NEW!
ILSI North America Research Design Challenge

Pitch a research design idea at ASN NUTRITION 2018 to compete for a prize award.

Abstract due January 18, 2018

Background: Non-essential bioactive dietary components hold promise for helping maintain optimal health and reducing risk of chronic disease. Recommended intakes of bioactive dietary components should have solid evidence of safe use at efficacious levels. Such evidence will improve the confidence of regulatory bodies with product oversight and health professionals providing advice to the general public. Currently, safety is based primarily on either historical use over periods of time or safety tests when appropriate.

Efficacy studies are not designed/powered to measure safety and typically report results in terms of subject's adverse events or reasons for dropouts. *However, evidence of safe use at efficacious levels could be greatly improved if safety related measures were proactively integrated and more thoroughly reported in clinical efficacy testing. Lower cost, highly efficient study designs are needed to increase collection of safety data as secondary measures integrated in clinical efficacy research.*

Research Design Challenge Objective:
Demonstrate proof of principle for novel research designs to integrate more safety measures in research with the primary purpose of testing efficacy of dietary bioactives.

Opportunity: Assemble and lead your own cross-functional team to develop a novel research design that meets the stated challenge objectives and then pitch it at ASN 2018. One team member must attend ASN's NUTRITION 2018 meeting in order to make the pitch as part of the challenge.

Benefits to teams selected to pitch to a panel of judges at NUTRITION 2018 annual meeting and scientific sessions.

- Opportunity to "pitch" the innovative research design to a panel of judges at NUTRITION 2018.
- Eligible for a prize award (winning team will receive $1,000 and up to two teams may win runner-up awards of $500 each).
- YouTube video of your pitch presentation.
- Inclusion in Methods and Protocol poster session.

- Networking opportunity with a mentor who will advise the team in preparing the pitch presentation and also the opportunity to interact with esteemed judges.

Logistics:

1. Start by **assembling a cross-functional team** to develop a novel research design that integrates more safety measures in research with the primary purpose of testing efficacy of dietary bioactives. Only the team leader needs to attend the ASN 2018 meeting however, the team developing the design should include experts relevant to the topic, including toxicology and biostatistics as well as any others specific to the design idea.

2. **Submit your abstract to the ASN NUTRTIION 2018 Methods & Protocols section (#097) due on January 18, 2018 indicating in the last sentence it is for the ILSI NA Research Challenge.** Data are not needed in the abstract, but keep in mind that proof of principle evidence (even if theoretical modeling) will be necessary when the idea is pitched at the June ASN NUTRTIION 2018 meeting.
https://meeting.nutrition.org/
https://meeting.nutrition.org/abstracts/

3. Selected teams will be notified by end of March that they were selected for the challenge session to pitch their idea in a challenge session to a panel of judges at NUTRITION 2018.

4. Mentors will be offered to work with teams as they develop their proposal into a pitch.

5. **Prepare a poster** for the poster session.

6. **Pitch the research design in a short presentation of less than 5 minutes (format and timing will be provided to the teams selected). YouTube videos will be posted for each presentation on the ILSI North American channel**.

Additional background information:
Currently, research studies designed to test efficacy of bioactive components of food collect safety information as part of clinical trial safety data monitoring. Results are typically reported in the study publication indicating the number of subjects who may have experienced side effects or as reasons for dropouts. Both collection and reporting of safety information could be improved if considered proactively in the design and conduct of efficacy studies. For example, efficacy studies typically exclude subjects for whom safety may be a question, including those with specific risk factors or susceptible

sub-populations. There are several opportunities to design efficacy studies such that they inform safety, including choice of dose, subject inclusions, duration, and specific test measures to be taken. The challenge is to design research that enables these secondary safety measures at a lower cost than running a separate safety trial, but must remain feasible for collecting the primary efficacy measures. Such novel ideas are being sought in this challenge.

Successful abstracts will state clearly what is new about the research design approach and the benefits (in terms of subject benefits, power calculations, costs savings, etc). Research ideas should consider relevant PICO criteria as part of the study design, statistical analysis, and cost-benefit calculations to demonstrate proof of principle. (PICO: Population, Intervention, Control, Outcomes). Research designs will be considered out of scope if they are existing standard toxicology testing, research designs focused on safety as the primary measure rather than efficacy, and ideas lacking clear differentiated benefits.

For questions on the challenge competition, please contact Barbara Lyle, PhD at blyle@ilsi.org.

For questions on submitting your abstract, please contact Michelle Crispino at mcrispino@nutrition.org.

Sponsor:

This challenge session is sponsored by the Bioactive Committee of the North America branch of the International Life Sciences Institute.