and entities that you specify within the Entry, and that your Entry (both the information and materials submitted in the Entry and the underlying approaches, information, technology and all materials contained in or described in the Entry):

(a) is your own original work and representative of your capability, or is submitted by permission with full and proper credit given within your Entry;

(b) does not contain confidential information or trade secrets (yours or anyone else's), except as specified in accordance section 12 above in limited circumstances;

(c) does not, to the best of your knowledge, violate or infringe upon the patent rights, industrial design rights, copyrights, trademarks, rights of privacy, publicity or other intellectual property or other rights of any person or entity;

(d) does not contain malicious code, such as viruses, malware, timebombs, cancelbots, worms, Trojan horses or other potentially harmful programs;

(e) does not and will not violate any applicable law, statute, ordinance, rule, or regulation or any agreement with a third party;

(f) does not trigger any obligation to any third party, and

(g) does not, to the best of your knowledge, contain any information falling within the import or export control laws and regulations of the United States Department of Commerce or any other US or other governmental agency relating to the import or export of technology.

A breach of any warranty set out above will result in the corresponding Entry being invalidated. In addition, you agree to indemnify Sponsors against all loss, damages and costs incurred by Sponsors arising from your breach of any such warranty.

14. **EVALUATION:** Challenge Phase Entries will be evaluated based on compliance with Entry Criteria Guidelines (as specified in Section 8).

ALL DECISIONS OF SPONSORS WILL BE FINAL AND BINDING ON ALL MATTERS RELATING TO THIS COMPETITION.

AWARDS: Prizes will be awarded for the best solutions. The Challenge Phase Competition will award up to twelve (12) US\$200,000 prizes across the four Topics. Prize Recipients of the Challenge Phase will be eligible to compete in the final Product Phase for prizes of US\$ 1 million or more. The selection of Prize Recipients will be at Sponsors' sole discretion.

All Prize Recipients will be notified by the e-mail address provided in the Entry. Return of any notification as "undeliverable" will result in disqualification. All Prize Recipients are subject to verification of eligibility and compliance with these Official Rules and Sponsors reserve the right to examine Entries for compliance with the Competition Rules. Prize Recipients will be subject to all applicable laws and regulations and may be disqualified if found to be ineligible under any applicable law or regulation.

After verification of eligibility and receipt of the requisite documents, awards will be distributed to the official representative specified in the winning Entry. Such official representative will have sole responsibility for further distribution of any cash award among participants in a group Entry or within a company or institution that has submitted an Entry. No substitution or transfer of awards is permitted and Sponsor will only award the entity designated as the lead for each Entry.

This is a voluntary contest of skill and innovation and no fee is required to enter. Submission of an Entry does not entitle an Entrant to an award or obligate Sponsors to make an award. Whether or not your Entry is determined as a Prize Recipient depends on how your Entry compares to the other Entries submitted in the Competition when evaluated based on the Evaluation Criteria within the sole judgment of the Sponsors. All awards are final and this is a one-time offer. There is no offer of a license, royalty, or other financial compensation implied beyond the award described above. Each Prize Recipient is responsible for all tax reporting obligations and all tax payments as applicable.

15. **PRODUCT PHASE AWARD ELIGIBILITY:** Challenge Phase Award recipients will be eligible to apply for consideration for a Product Phase award in accordance with the following:
- Lead applicant must be an in-state entity (O.R.C 184.10) or establish a principal place of business in Ohio or:
 - Partner, for purposes of project demonstration, with an in-state entity.
 - Additional rules and restrictions may apply.

Based on current funding, the Product Phase will award up to 4 US\$1 million grants across the four Challenge Phase Topics.

16. **LIMITATION OF LIABILITY:** By participating in the Competition, you agree to release, indemnify and hold harmless, Sponsors and their respective affiliates, subsidiaries, advertising and promotions agencies, and each of their respective agents, representatives, officers, directors, shareholders, and employees (collectively, "Sponsor Entities") from and against any injuries, losses, damages, claims, actions and any liability of any kind (including attorneys' fees) resulting from or arising out of your participation in, association with, or submission to the Competition (including any claims alleging that your Entry infringes, misappropriates, or violates any third party's intellectual property rights). Sponsor Entities are not responsible for any technical failures related to communication or submission failures, such as unavailable networks or server connections; other failures related to hardware, software, viruses, or incomplete, late or misdirected Entries. Any compromise to the fair, proper and legal conduct of this Competition may result in the disqualification of an Entry, the termination of the Competition, or other remedial or

legal action at the sole discretion of Sponsors. Sponsors reserve the right, in their sole discretion, to extend or modify the dates of the Competition and to change the terms of the Official Rules governing any phase or portion thereof. By entering, you agree to be bound by these Official Rules and acknowledge that all decisions of Sponsors, and their respective agents and representatives are final and binding in all respects.

17. **NO OBLIGATION:** You acknowledge that multiple participants may submit Entries that contain designs, concepts, approaches, or technologies similar to your Entry and that the Sponsor, and/or its respective subsidiaries and business partners may already be investigating or developing technical solutions or have business activities that are related to or similar to those disclosed in your Entry. You acknowledge and agree that Sponsor's actions with respect to another Entry or one of its own solutions, investigations, or business activities, even if similar to your Entry, shall not create any liability, of any kind, by Sponsor to you or others. Further, Sponsor is not or shall not be restricted in any way from pursuing, developing, or commercializing, in any way that they see fit, independent of you and at its sole discretion, any activity or technology that is created independent of your Entry. For the avoidance of doubt, you acknowledge that Sponsor is not obligated to take any action whatsoever with regard to your Entry.
18. **SEVERABILITY:** The invalidity or unenforceability of any provision of these Official Rules shall not affect the validity or enforceability of any other provision. In the event that any provision is determined to be invalid or otherwise unenforceable or illegal, these Official Rules shall otherwise remain in effect and be construed in accordance with their terms as if the invalid or illegal provision was not contained herein.
19. **WAIVER:** By entering the Competition, you thereby waive all rights to seek injunctive or equitable relief, or to claim punitive, incidental or consequential damages, or attorneys' fees against Sponsors or their affiliates, employees, agents or representatives.
20. **APPLICABLE LAW:** You agree that these terms and the relationship between you and Sponsors shall be governed and construed under the laws of the United States. You acknowledge and agree that all aspects and content of your Entry, including all information, developments, inventions, and works of authorship, shall be treated as if made in the United States of America and U.S. laws relating to patents, inventions, assignments, and innovation compensation shall supersede the relevant laws of any country in which the Entry may have been conceived, developed, or reduced to practice.

For Entrants living outside the United States of America, you expressly acknowledge that this competition is free and voluntary. By entering this Competition, you accept Ohio law as governing law, the specific terms, conditions and policies outlined in the Official Rules, and consent to having your Entry data, including all provided personal information, transferred to, processed in, and stored in the United States of America pursuant to the Ohio Development Services Agency Privacy Statement.