



BSC Strategy & Conclusions

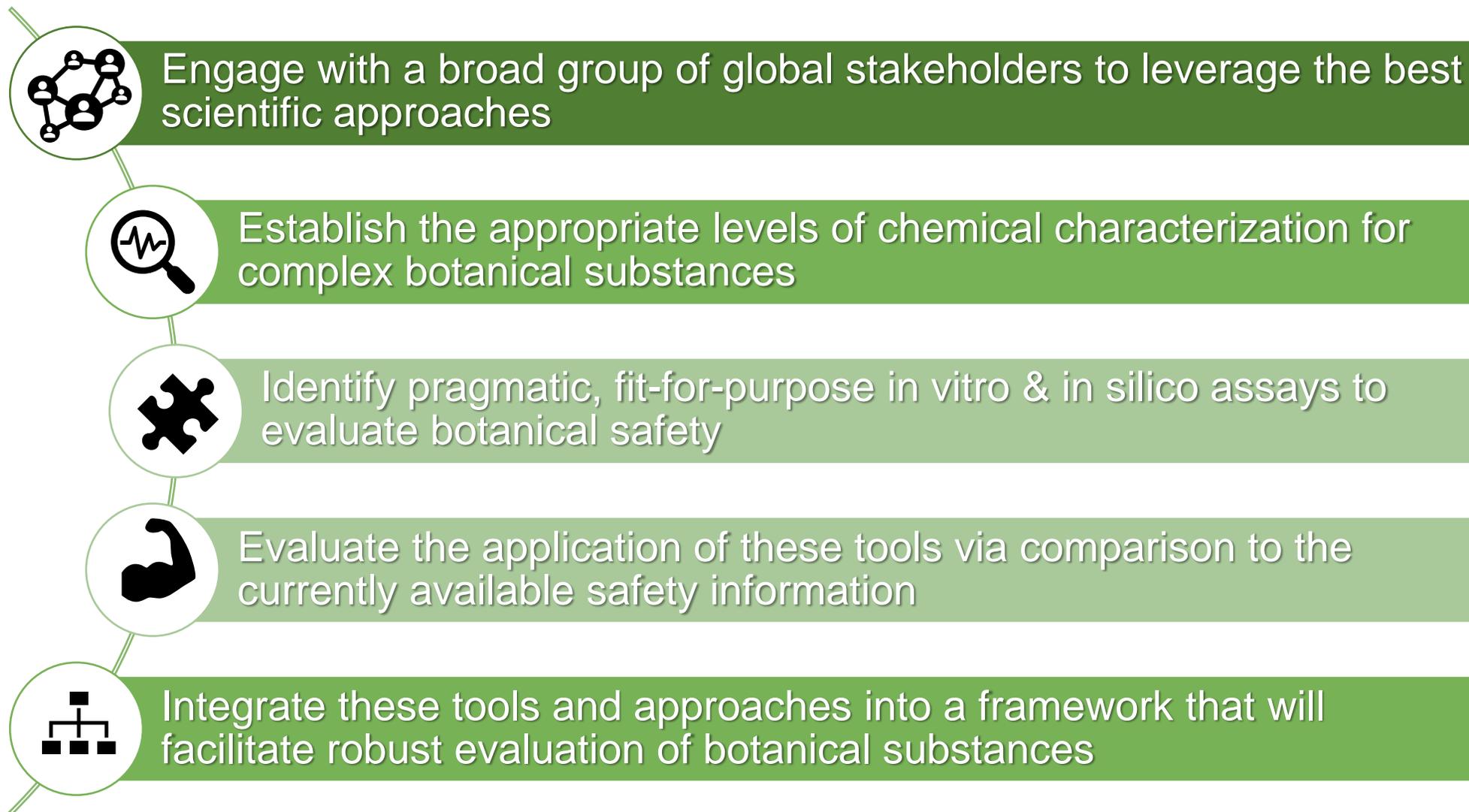
James Griffiths

Council for Responsible Nutrition

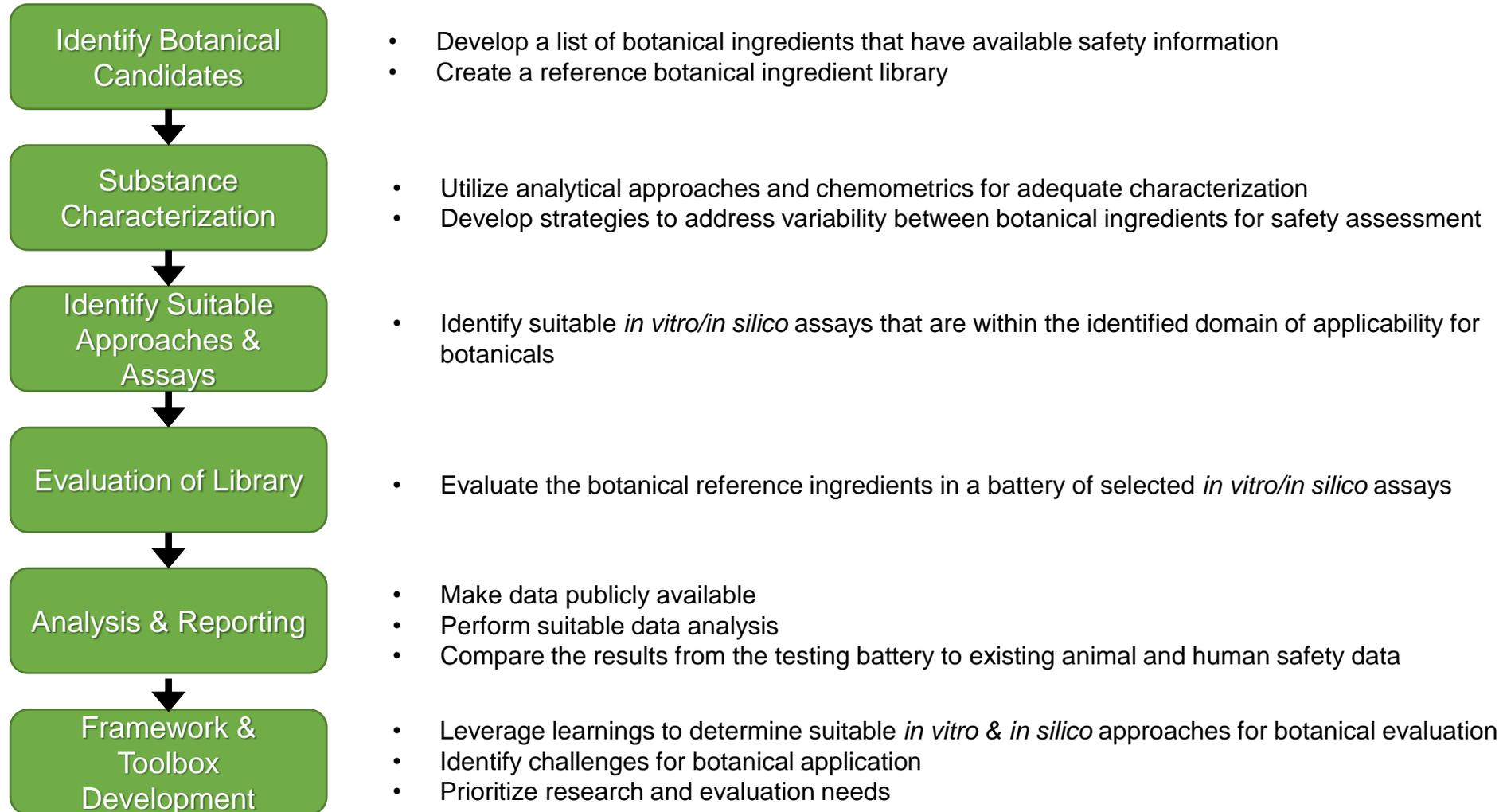


BOTANICAL
SAFETY CONSORTIUM

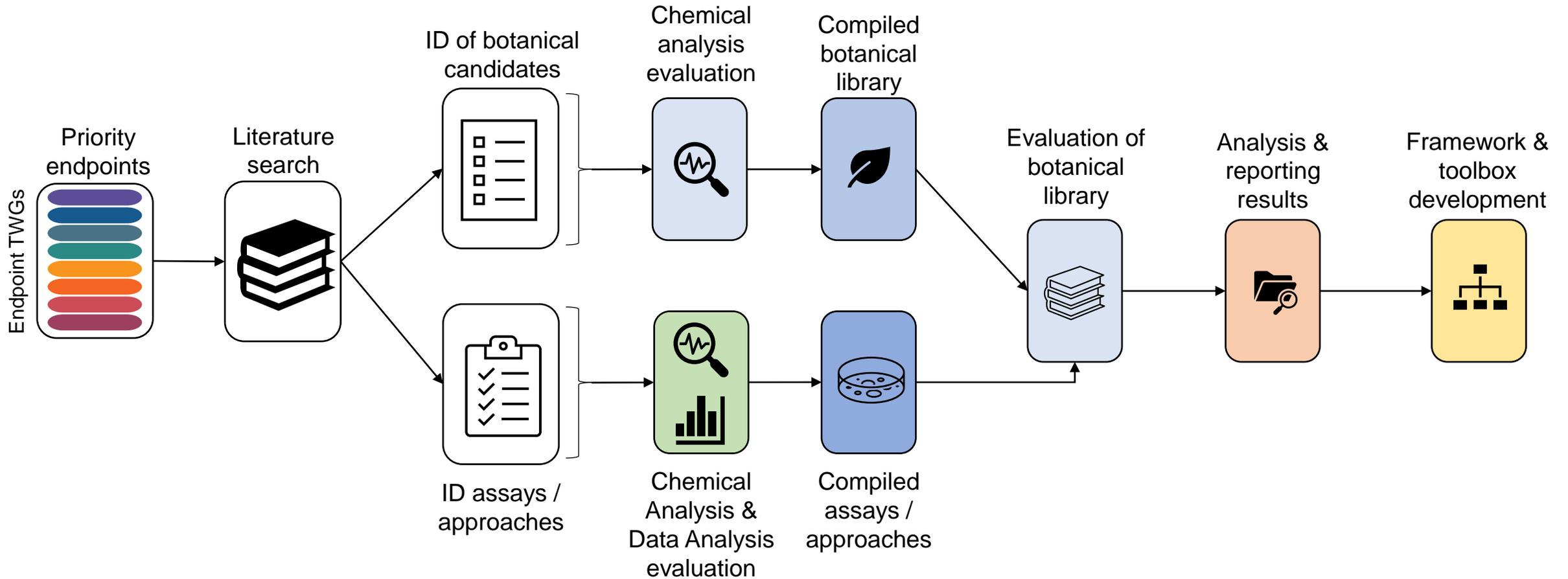
Botanical Safety Consortium Objectives



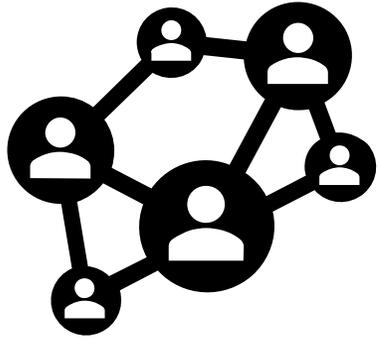
Botanical Safety Consortium Strategy



Strategy Details....



Ongoing stakeholder communication & engagement



BSC Network

- Objective: Engage with a broad group of global stakeholders to leverage the best scientific approaches
 - Academia, government, industry, NGOs, CROs, Consultancies, Trade Associations
 - Global
 - Scientific focus; regulatory application
 - Various BSC groups for engagement:
 - Public
 - Stakeholder Council
 - Technical Working Groups
 - Leadership
 - Regular outreach and communication at scientific meetings / events

How can we expand and enhance our network?



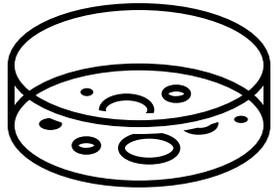


Chemical Characterization

- Objective: Work to establish the appropriate levels of chemical characterization for complex botanical ingredients
 - Utilize non-targeted and targeted analytical approaches and chemometrics for adequate characterization
 - Develop strategies to address variability between botanical ingredients for safety assessment

What are some key challenges regarding chemical characterization that you have experienced?





Assays and Approaches

- Objective: Identify pragmatic, fit-for-purpose *in vitro* & *in silico* assays to evaluate botanical safety
 - Which approaches are within the domain of applicability for botanicals?
 - What modifications / considerations need to be made when applying these approaches for botanicals?
 - For *in vitro* methods
 - For computational approaches

Are there examples of assays that may be suitable for the BSC?



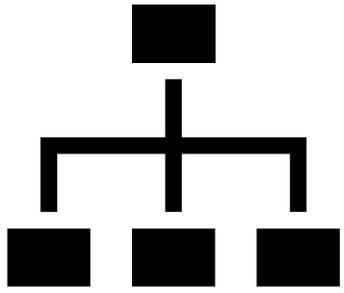
Analysis & Application

- Objective: Evaluate the application of these tools via comparison to the currently available safety information
 - Evaluate the botanical reference ingredients in a battery of selected *in vitro/in silico* assays
 - Perform suitable data analysis
 - Compare the results from the testing battery to existing animal and human safety data

What are some key challenges regarding data analysis and interpretation that must be considered?

What types of data sharing formats will be most useful?

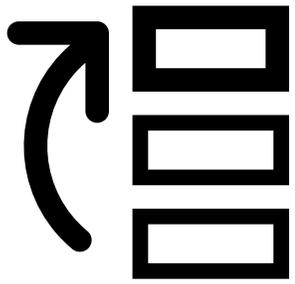




Development of a Framework / Toolbox

- Objective: Integrate these tools and approaches into a framework that will facilitate robust evaluation of botanical ingredients
 - Leverage learnings from the library analysis to determine suitable *in vitro* & *in silico* approaches for botanical evaluation
 - Identify challenges for botanical application
 - Evaluate the application of these tools via comparison to the currently available safety information (e.g., existing data, historical use information)
 - Prioritize research and evaluation needs

Do you have some ideas of how the BSC might demonstrate the utility of this framework?



Priority Endpoints

- Severity of associated disease
 - (e.g., genotoxicity and cancer, cardiotoxicity and heart disease)
- Adverse event reporting and research on botanicals
 - (e.g., hepatotoxicity, cardiotoxicity)
- Building bridges with current gold standard - animal safety data
 - (e.g., *in vitro* systemic toxicity vs repeat dose *in vivo*)
- Availability of alternative assays to measure effects in that system
 - *in vitro*
 - *in silico*
- Hepatotoxicity, genotoxicity, DART, systemic toxicity, cardiotoxicity
 - Scoping out others (immunotox, neurotox, nephrotox)

What other endpoints should be considered as high priority?





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