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Course Introduction

Krista Ternus, PhD, PMP
Signature Science, LLC



RICE



aclid

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science LLC

Welcome!

- Objectives for course participants:
 - Become familiar with important biosecurity concepts and regulations
 - Gain experience by performing sequence screening with open-source software
 - Learn how to interpret sequence screening results
- We encourage you to:
 - Complete all portions of the course
 - Try running software and/or interpreting the example software outputs
 - Fill out pre- and post-course surveys
- The views, conclusions, software, and databases contained herein are those of the authors and should not be interpreted as endorsements by the U.S. Government.

HHS Updated Guidance Document

U.S. Department of Health & Human Services
Administration for Strategic Preparedness and Response

Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids

October 2023



<https://aspr.hhs.gov/legal/synna/Documents/SynNA-Guidance-2023.pdf>

“Non-regulated pathogens and toxins, as well as other novel types of nucleic acid sequences, may also pose significant risks if they are misused. To minimize these risks, a shift is needed from relying solely on lists of regulated pathogens and toxins to also assessing the risks associated with other nucleic acid sequences that may contribute to pathogenicity or harm if introduced into new genetic frameworks (i.e., Sequences of Concern [SOCs]).”

To Share or Not to Share...

- As of October 2023 (and to the best of our knowledge), SeqScreen (Balaji et al. 2022) is the only open-source software that labels sequences of concern via machine learning and manual curation, and this is the only training course of its kind.
- The open-source nature of SeqScreen has raised questions about dual use.
- Reasons we have decided to openly share SeqScreen:
 1. SeqScreen **fills a gap** for legitimate, basic research purposes.
 2. The SOC ontology labels were **developed by a team of scientists**. SeqScreen does not include data from, and is not endorsed by, any regulatory authority or government agency.
 3. Everything in SeqScreen was derived from **publicly available data**.
 4. While individual SOC labels are labeled by SeqScreen, there are **no automated threat calls**.
 - Final threat calls are challenging, nuanced, and may require additional security if automated.
 - However, we believe the concepts involved in teaching others how to make final threat calls should be openly available and transparent to promote good biosecurity practices.

Options to Implement Sequence Screening



Bioinformaticians
running in-house
command line tools



Biologists
interpreting outputs
from commercial
software



Commercial
outsourcing of the
entire screening
and interpretation
process

Course Acknowledgements



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Founder
Aclid



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Bioinformatics
Signature Science



Gene Godbold
Biocuration
Signature Science



Beth Vitalis
Director of 4S
BioMADE



Steve Evans



Louise Petruzzella



Kristin Jenkins

BioMADE Program Management and Technical Insights

Matthew Sharkey of the U.S. Department of Health and Human Services will give a guest lecture about updated guidelines for DNA screening

Course Agenda

- Video Lecture #1: Course Introduction
- Video Lecture #2: Relevance of Sequence Screening to the BioMADE Community
- Video Lecture #3: Screening Framework Guidance
- Video Lecture #4: DNA Screening Basics
- Video Lecture #5: Alignment to Biothreat Genomes
- Video Lecture #6: What Are “Bad” Sequences?
- Video Lecture #7: SeqScreen Software Overview
- Video Lecture #8: Known Test Sequences
- Video Lecture #9: Case Studies
- Video Lecture #10: Future Directions
- Video Lecture #11: Course Conclusion
- A more detailed agenda is available here: https://github.com/signaturescience/screening_course

Pre-Course Survey



Thank
You

<https://forms.gle/tpeF1SmhvYx5Sv5U9>



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