Successfully Bridging Innovation and Application: Exploring the Utility of a Risk Innovation Approach in the NSF Engineering Research Center for Advanced Biopreservation Technologies (ATP-Bio)

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Abstract: This exploratory study set out to pilot use of a Risk Innovation approach to support the development of advanced biopreservation technologies, and the societally beneficial development of advanced technologies more broadly. This is the first study to apply the Risk Innovation approach — which has previously been used to help individual organizations clarify areas of value and threats — to multiple entities involved in developing an emerging technology.

I. Introduction

The pathway between potentially transformative science and engineering and positive societal impact has always been tortuous. Even the best ideas face a convoluted landscape of possible adverse health and environmental impacts, societal acceptance, consumer buy-in, economic viability and regulations that sometimes seem to create more barriers than opportunities. This landscape is becoming harder to navigate as the rate of innovation outpaces social norms, understanding, and established regulatory frameworks. Yet there is a growing need to ensure that research on new and transformative technologies translates successfully to applications that benefit society.

This is an acute challenge for the National Science Foundation (NSF)-funded Engineering Research Centers (ERCs). The ERC program was established in 1985 to support "interdisciplinary, multi-institutional centers that bring academia, industry, and government together in partnership to produce transformational engineered systems and engineering graduates who

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are adept at innovation and primed for leadership in the global economy."[1] The ERC emphasis on societal impacts was further highlighted with the launch of the 4th generation ERC program (Gen-4 ERCs) in 2020.[2] In response to a 2017 National Academies of Science report on center-based engineering research,[3] the Gen-4 ERCs are expected to "focus on advancing an engineered system through inclusive cross-disciplinary and cross-sector partnerships, while placing greater emphasis on research with high-risk/high-payoff ideas that lead to societal impact through convergent approaches, engaging stakeholder communities, and using team science concepts for their team formation."[4]

The ERC for Advanced Technologies for the Preservation of Biological Systems (ATP-Bio) was one of the first Gen-4 ERCs. Focused on technologies and engineering approaches that aim to "stop biological time" and extend availability of biological samples (cells, aquatic embryos, and tissues — including skin, whole organs, microphysiological systems, and whole organisms), ATP-Bio operates at a nexus of transformative possibilities and desired societal impact, which can be threatened by potential barriers to success that are often hard to identify or quantify. As part of this the ATP-Bio ERC has an Ethics & Public Policy Panel (EP3) that includes the goal of guiding "research and development to manage risk and secure societal benefit."[5]

This exploratory study is an outcome of EP3's research into Risk Innovation as an approach to meeting the expectations of the Gen-4 ERC program, and is an effort to pilot an approach to bridging the gap between research and positive societal impacts that can be used in other areas of advanced technology research and development. This study was designed: (1) to assess the utility of the Risk Innovation approach to supporting the development of beneficial and successful biopreservation technologies — in particular within the context of the ATP-Bio ERC; (2) to develop an understanding of the perceived risk landscape in three key areas of ATP-Bio application spanning food systems, human health, and biodiversity; and (3) to more broadly assess the usefulness of the approach to researchers and developers investigating emerging technologies and their successful and beneficial use within society.

II. Opportunities and Challenges Presented by Advanced Biopreservation Technologies

Emerging science and technology focused on extending the timescales over which viable biological materials can be preserved and reused — collectively referred to here as advanced biopreservation technologies — is opening up transformative possibilities.[6] These include extending the usable time window of viable human tissue and organs,[7] protecting and preserving non-human species and tissues,[8] and preserving the biological sources of food supplies,[9] for instance through biopreservation focused on aquaculture. These emerging capabilities have the capacity to substantially extend time limitations that currently constrain the use and usefulness of biologically preserved biological materials. In doing so, these technologies are opening up possibilities that include greater access to replacement organs and tissues, preservation of endangered species, and protection of biodiversity.

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However, advanced biopreservation techniques are also potentially disruptive technologies. If successful, they are likely to challenge societal, policy, and governance systems, as well as norms and expectations surrounding biopreservation.[10] Beyond the benefits of being able to extend the viable window of, say, a living heart, or preserved seeds, the ability to "extend time" within preserved biological samples holds the possibility of upsetting the delicate balance of systems that have been built around clear time constraints. The result is a growing ecosystem of technologies that, while beneficial in principle, could threaten the status quo in ways that may jeopardize their long-term socially and economically beneficial development and use.

This potential for disruption is seen clearly in the systems, processes, procedures, and regulations surrounding access to vital organs for transplant.[11] While the number of organs available for transplant in the

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United States falls far short of the number of patients requiring heart, liver, lung, and kidney transplants, established systems are in place that ensure predictable and tested pathways between donors and recipients so that transplants are safe and ethical. However, substantial perturbations within this system — such as greatly extending the time-window within which an organ is usable — have the potential to upset the balance in what is a complex sociotechnical system, to the point where the potential benefits of seemingly positive advances cannot be realized in practice.

Such perturbations are likely to impact the governance norms, systems, and practices that surround the use of biopreserved materials — not just in organ transplantation, but wherever systems for managing biological materials have been established that depend on constrained and well-defined timescales. If care is not taken, new biopreservation capabilities will disrupt existing processes, infrastructure, and economics in ways that will raise novel and challenging barriers to progress. Such barriers — for instance, where advanced biopreservation substantially extends viability and thus the availability of vital organs in ways that threaten the smooth operation of existing systems — represent threats to progress that lie outside many conventional approaches to risk assessment and management.

Navigating this complex "risk landscape" requires an early understanding of emerging risks and opportunities by researchers, developers, companies, policy makers, and others. Given the complex coupling between societal and technological systems, this will need to encompass an understanding of the social, political, and economic context within which advanced biopreservation technologies are developed and deployed. It will also require applying theories and practices guiding advanced technology transitions[12] to help ensure that advanced biopreservation technologies lead to long-term societal good. These include concepts that draw from responsible innovation[13] and participatory technology assessment[14] as well as anticipatory governance,[15] agile governance,[16] and soft-law approaches to the governance of emerging technologies.[17] Undergirding all these areas is a need for practical insights into how key stakeholders — including organizations developing advanced biopreservation techniques — understand and navigate an increasingly complex emerging risk landscape.

III. A Risk Innovation Approach to Supporting Positive Societal Impact

In this exploratory study we considered the application of Risk Innovation[18] — an approach to guiding risk-informed actions developed by the Risk Innovation Lab at Arizona State University. This approach was formalized through the Arizona State University-based "Risk Innovation Nexus" in 2019.[19] It is an approach that has previously been applied in the context of single companies — primarily startups. This is the first study to test the approach in the context of a community of multiple and diverse entities collaborating in the development and application of a new and emerging technology. The goal of applying the Risk Innovation approach in this study was to see if it could help ATP-Bio stakeholders —public and private organizations, as well as individuals — to identify perceived risks and navigate the emerging risk landscape around advanced biopreservation technologies.

The Risk Innovation approach conceptualizes risk as a multifaceted threat to value and is designed to provide key stakeholders with a subjective, but informative, understanding of a threats-based landscape that potentially stands to inhibit progress toward goals[20] — in this case, the successful development and application of advanced biopreservation technologies. By helping enterprises understand areas of agreement and disagreement with key stakeholders on the creation and protection of value, the Risk Innovation approach should allow the enterprise to reduce or avoid risks associated with value misalignment or clashes. Building on this, the approach was initially constructed as a way of helping individuals and organizations to better understand how to navigate risks they may otherwise neglect in achieving their goals. It was also developed for use by small groups with a common focus and vision and has previously been applied within single organizations.

Risk Innovation as a tool was conceived from the outset as complementary to more-established risk analysis and decision-making tools available to organizations such as Enterprise Risk Management; Strengths Weaknesses Opportunities and Threats analysis (SWOT), and standards-based approaches such as ISO 31000[21] (Risk Management). While these and other tools provide important frameworks for addressing more conventional risks, the Risk Innovation approach was designed to foster a risk-based mindset that was attuned to less conventional risks.

In this study, we explored whether the approach could allow organizations within a community of stakeholders to identify and navigate potential risks. Applying the Risk Innovation approach within such a community would make it potentially valuable to initiatives such as the ATP-Bio ERC. The Risk Innovation approach respects the expertise of stakeholders involved in development and application of a technol-

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ogy, by giving them a structured way to identify the areas of value they are seeking to promote and risks that are easy to overlook. This kind of systematic, upstream reflection early in the development and use of emerging technology can increase the likelihood of successful development and positive societal impact.

By working with stakeholders developing advanced biopreservation technologies in the domains of human health, food supply systems, and biodiversity, our study explored the utility of Risk Innovation approaches to aid the successful development and beneficial use of advanced biopreservation technologies.

IV. Applying Risk Innovation to Advanced Biopreservation Technologies

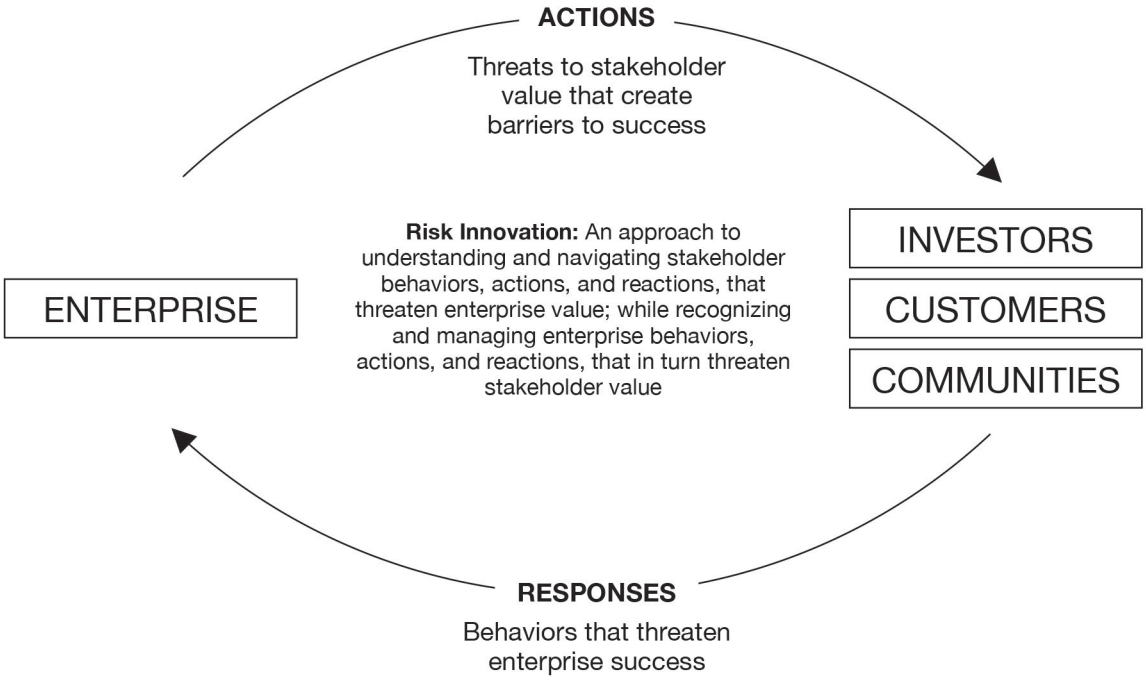
The theory and practice of Risk Innovation frame risk as a threat to value, and thus help individuals and organizations make pragmatic decisions on how to navigate risks that are hard to quantify but that nevertheless present substantial barriers to success.[22] In this framing, "value" can take on any dimension that is relevant to an individual or organization. For instance, in a conventional risk assessment, "value" may refer to human health or well-being, environmental well-being, or fiscal security. Yet in reality, "value" may also extend to less conventional and less-easily quantified dimensions, including human flourishing, an equitable society, mental well-being, social and individual identity, autonomy, and dignity. These and similar dimensions are rarely quantifiable and are often ignored in formal risk assessments, and yet are frequently pivotal to the success of new endeavors.[23]

In this respect, advanced biopreservation technologies are no exception. Researchers and companies developing these technologies have specific ambitions that depend on the success of the technologies they are developing. These may include turning a profit. But for many, their ambitions extend to advancing human flourishing, whether this means saving lives, improving quality of life, increasing access to transplant services, ensuring resilience through biodiversity, or accomplishing other goals. These are all areas of value that, if threatened, could prevent emerging biopreservation technologies and the organizations that develop and deploy them from succeeding.

The Risk Innovation approach also recognizes that organizations developing advanced technologies do not operate in a vacuum but are part of a network of influential stakeholders. Because of this, actions that an organization takes that potentially threaten what is of value to key stakeholders also represent potential risks. For instance, if the actions of a company deploying advanced biopreservation techniques are perceived as unethical, this "threat to stakeholder value"

Figure 1

A schematic representation of the Risk Innovation approach to identifying and navigating risk as a threat to value within a multi-stakeholder environment.



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becomes a threat to the success of that organization and potentially others deploying the technology. Likewise, if an emerging biopreservation technology undermines established supply chains (and, by extension, organizations with a financial interest in maintaining them), this may pose a risk to organizations developing the new technology.

Because of this interplay between threats to value and stakeholders, the Risk Innovation approach considers both threats to areas of value that are important to an organization — referred to as the "enterprise" — and threats to areas of value that are important to key stakeholders. Both may lead to risks that need to be navigated, as illustrated in **Figure 1.**

Many areas of value addressed in the Risk Innovation approach are not quantifiable. This is precisely the type of challenge that the Risk Innovation approach was designed to address. Building on the framing of risk as a threat to value, the Risk Innovation approach identifies 18 "orphan risks" across three domains (social and ethical factors, unintended consequences of emerging technologies, and organizations and systems) that potentially threaten the preservation of existing value or the growth of new value (**Table 1**).[24] The term "orphan risks" refers to the tendency of organizations and individuals to ignore such risks, despite their importance in informing strategic decisions. The 18 orphan risks were developed by drawing on the types of challenges that emerging technologies startups and founders in particular struggle to address. The list is not exhaustive, and there are many risks — for instance, the "risk" of hype and overblown claims of benefits, or the "risk" that may be posed by political or ideological agendas and narratives — that are captured implicitly in the list but not explicitly named.

One of the most basic tools in the Risk Innovation portfolio is the Risk Innovation Planner.[25] This was initially developed to guide new thinking with users who have limited time to devote to this process, and yet need to increase their awareness of orphan risks and identify approaches to navigating them. The Planner consists of a 2-page online worksheet that can be completed within 1 – 2 hours, and takes users through a process of (1) identifying key areas of value to their enterprise, investors, customers, and the communities associated with them and their products; (2) mapping areas of value onto orphan risks; (3) exploring how threats to enterprise and stakeholder areas of value potentially lead to hurdles to progress; and (4) identifying next steps in navigating the resulting risk landscape. The process is intended to catalyze thinking, rather than providing definitive solutions.

The Risk Innovation Planner is foundational to a more extended approach that is designed for groups exploring emerging risk landscapes. This is the approach used in this study. The extended approach we employed takes a small group of stakeholders through a workshop process of identifying key areas of value relevant to a specific enterprise or sector, mapping these to orphan risks to produce a risk innovation landscape, and exploring strategies for navigating these risks.

Given the potential of advanced biopreservation technologies and the uncertainty associated with their successful development and use, we were interested in the use of the Risk Innovation approach to generate a subjective, but informative and actionable, assessment of barriers to progress that might otherwise be overlooked.

V. Methodology

In this study we used established Risk Innovation approaches but extended them to working with diverse stakeholder groups within three specific domains of advanced biopreservation technologies. As this was a novel extension of an approach that was originally designed as a guide to decision-making within an organization, the study was meant to explore the utility of the approach as much as it was designed to develop insights into the successful and socially beneficial applications of advanced biopreservation technologies.

To develop a clearer understanding of the risk landscape around emerging advanced biopreservation technologies using a Risk Innovation approach, we developed and convened three 90-minute workshops. We invited ATP-Bio Partners (described below) to each workshop. We specifically invited Partners in three areas of application: food systems, human health, and biodiversity. Each workshop was devoted to one of those areas, with Partners involved in the area being invited to the relevant workshop. The protocols followed were approved by the Institutional Review Boards (IRBs) of Arizona State University and the University of Minnesota, the home institutions of those researchers directly involved in the workshops (A.M., M.S., T.T., S.W.). In each workshop the two leaders (A.M. and M.S.) took participants through a 2-step protocol based on the Risk Innovation Planner. This was designed to draw on participant insights to identify key areas of value for enterprises, investors, customers, and communities associated with advanced biopreservation technologies in each of the workshop focus areas.

Invitees and participants in each workshop were drawn from the member Partners of ATP-Bio. NSF

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defines Partners as (1) industrial Partners — companies that help build an industrial constituency within the center; and (2) practitioner Partners — organizations that support research and will use the outcomes in the delivery of services. The member Partners within ATP-Bio include large, small, and start-up businesses; non-profit organizations; government agencies; and museums. At the time of the study, ATP-Bio had a total of 36 Partners. Eighteen organizations were invited to send a representative to the workshops, based on their alignment with the focus areas. Sixteen organizations par-

Table 1

Orphan risks as used in the Risk Innovation methodology.

SOCIAL & ETHICAL FACTORS			
Ethics	Risks from business practices overstepping the often-indistinct line between ethical and unethical behavior.	Social Justice & Equity	Risks from business practices and technologies that marginalize or disadvantage specific segments within society.
Perception	Risks created from how people perceive a technology to impact/threaten what they think is important.	Social Trends	Risks from shifts in social norms, changing consumer expectations, or evolving cultural behaviors.
Privacy	Risks from the social pitfalls associated with the use and misuse of individual's data.	Worldview	Risks from people's deeply-held beliefs about how they view the world and how it should function.
UNINTENDED CONSEQUENCES OF EMERGING TECHNOLOGIES			
Black Swan Events	Risks from very low probability but high impact events.	Intergenerational Impacts	Risks from technologies that have potential impacts from one generation to another.
Co-Opted Tech	Risks from technologies and products that are used in ways that undermine the intention of the original business or business owner.	Loss of Agency	Risks from products or business practices that reduce the ability of organizations and individuals to make decisions.
Health & Environment	Risks from new technologies, and the products they are associated with, behaving in sufficiently novel ways that potentially lead to threats to human health and the environment.	Product Lifecycle	Risks from unintended impacts of where and how a product's materials are sourced and manufactured, how it is used, and its disposal and/or reuse.
ORGANIZATIONS & SYSTEMS			
Bad Actors	Risks from enterprises that behave in ways that are ethically questionable or that lead to unacceptable harm.	Organizational Values & Culture	Risks from tensions between business practices, both internal and external, and the set of values that reflect what is important to a business' founders and members.
Geopolitics	Risks from a lack of awareness of or strategies for navigating a shifting geopolitical landscape.	Reputation & Trust	Risks from a business having only a rudimentary understanding of how their behavior and actions strengthen or weaken reputation and trust.
Governance & Regulation	Risks from often evolving laws, policies, and practices that govern and guide business operations.	Standards	Risks from a business' lack of engagement with an often evolving operational framework for businesses that spans legal requirements, informal guidelines, and norms and codes.

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ticipated. The number of participants and the sectors represented in each workshop are shown in **Table 2**.

All the organizations, except for one, sent a single individual to participate in a session. One organization sent two individuals representing different functional areas of the organization, giving a total of 17 individual participants from a total of 16 Partners. Overall, this represents an 89% participation rate from the invited ATP-Bio member Partner organizations (16/18). Each workshop had between 4 and 8 participants. All participants consented to participation and use of their de-identified data.

Each workshop was conducted using the same protocol. Prior to each workshop participants were encouraged to access various Risk Innovation resources on the Risk Innovation website,[26] including a description of the Risk Innovation approach and orphan risks. These included downloadable Risk Definition cards and a Risk Innovation Landscape template. In each workshop, participants were initially given a brief introduction to the Risk Innovation approach and process. This included a description of risk as a threat to value, the concept of orphan risks, how to construct a visual risk landscape that matches perceived areas of value to perceived orphan risks, plus a short case study from the field of artificial intelligence (AI) demonstrating the application of the approach.

Each participant was then given 15 minutes to complete an initial online worksheet where they identified key stakeholders in the following categories, along with key perceived areas of value of relevance to them: (1) enterprises associated with advanced biopreservation technologies (participants were asked to consider their own enterprise, or enterprises that they considered important to the domain); (2) investors in the enterprises they had previously identified; (3) enterprise customers; and (4) communities potentially impacted by the identified enterprises. Participants were provided with 73 pre-identified types of value as they filled in the worksheet (see **Appendix 1**). They were encouraged to either use these or write down other areas of value as they saw fit.

Participants were subsequently provided with a more complete description of orphan risks. They were then given 15 minutes to complete a second online worksheet that asked them to visually align areas of value identified for each stakeholder category with the orphan risks as described in **Table 1**.

After each workshop, the collected data for each workshop were de-identified, cleaned up, and aggregated with respect to areas of value and orphan risk. As participants used a variety of methods and shorthand notes to complete the worksheets, cleanup included transferring responses from each worksheet to a separate document where they were reformatted and, where necessary, articulated in complete and coherent sentences.

To create an aggregated risk landscape for each workshop, identified areas of value for each stakeholder category were manually clustered into groups by identifying common themes and foci. These in turn were summarized using language that captured the essence of each cluster. Following the Risk Innovation approach typically used with organizations, we used participant feedback to identify areas of value and orphan risks that particularly stood out. This is an intentionally subjective process that is designed to avoid "paralysis by analysis" when working with organizations by forcing them to focus on a small but relevant number of areas of value and associated orphan risks.

Table 2

Number of participants in each workshop, and sectors represented by participants.

Workshop focus	Number of participants	Sectors represented
Food systems	4	• Non-profits • Start-ups
Human health	8	• Non-profits • Start-ups • Large companies
Biodiversity	5	• Non-profits • Museums • Companies

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Using this approach, we identified 3–5 areas of value for enterprises, investors, customers, and communities, around the development and use of advanced biopreservation technologies in food systems, human health, and biodiversity. We also identified a subset of orphan risks associated within each stakeholder category that particularly stood out: For each category, orphan risks were clustered according to the number of times they were identified within a workshop, and the stand-out orphan risks noted. To reduce the chances of analyst bias, the identified areas of value and orphan risks were checked by three researchers who were present in each workshop.

The processed data were then used to construct visual summaries of identified areas of value and orphan risks for each advanced biopreservation technology domain (**Tables 4–7**). These tables reflect the manner in which areas of stakeholder value and orphan risks are typically presented when using the Risk Innovation approach. The relative frequency with which each orphan risk was identified as relevant in each workshop was further noted. These frequencies are shown in **Figure 2**.

Tables 4–6 and **Figure 2** reveal participants' perceptions of areas of value and associated orphan risks. As the workshop participants were stakeholders familiar with advanced biopreservation in organizations that were established ATP-Bio Partners, the data offer an initial indication of types of value and risk within the three domains of food systems, human health, and biodiversity. They also indicate areas of potential convergence and divergence across these domains.

Table 3

Areas of value identified by workshop participants for each stakeholder group (enterprise, investors, customers, and communities), and domain of advanced biopreservation technologies (food systems, human health, and biodiversity).

	Identified areas of value		
Stakeholder	**Food Systems**	**Human Health**	**Biodiversity**
Enterprise	• Recognized for technological leadership • Profitable product • Sustainable solutions that improve lives and wellbeing • Delivering reliable products and solutions	• Performance and quality of products • Improved lives • Reputation and trustworthiness • Successful business strategies • Innovation	• Impactful innovation • Products that deliver on promise • Improved lives and wellbeing • Return on investment • Flourishing ecosystems
Investors	• Maintaining a reputation for being ethical and responsible • Creating social value • A high financial return on investment • Enabling innovation	• Trustworthiness and social responsibility • Ability to deliver • Return on investment • Safe and effective products	• Innovation that benefits human health • High return on investment • Socially & environmentally beneficial innovation • Promoting social equity • Maintaining bio- and genetic diversity
Customers	• Low cost • Quality products that deliver on their promise • Predictable and reliable performance • Ease of use • Safety and environmental impact	• Accessibility and inclusivity • Safety and quality • Improved health • Innovation • Trustworthiness	• Improved health and wellbeing • Investment in the customer community • Trustworthiness • Cost effective products • Socially equitable products and services
Communities	• Improved lives and wellbeing • Cost and convenience • Trustworthiness of products • Safety of products	• Prolonged life and wellbeing • Equitable access • Innovation	• Health and safety of communities • Social inclusivity and equity • Preservation of community heritage • Shared values • Trustworthiness

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VI. Results

Table 3 summarizes areas of value for each workshop as our participants considered four stakeholder groups (enterprise, investors, customers, communities), while **Tables 4–6** show a subset of orphan risks identified using the approach described above (identified by the icons listed in **Table 1**) associated with each stakeholder group for each of the workshops. Note that orphan risks shown in **Tables 4–6** are sorted by stakeholder group, as we aggregated across all listed areas of value for each particular stakeholder group.

These summary tables show our workshop participants' perceptions, and do not purport to fully

Figure 2

Relative frequency with which each orphan risk was identified as a risk in each of the three workshops: A) Food Systems, B) Human Health, C) Biodiversity.

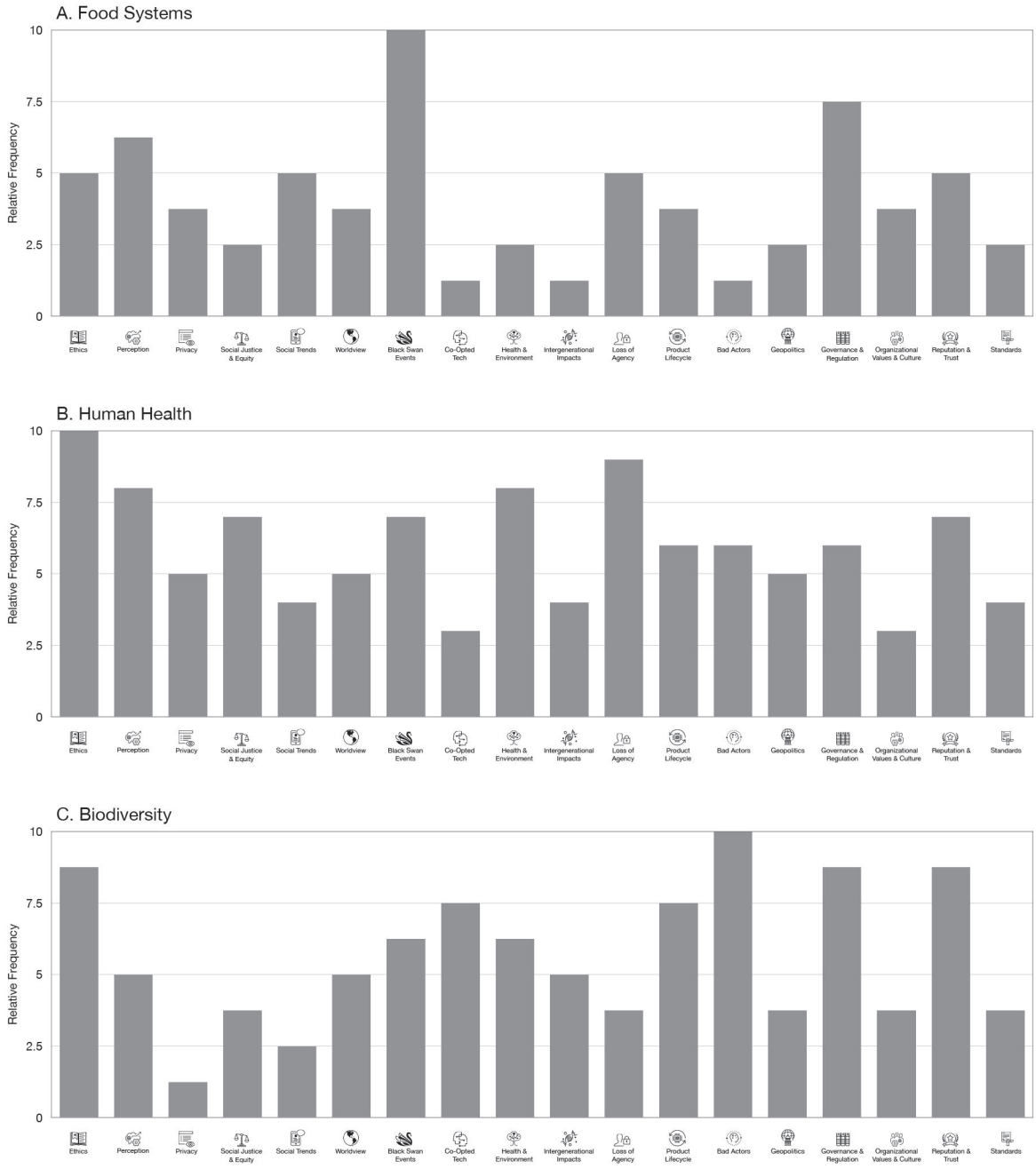

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Table 4

Areas of value versus orphan risks identified for advanced biopreservation technologies in the domain of food systems.

Areas of Value	Orphan Risks					
ENTERPRISE • Recognized for technological leadership • Profitable product • Sustainable solutions that improve lives and wellbeing • Delivering reliable products and solutions			Black Swan Events		Governance & Regulation	Organizational Values & Culture
INVESTORS • Maintaining a reputation for being ethical and responsible • Creating social value • A high financial return on investment • Enabling innovation	Ethics		Black Swan Events		Governance & Regulation	
CUSTOMERS • Low cost • Quality products that deliver on their promise • Predictable and reliable performance • Ease of use • Safety and environmental impact			Black Swan Events	Loss of Agency	Standards	
COMMUNITIES • Improved lives and wellbeing • Cost and convenience • Trustworthiness of products • Safety of products	Social Trends	Perception	Health & Environment		Reputation & Trust	

Table 5

Areas of value versus orphan risks identified for advanced biopreservation technologies in the domain of human health.

Areas of Value	Orphan Risks					
ENTERPRISE • Recognized for technological leadership • Profitable product • Sustainable solutions that improve lives and wellbeing • Delivering reliable products and solutions			Black Swan Events		Governance & Regulation	Organizational Values & Culture
INVESTORS • Maintaining a reputation for being ethical and responsible • Creating social value • A high financial return on investment • Enabling innovation	Ethics		Black Swan Events		Governance & Regulation	
CUSTOMERS • Low cost • Quality products that deliver on their promise • Predictable and reliable performance • Ease of use • Safety and environmental impact			Black Swan Events	Loss of Agency	Standards	
COMMUNITIES • Improved lives and wellbeing • Cost and convenience • Trustworthiness of products • Safety of products	Social Trends	Perception	Health & Environment		Reputation & Trust	

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depict the risk landscape associated with developing advanced biopreservation technologies in each of the domains addressed. In addition, the information in **Tables 4–6** is limited by the number of workshop participants, the areas of expertise they represented, the domains and sectors with which they are most closely associated, and their understanding of what was expected of them in the workshop. Nevertheless, these tables provide an accessible and actionable perspective on what key stakeholders associated with advanced biotechnologies may wish to consider as they navigate a complex landscape to achieve societally beneficial outcomes. The tables illuminate perceived areas of value to protect and areas of risk that may otherwise remain obscure.

While **Tables 4–6** show a subset of identified orphan risks (remembering that the Risk Innovation methodology used intentionally focuses on a small number of risks that particularly stood out), **Figure 2** summarizes the relative number of times all orphan risks were identified in each workshop. Orphan risks identified by participants in each workshop were summed across all participants and all stakeholder categories. To allow comparison between the three workshops, which had different numbers of participants, the relative prevalence of identified risks in each workshop was scaled to lie between 1–10, with 10 representing the highest prevalence and 1 the lowest (no risks had zero prevalence). **Figure 2** provides a qualitative comparison of the relative importance that participants placed on different risks, together with the highest-ranking risks associated with each workshop.

While qualitative, the data in **Figure 2** nevertheless provide insights discussed below into possible differences in the perceived orphan risks across the three domains of food systems, human health, and biodiversity, as well as areas where there is a common recognition of possible risks.

VII. Analysis

A. Areas of Value

Table 3 provides an indication of what is perceived as being of value to enterprises developing or otherwise engaged in advanced biopreservation technologies, and the areas of value that key stakeholders of an enterprise may consider important. These match the areas of value listed in **Tables 4–6**, but by showing them together in **Table 3** it is possible to identify similarities and differences between the three workshops. In looking for commonalities across **Tables 4–6** our

Table 6

Areas of value versus orphan risks identified for advanced biopreservation technologies in the domain of biodiversity.

Areas of Value	Orphan Risks				
ENTERPRISE • Impactful innovation • Products that deliver on promise • Improved lives and wellbeing • Return on investment • Flourishing ecosystems	Ethics	Co-Opted Tech		Reputation & Trust Bad Actors	Organizational Values & Culture Governance & Regulation
INVESTORS • Innovation that benefits human health • High return on investment • Socially & environmentally beneficial innovation • Promoting social equity • Maintaining bio- and genetic diversity	Worldview	Product Lifecycle	Black Swan Events	Bad Actors	
CUSTOMERS • Improved health and wellbeing • Investment in the consumer community • Trustworthiness • Cost effective products • Socially equitable products and services	Perception			Reputation & Trust Standards	Geopolitics
COMMUNITIES • Health and safety of communities • Social inclusivity and equity • Preservation of community heritage • Shared values • Trustworthiness	Ethics	Health & Environment		Reputation & Trust Bad Actors	Governance & Regulation

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analysis interprets the areas of value identified, rather than simply looking for replicating language used in each table.

Starting with the enterprise, **Table 3** shows a cross-workshop emphasis on innovation, products that are economically successful, and improved lives and well-being (including flourishing ecosystems in the Biodiversity workshop). These are areas of value that participants considered important to enterprises involved in developing and utilizing advanced biopreservation technologies. They represent value that is tied up with the success of an enterprise, where threats to these areas of value constitute a threat to success.

In the Human Health workshop, reputation and trustworthiness were also flagged as an area of value for the enterprise. This is not surprising given how important trust and reputation are in ensuring success associated with products and services that directly impact human health. It does, however, highlight the need to understand what is of value to key stakeholders so that actions and behaviors do not inadvertently undermine trust and reputation.

Moving to investors, customers, and communities, the areas of value associated with these stakeholder groups represent areas that, if threatened by an enterprise, could in turn lead to barriers to success for the enterprise (**Figure 1**). Here it is important to note that, while the Risk Innovation approach is useful in mapping a broad landscape of stakeholder value, its primary purpose is to help enterprises (or associated individuals/groups) understand the risk landscape that arises at the intersection between enterprise and stakeholder value.

Here again there are similarities and differences across the workshops. Not surprisingly, return on investment is identified as a key area of value for investors across all workshops. However, there is also a recognition that creating social value and innovation that is socially and environmentally beneficial will be important to some investors, and that threats to these areas of value are likely to create barriers for enterprises.

Moving to customers, the performance, safety, and cost-effectiveness of products are indicated to be important across all three domains. However, societal and environmental value is also highlighted across the three domains — including trustworthiness (Human Health and Biodiversity) and accessibility and inclusivity (Human Health). Again, the workshops highlighted what may be intuitive but is often overlooked or unstated when developing new products — especially those that depend on new and potentially disruptive technologies: consumers care about what product and service providers stand for, not just what they produce.

This is seen even more clearly looking at areas of value associated with communities. Here, what constitutes a community likely varied among participants, so a diversity of areas of value was expected. That said, there is a convergence around areas of societal value, including (once again) trustworthiness (Food Systems and Biodiversity), improved or prolonged lives and well-being, and equity (Human Health and Biodiversity).

Table 3 provides a snapshot of potential areas of enterprise and stakeholder value associated with advanced biopreservation technologies that is unique to the time, place, and participants in the workshops. It nevertheless illuminates areas of value that need to be addressed early in the research and development process in order to realize the positive potential of these technologies. It also illustrates the usefulness of the Risk Innovation approach in revealing areas of possible importance that may otherwise be overlooked in the push to develop technologically advanced solutions without considering the broader societal and environmental landscape into which they are being introduced.

B. Areas of Value vs. Orphan Risks

Tables 4–6 show orphan risks identified for each stakeholder group in the three workshops. The format of the tables mirrors that used in the Risk Innovation approach, and provides a visual representation of the "risk landscape."

In each table, the orphan risks associated with the enterprise represent risks that directly threaten the areas of value associated with the enterprise. In **Table 4** (Food Systems) it can be seen that "black swan" events, governance and regulation, and organizational values and culture, were considered as some of the more prominent threats to maintaining and growing value for the enterprise.

In contrast, the orphan risks associated with investors, customers, and communities represent potential threats to value associated with these specific stakeholders, and not directly with the enterprise. Thus, in the Food Systems workshop (**Table 4**), ethics, "black swan" events, and governance and regulation were identified as potential threats to value for investors, while threats to value for customers were "black swan" events, loss of agency, and standards. Orphan risks for communities included social trends, perception, health and environmental impacts, and reputation and trust.

Where an enterprise engages in behaviors and actions that threaten areas of stakeholder value

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through these risks, there is an elevated chance that it will encounter barriers to success. Of course, not every orphan risk identified with a stakeholder will be relevant to the enterprise. But the maps shown in **Tables 4–6** indicate potential orphan risks that developers and users of advanced biopreservation technologies may want to be aware of. We should note that the single orphan risk that cut across all stakeholder groups in a given workshop was ethics. **Table 5** shows that participants in the Human Health workshop saw ethics as an orphan risk germane to areas of value for all four stakeholder groups — the enterprise, investors, customers, and communities.

This mapping of risks to areas of value is at the heart of the Risk Innovation process. When working with individual organizations, the map will be unique to the person or organization carrying out the exercise and will act as a guide to areas that they may need to pay closer attention to. In this study, the mapping aggregates across multiple persons and organizations in a particular domain of application for ATP-Bio technologies. Our process demonstrates how bringing together a community of stakeholders can begin to identify areas requiring attention that may otherwise remain obscured.

C. Relative Importance of Orphan Risks Across Domains of Advanced Biopreservation Technologies

Figure 2 plots the relative frequency with which each orphan risk was identified by participants in each of the three workshops. Data have been normalized between the workshops (given the different numbers of participants in each workshop) to enable direct comparison between them.

Care needs to be taken in interpreting these data, as risks are aggregated across the stakeholder groups for each workshop. However, the distributions provide insights into the risks that participants considered to be most relevant in each of the three domains of food systems, human health, and biodiversity.

Looking for commonalities across the workshops, the 5 orphan risks that have a relative frequency of **at least 5** in each of the workshops (the midway frequency) are ethics, perception, "black swan" events, governance and regulation, and reputation and trust. With the exception of "black swan" events (which participants may have considered a catch-all category for risks they could not foresee) these are all risks that are associated with societal behavior or policy. This cluster of orphan risks underlines the importance of engaging with stakeholders to understand and navigate a complex societal and policy landscape between potentially transformative ideas and positive social impact.

Contrasting participant perspectives across the 3 workshops, 3 risks have a frequency **greater than 5** in the Food Systems workshop (perception, "black swan" events, and governance and regulation). This compares to 10 in the Human Health workshop (ethics, perception, social justice and equity, "black swan" events, health and environment, loss of agency, product lifecycle, bad actors, governance and regulation, and reputation and trust); and 8 in the Biodiversity workshop (ethics, "black swan" events, co-opted tech, health and environment, product lifecycle, bad actors, governance and regulation, and reputation and trust). There is less variation in frequency across orphan risks in the Human Health and Biodiversity workshops when compared to the Food Systems workshop (where there is subjectively greater variation in the frequency with which different risks are identified), indicating a wider range of orphan risks being considered relevant by participants. Here it is worth noting that, because **Figure 2** represents all identified risks across all stakeholder groups, there are differences in the number of times a particular risk appears in **Tables 4–6** (which show only a subset of risks as described above), and in **Figure 2**.

Comparing the data in **Figure 2** from the Human Health and Biodiversity workshops, ethics is identified in both cases as being important to the success of advanced biopreservation technologies, as is reputation and trust, and governance and regulation, while the behavior of "bad actors" (organizations that give the technology a bad name) is a clear threat. Health and environmental impacts also rank high. In contrast, the risk of co-opted technologies (those that are used for purposes for which they are not intended) ranks higher in the Biodiversity workshop than in the Human Health workshop, while privacy is flagged as being more important in human health applications.

These comparisons in risks identified across the 3 workshops reveal 2 threats to value with scores above 5 across all three domains of application for advanced biopreservation technologies — "black swan" events, and governance and regulation. This suggests the importance of (1) building "safety net" strategies to deal with unexpected threats in developing new technologies such as advanced biopreservation, and (2) engaging early with problems of governance and with potential regulators.

Comparing identified risks across the three workshops also reveals those risks seen as more relevant to specific application areas. For instance, privacy is a lower concern for biodiversity than human health and food systems, as are social trends, while co-opted tech is indicated to be a higher concern for biodiver-

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sity. Similarly, concerns around loss of agency are indicated to be more important in the domain of human health than the other two domains. These differences indicate that the perceived risk contours within different application domains of advanced biopreservation technology are not convergent, and that advanced biopreservation should not be approached as a monolith when considering potential barriers to success.

In the process of running the workshops and analyzing the data, lessons emerged that will help strengthen the future use of the Risk Innovation approach in this context. A key takeaway was that allowing more than 90 minutes per workshop would provide time for participants to better understand the Risk Innovation process and to give more consideration to their responses to questions. It would also allow more open-ended discussion among participants concerning possible

Our data and analysis suggest that a Risk Innovation approach can have considerable utility in helping bridge innovation and application in areas where advanced technologies face a complex array of orphan risks. While further research is needed to fully explore the utility of this method, both with advanced biopreservation technologies and for a wider range of emerging technologies, we conclude that Risk Innovation approaches should be considered an important set of tools to help support the development and application of new technologies to secure social benefit — particularly within the context of the National Science Foundation's Gen-4 ERCs.

VIII. Discussion

This study had three aims: (1) to assess the utility of the Risk Innovation approach to supporting the development of beneficial and successful biopreservation technologies — in particular within the context of the ATP-Bio ERC; (2) to develop an understanding of the perceived risk landscape in three key domains of application spanning food systems, human health, and biodiversity; and (3) to assess more broadly the usefulness of the approach to researchers and developers investigating emerging technologies and their successful and beneficial use within society. In section VII we showed that, while subjective, the Risk Innovation approach can provide novel insights into the nature of the risk landscape around advanced biopreservation technologies. These insights are subject to the limitations of the methodology used — including running workshops with a small number of participants from diverse organizations. Nevertheless, our workshops successfully illuminated perceived areas of value being pursued and risks to those areas of value in the development and application of advanced biopreservation. The workshops provided new insights into potential barriers to securing the societal benefits of advanced biopreservation technologies. The workshops also indicated how the Risk Innovation approach can help bridge research to practice in other areas of emerging technology focused on benefiting society.

areas of value and risk. There is also scope for further adapting the Risk Innovation approach to situations — such as the one explored here — where participants reflect multiple enterprises and stakeholders. Based on our experiences, better understanding the perspectives of participants would further enhance the utility of the data collected.

With these caveats, the study indicated that using Risk Innovation was highly effective in providing insights that will help support stakeholders in developing and applying biopreservation technologies. The areas of value and associated orphan risks presented in **Tables 3–6** and **Figure 2** provide a unique perspective on the potential challenges these stakeholders face. Mapping this "risk landscape" also provides insights into how early decisions and actions can protect value and address conflicts of value between different stakeholders. Even though the study was exploratory, we were able to develop a clearer understanding of how research and development within the ATP-Bio ERC may be more effectively translated into initiatives, products, processes, and services that are regarded as economically sustainable and socially beneficial.

The study also suggests that there is utility in extending the Risk Innovation approach beyond ATP-Bio to other initiatives that are focused on developing emerging technologies and securing positive societal impact — including other Gen-4 ERCs. The Risk

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Innovation approach allows stakeholders to see that which may otherwise remain hidden from them. Participation in the process encouraged participants to think more broadly and strategically about risks and benefits.

Although this was an exploratory study, the results indicate that there are potential barriers to developing societally beneficial biopreservation technologies, but that these barriers can be identified using a Risk Innovation approach. Our results also indicate that Risk Innovation workshops offer a helpful opportunity for researchers and developers to better understand the challenges they face and how to overcome them. Risk Innovation methods may be extendable to other programs that are focused on developing new technological capabilities designed to improve lives and the environment.

One important caveat here is that, while this study indicated that a Risk Approach can be useful in identifying and navigating orphan risks, it was not designed to provide proof of positive impact. Follow-on research to better understand the extent to which adopting a Risk Innovation approach leads to positive outcomes would be valuable. However, our work to date suggests that implementing a Risk Innovation approach has utility and is unlikely to have adverse impacts.

IX. Conclusion

In this exploratory study we set out to assess the utility of the Risk Innovation approach in supporting the development of beneficial and successful advanced biopreservation technologies. We also aimed to develop an understanding of the perceived risk landscape in three key areas of application that span food systems, human health, and biodiversity. Finally, we sought to more broadly assess the usefulness of a Risk Innovation approach in other domains of emerging technology.

Our data and analysis suggest that a Risk Innovation approach can have considerable utility in helping bridge innovation and application in areas where advanced technologies face a complex array of orphan risks. While further research is needed to fully explore the utility of this method, both with advanced biopreservation technologies and for a wider range of emerging technologies, we conclude that Risk Innovation approaches should be considered an important set of tools to help support the development and application of new technologies to secure social benefit — particularly within the context of the National Science Foundation's Gen-4 ERCs.

Disclosures

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Appendix 1: Pre-Identified Areas of Value

In each workshop, participants were presented with 73 areas of value that may be relevant to the stakeholders they identified (**Table A1**). These are areas that are used when taking organizations and individuals through the Risk Innovation process, and are designed to provide some guidance as to the types and areas of value that may be relevant. Participants were given the option of drawing on these, being inspired by them, or identifying different areas of value.

Table A1

Areas of value used in each workshop to help guide participants.

• Ability to deliver	• Happiness	• Professional partnerships
• Acceptable health risk	• High dollar valuation	• Profitable product
• Access to future iterations or improvements of the product	• High performance products	• Quality
• Accuracy	• High ROI	• Real-time access to information
• Accurate healthcare testing	• Highly accessible	• Recognized for industry leadership
• Addressing global poverty	• Impressive board	• Recognized for technological leadership
• Attracting top talent	• Improved health	• Relatable products
• Autonomy	• Improved lives / wellbeing	• Reliable
• Available to the mainstream	• Inclusive	• Representative of the community
• Brand trustworthiness	• Increase users	• Reputation for doing the right thing
• Building up / investing in the community	• Innovation	• Respect
• Clarity	• Integrity	• Retaining top talent
• Common goal internally	• Leveraging expertise	• Revolutionary innovation
• Convenience	• Life-saving innovation	• Safety
• Creates new jobs	• Low cost to customers	• Security
• Culture of doing the right thing	• Low product cost	• Social equity
• Customers who use the product	• Minimal overhead	• Stability

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• Customers who value philanthropy	• Next generation healthcare solution	• Successful poverty interventions
• Customers with shared values	• Philanthropy	• Support
• Data that can be monetized	• Predictable performance	• Transformational medical interventions
• Effective poverty solutions	• Preservation of community land/ landmarks, traditions, health, safety, etc.	• Transparency
• Fair price	• Privacy for sensitive information	• Trust of customers
• Fair work practices	• Products that benefit a global community	• Trustworthy
• Giving back to the community	• Products that create an innovative way to…	
• Growth	• Products that deliver on their promise	

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