



Governing emerging biotechnology: The iGEM Experience

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As an international synthetic biology competition, iGEM is a microcosm of the governance challenges facing the field. The international nature of the competition requires us to operate across different legislative and regulatory frameworks and across cultural boundaries. The technologies chosen by our teams often sit on the cutting edge of what is possible, often in advance of national or international oversight arrangements. By embedding projects in real-world problems, our projects can affect many different peoples, with their own rules, processes and cultures. The interdisciplinary nature of the enterprise, brings together teams from different backgrounds, fields, and levels of experience, often requiring participants to work outside of their traditional comfort zones. The parts-based nature of synthetic biology also challenges traditional safety and security frameworks based upon the origin of parts, rather than their function in context.

iGEM has three programs to facilitate good governance and manage risks to participants, their colleagues, communities and the environment. Our Human Practices efforts help ensure all teams focus on how their work affects the world and how the world affects their work. Our Safety and Security Program helps ensure that biosafety and biosecurity risks from iGEM are managed appropriately. Our value-led ethical framework is enforced by a Responsible Conduct Committee that ensure all teams and their projects comply not only with international good practice but the expectations of our own community. Each of these initiatives supported with its own committee comprised of relevant experts and competition alumni from around the world.

This presentation explains the procedures and practices that iGEM uses to overcome these challenges, manage these risks, and implement a more participatory form of governance. It draws on lessons learned from over 15 years experience in the practical implementation of good governance. A series of case studies -- from context-specific risk assessment, through oversight of gene drives, to human subjects research -- showcase how our policies are derived from, and help to address, real-world practical challenges. We highlight examples of excellence in human practices and safety and security, illustrating how our teams contribute to improving these fields. We also highlight how iGEM is an innovator of, and a test-bed for, new governance practices better adapted for engineering biology.