



Chapter 17

Engaging Scientists in Biorisk Management

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- ***Biorisk Management requires a set of elements:***
 - ✓ formal regulations and policies
 - ✓ management systems
 - ✓ technical standards
 - ✓ informal settings such as responsible culture

- ***Importance for engaging scientists in biorisk management.***
 - ✓ **Compliance** with relevant policies and their **awareness of biosafety** issues are essential for tackling these traditional laboratories biosafety risks.
 - ✓ When face with dual-use dilemma which arising within life sciences, scientists are expected to be more **proactively reflective** and **responsible** for the research process and also its product beyond the passive compliance with policies or other ethical rules

- ***Gaps in Biorisk Management:***
 - ✓ Scientists' motivation
 - ✓ Scientists' capability

- ***Explorative Tools and Cases: providing the techniques to scientists to participate in biorisk management as well as strengthening their motivation***
 - ✓ IWG: Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences: (Self) Assessment Framework (international level)
 - ✓ Netherlands Biosecurity Office: Quicksan Series (national level)
 - ✓ iGEM: Responsibility Program (community level)

IWG Assessment framework



International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences (IWG)

International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences

Elements of Culture

- I. Management Systems
- II. Behavior of Leadership and Personnel
- III. Principles for Guiding Decisions and Behaviors
- IV. Beliefs, Opinions, and Attitudes

Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences

-- (Self) Assessment Framework --

January 2020
Working Draft

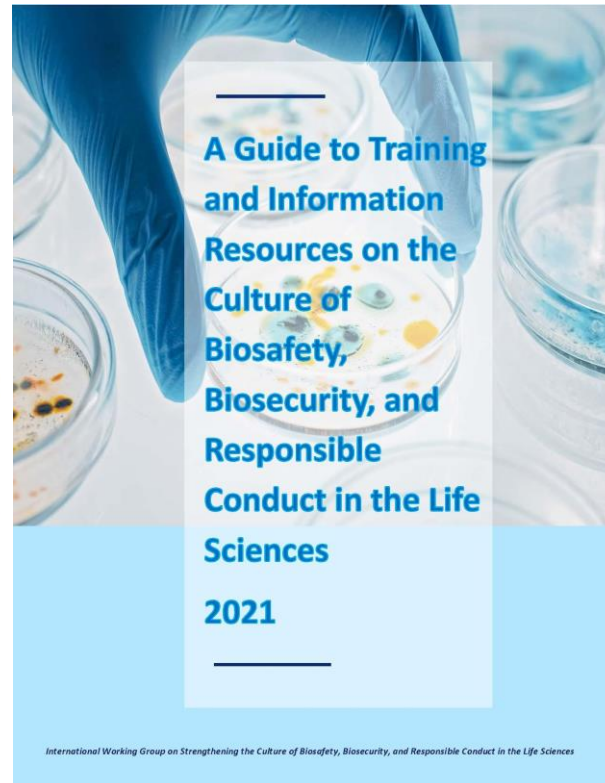
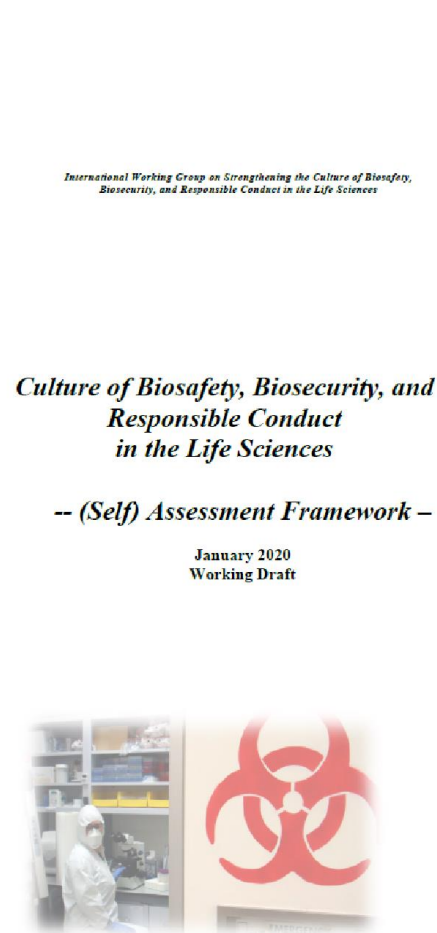
Example: Overall Culture Assessment and General Interpretation (red: 0%-40% (improvement needed); yellow: 41-60% (caution); green: 61-100% (adequate to excellent))



Management Systems [YELLOW]	Behavior of Leadership and Personnel [YELLOW]	Principles for Guiding Decisions and Behaviors [RED]	Beliefs and Attitudes [GREEN]
<ul style="list-style-type: none"> ▪ Element flagged for concern ▪ Actions should be considered to boost endorsement of a positive culture of biosafety, biosecurity, and responsible conduct 	<ul style="list-style-type: none"> ▪ Element flagged for concern ▪ Actions should be considered to boost endorsement of a positive culture of biosafety, biosecurity, and responsible conduct 	<ul style="list-style-type: none"> ▪ Element of great concern ▪ Corrective actions should be taken ASAP 	<ul style="list-style-type: none"> ▪ Adequate or excellent element ▪ There may still be room for improvement upon further data analysis ▪ Maintenance/sustainability actions recommended.

Example of Numerical Calculation and Color Coding:

I. Management Systems		N/A or I don't know	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree	FOR ASSESSOR TEAM USE ONLY Color Scale 0-1-red, 2-3-yellow, and 4-5-green
1	My organization has procedures in place to keep employees informed on the risks of unintentional and/or intentional release of, or exposure to, biological agents and/or toxins that are stored or handled at our facilities.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Green
2	My organization publicly explains the procedures and rules of conduct related to biosafety and biosecurity during new employee orientation.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Green
3	My organization has a systematic risk-benefit analysis process in place for dual-use research.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Green
4	The organization has mitigation procedures in place to reduce the risk of unintentional and/or intentional release of, or exposure to, biological agents and/or toxins stored or handled at our facility.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Yellow
5	My organization has implemented mitigation procedures to reduce the risk of unintentional and/or intentional release of, or exposure to, biological agents and/or toxins stored or handled at our facilities.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	Yellow
6	My organization has procedures in place which detail the actions required during an incident.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Green
7	Lessons learned from emergency drills have improved organizational performance.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Green
8	My organization conducts emergency response drills on a regular basis.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Green



Implications from IWG Framework for Engaging Scientists Biorisk Management

- 1. Building** the culture of responsibility: the key **elements** and **approaches** of engaging scientist in biorisk management
 - *Management Systems*
 - *Behavior of Leadership and Personnel*
 - *Principles for Guiding Decisions and Behaviors*
 - *Beliefs, Opinions and Attitudes*
- 2. Improving** the culture of responsibility: engaging scientist in the **assessment** of biorisk management systems

Building the Culture Of Responsibility: the Key Elements and Approaches of Engaging Scientist in Biorisk Management

- **Management Systems**
 - ✓ Information and explanation
 - ✓ Channel of participation and report
 - ✓ Systematic risk benefit analysis for dual use research
- **Behavior of Leadership and Personnel**
 - ✓ Communication
 - ✓ Trust and encouragement
 - ✓ Support
 - ✓ Vigilance on biosafety and biosecurity
 - ✓ Report and self-report without fear
 - ✓ Involve in the risk assessment and decision-making process of risks reduction
- **Principles for Guiding Decisions and Behaviors**
 - ✓ Organizational guiding principle in reinforce the scientists' engagement
 - ✓ Personnel guiding principles in dealing with the diverse biorisks
- **Beliefs, Opinions and Attitudes**

Improving the Culture of Responsibility: Engaging Scientist in the Assessment of Biorisk Management Systems

- The information and feedback provided by scientists
- The assessment processes will actually involve scientists in the biorisk management deeply inducing their reflection about safety and security
- Encourages that leadership and scientists engagement at all levels should foster self-exploration and learning about biosafety and biosecurity

Netherlands Biosecurity Office: Quickscan Series



Self-scan Toolkit

The [self-scan toolkit](#) is a relatively fast scan with a limited number of closed questions that can easily form an indication of strong and weak biosecurity aspects within your organisation.

Vulnerability Scan

The [vulnerability scan](#) is a more extended scan compared with the self-scan toolkit with questions, scenarios and best practices built around the eight pillars of biosecurity. [More information.](#)

Dual-Use Quickscan

The [Dual-Use Quickscan](#) aims to identify potential dual-use aspects in the research. In addition, this tool contributes to stimulating dual-use awareness among researchers. [More information](#).

Bureau Biosecurity

Home Start Quickscan Uitleg Quickscan Informatie Eindresultaten

Dual-Use Quickscan

Welkom bij de Dual-Use Quickscan van Bureau Biosecurity. Het doel van de Dual-Use Quickscan is om onderzoek te kunnen monitoren op potentieel dual-use aspecten. Daarnaast draagt deze tool bij om dual-use bewustwording bij onderzoekers te stimuleren. De resultaten van de Dual-Use Quickscan kunnen gebruikt worden voor overleg over het onderzoek dat mogelijk een dual-use karakter krijgt of kan krijgen en hoe hiermee zorgvuldig om te gaan. Dit overleg is tussen de onderzoekers en een persoon in uw organisatie die verantwoordelijk is voor biologische veiligheid.

Vragenlijst
De Dual-Use Quickscan bestaat uit een 15-

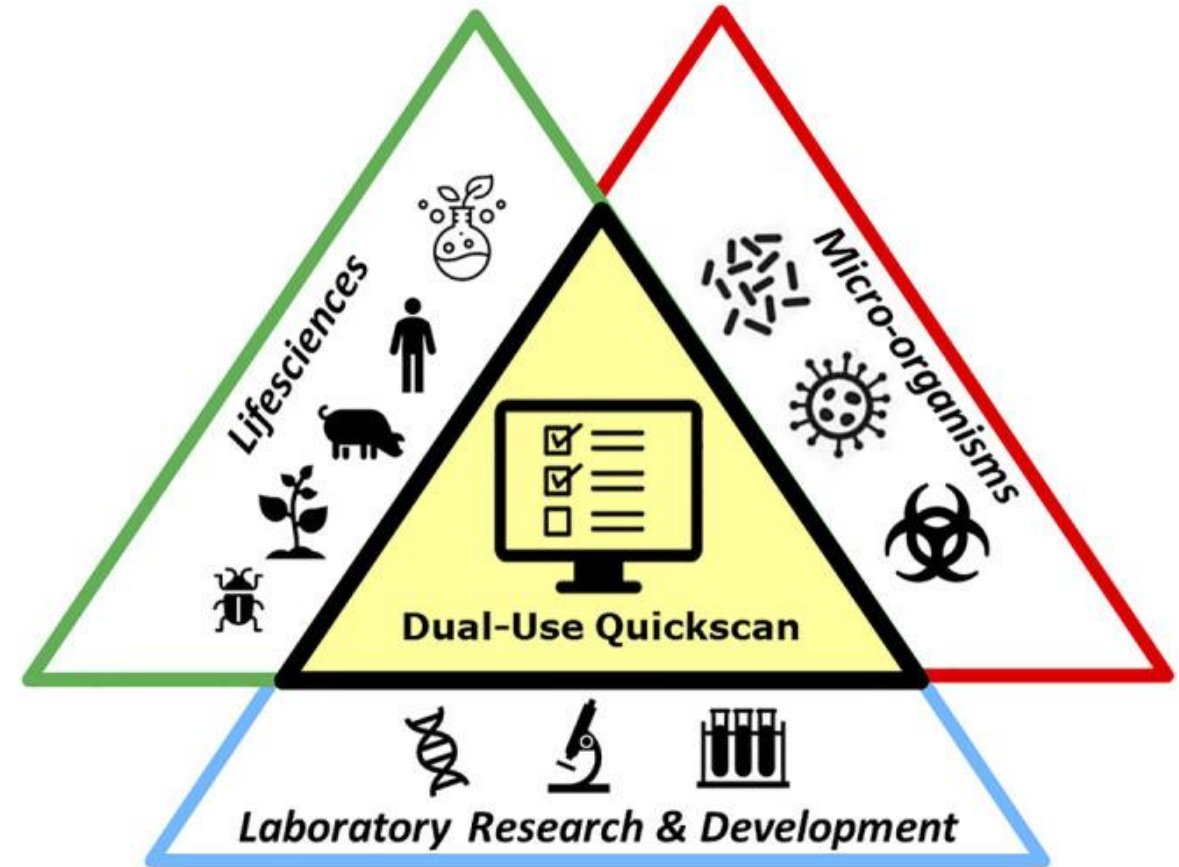
Uw gegevens
De gegevens die u in deze tool invult

Dual-Use Quickscan

0 van 15 vragen beantwoord

Thema's

- Hoogrisico biologisch agens
- Hostrange en tropisme
- Virulentie
- Stabiliteit
- Verspreiding
- Opname en toxicokinetiek



Dual Use Quickscan: Engaging Scientists through Dual Use Risk Factors Identification

High-risk biological agent

1. Are you working with a biological agent, or parts of it, that can be considered a high-risk pathogen?

Yes No Unknown

∨ Explanation

Host range and tropism

2. Is the host range or tropism of the biological agent likely to be altered?

Yes No Unknown

∨ Explanation

Virulence

3. May your research increase the virulence of the biological agent?

Yes No Unknown

∨ Explanation

No	Themes	No	Themes
1	High-risk biological agent	9	Detection methodology and diagnostics
2	Host range and tropism	10	Reconstruction
3	Virulence	11	Harmful effects
4	Stability	12	Knowledge and Technology
5	Transmissibility	13	Ecological consequences
6	Absorption and toxicokinetics	14	Economic consequences
7	Drug resistance	15	Consequences for society
8	Population immunity		

- **Basic awareness of biorisk by self- assessment**
- **Starting tool to perform formal assessment & management**
- **Deep understanding of biorisk by reference materials**

Local people solving local problems all over the world

Through iGEM, people are creating synthetic biology ecosystems around the world. There are hundreds of success stories originating at iGEM.

iGEM TEAMS SINCE 2004

1 817	1 259	1 059	192	30
ASIA	NORTH AMERICA	EUROPE	LATIN AMERICA	AFRICA



iGEM is international and large.

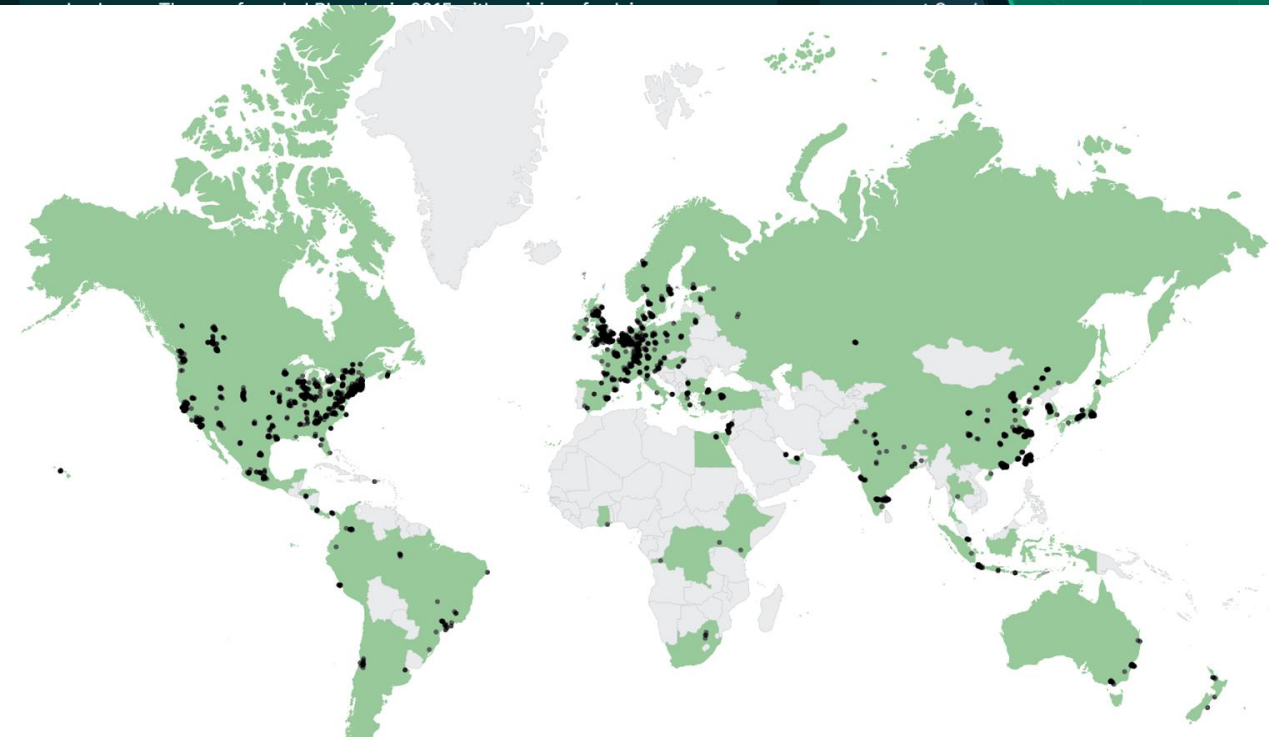
2004: 5 teams

2019: 353 teams
6375 participants

2020: 249 teams
4800 participants

2023: 397 teams
More than 8000 participants

There are over 75,000 iGEM alumni; many first encounter synthetic biology through iGEM.



iGEM: Responsibility Program



Governing using the competition structure



Medals

All teams compete for medals, criteria on responsibility + collaboration



Awards

Special awards for work in biosafety, public engagement, responsible design



Celebration

Build culture through celebrating great examples of responsible work

Safety Rules Checklist and Safety Screening System

Does any of your work require extra caution?



Release Beyond Containment



White List



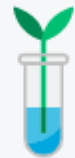
No Human Experimentation



Animal Use



Environmental Samples



Human Subjects Research



Antimicrobial Resistance



Gene Drives



Coronavirus



Safety Rules Checklist and Safety Screening System

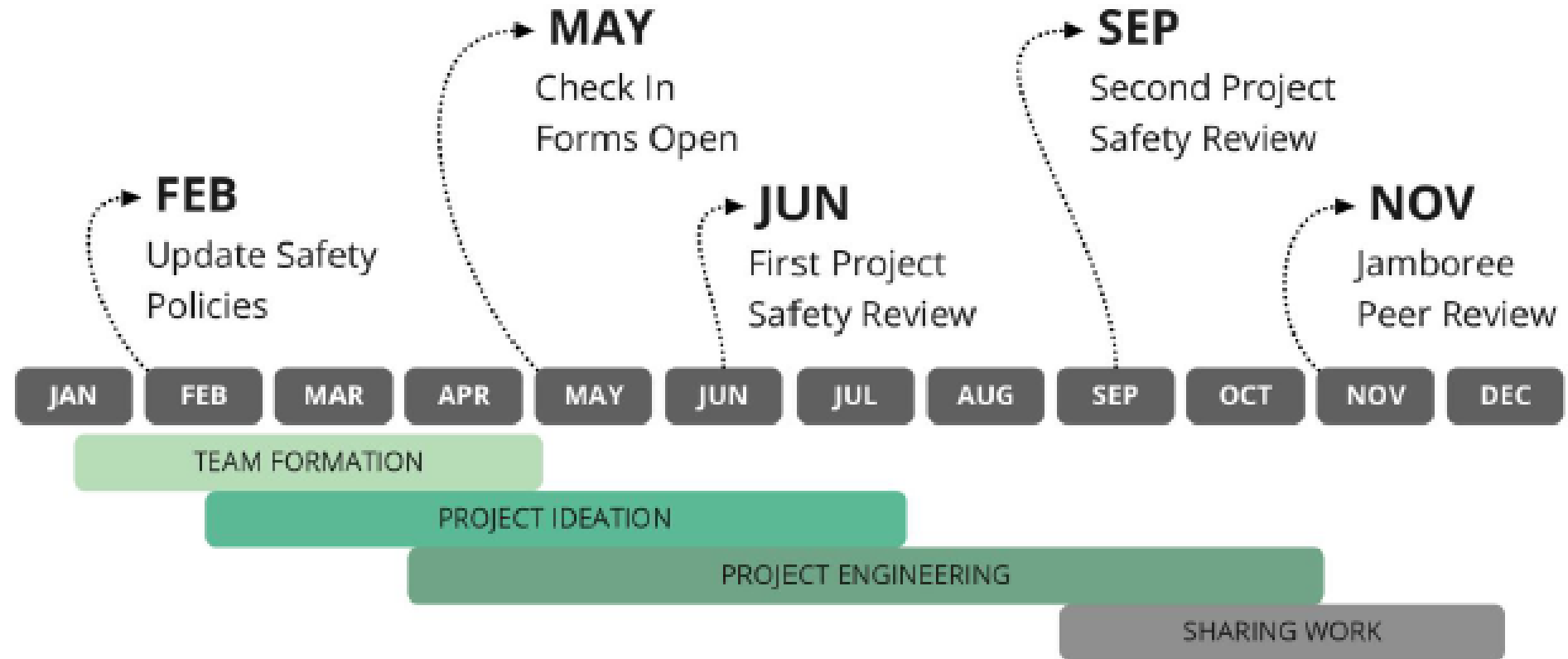


FIGURE 1 iGEM Competition cycle, highlighting the periodic review of projects and policies

Safety Rules Checklist and Safety Screening System

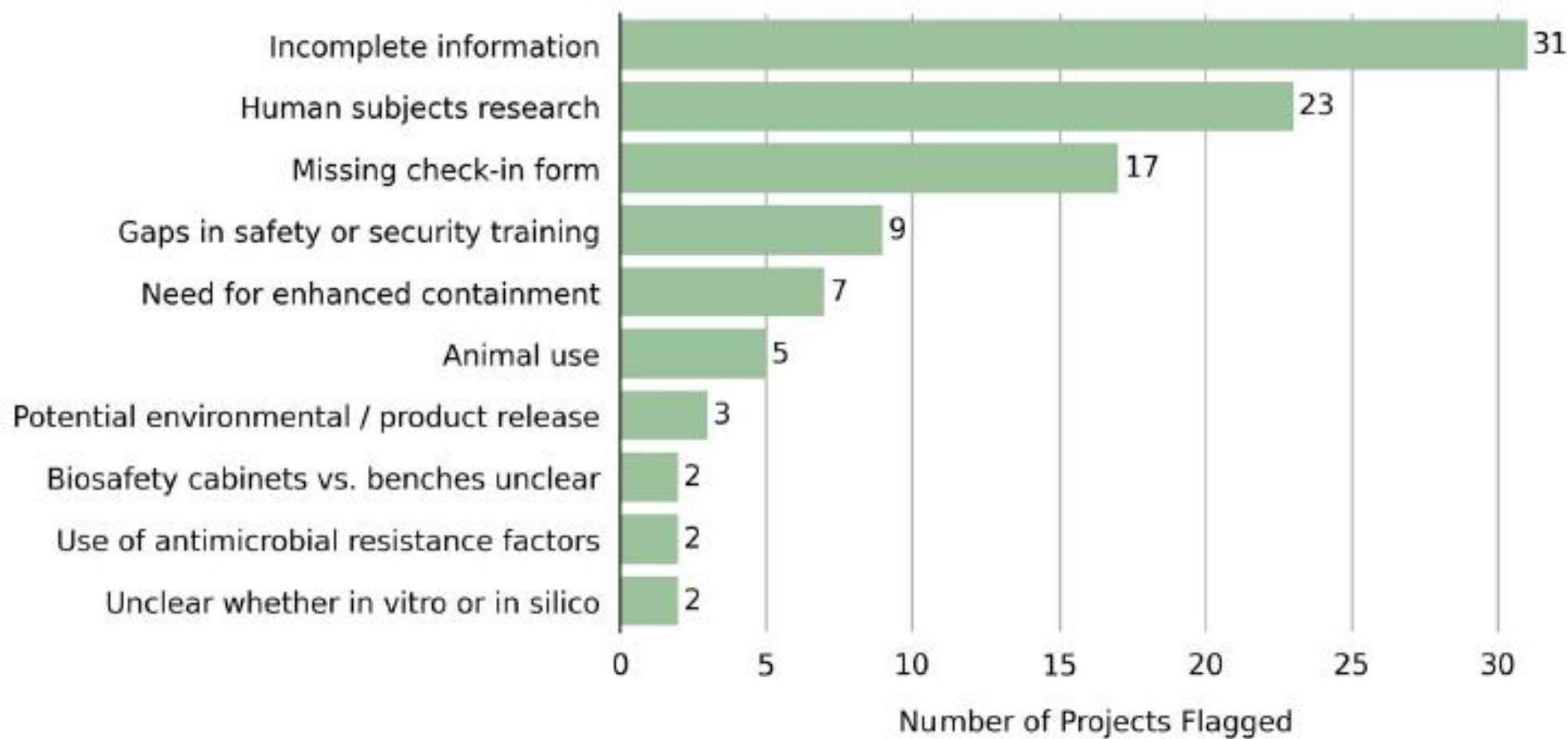


FIGURE 2 Reasons projects were flagged by external reviewers in 2020

Engaging Scientists through Human Practices Program

Is your project responsible and good for the world?



BE REFLECTIVE

Think about what values and needs you are prioritizing, and where you are compromising.



BE RESPONSIBLE

Communicate honestly and consider how your project could impact the world, for better or worse.



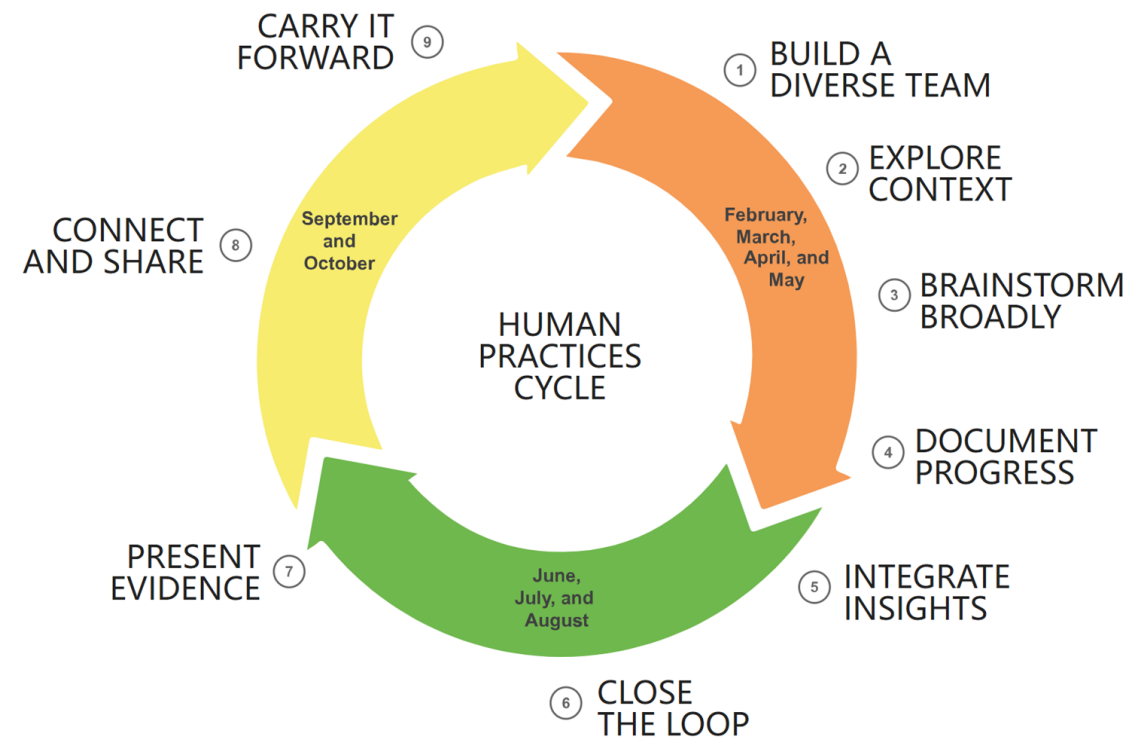
BE RESPONSIVE

Listen to and learn from stakeholders and others you engage with.

Engaging Scientists through Human Practices Program

Teams can integrate Human Practices into **every step of their engineering cycle**, from team building to final presentations.

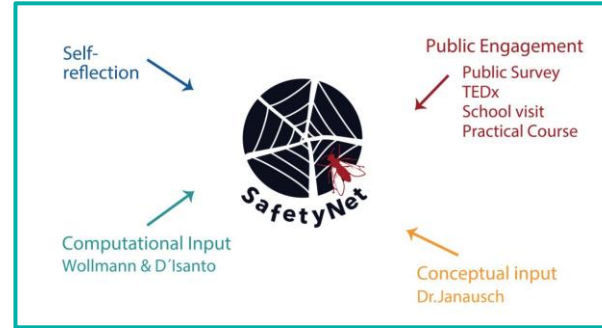
Example messages: “**explore the context**” = the communities, institutions, or individuals affected by the problems a team wants to work on.



Engaging Scientists through Human Practices Program



Researching policies and practices



Designing and/or documenting new frameworks and tools




Enabling equal opportunity in scientific practice



Engaging with stakeholders, users, and other experts




Developing new philosophical and ethical insights




Education

With a friendly-user software, Printeria is designed to be an educational tool



Research groups

Printeria automatizes protocols, and enhances the experiments reproducibility.



Bioartists

Printeria offers a compact and friendly toolkit for the bioartist entire disposal

Assessing the impact and feasibility of potential products

Engaging Scientists through Responsibility Program

iGEM Policy on Gene Drive

- iGEM responded to the gene drive project by **engaging with the students, convening a group to work with them**, and developing a policy to govern future gene drive-related projects.
- iGEM draw on **existing relationships with key researchers** in the field and thought leaders who could provide oversight of the technology.

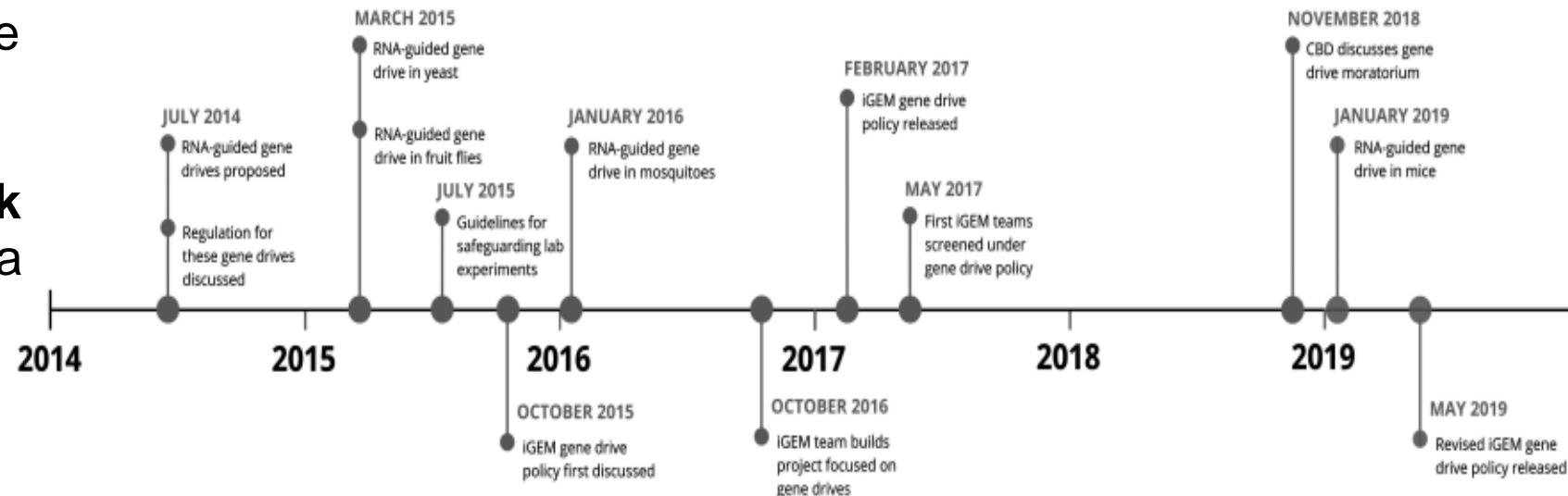


Figure. A timeline of gene drive-related policy and technological developments. Abbreviation: CBD, Convention on Biological Diversity.

Conclusion



Key expected performance of scientists engagement

- The wariness of biorisk
- Self-assessment
- Report of concern and Improvement

Tools and Approaches

- Easily-available tools that guide scientists into a self-assessment
- The availability of “background/reference material” or clear guidance and rules
- Effective encouragement and trust within the management system