

April 12, 2023

Bob Sivinski
Chair, Interagency Technical Working Group on Race and Ethnicity Standards
1650 17th St. NW
Washington, DC 20500

Re: Docket No. OMB-2023-0001: Initial Proposals For Updating OMB's Race and Ethnicity Statistical Standards

Dear Sir/Madam:

The Biotechnology Innovation Organization (BIO) thanks the Office of Management and Budget (OMB) for the opportunity to submit comments regarding the **Initial Proposals For Updating OMB's Race and Ethnicity Statistical Standards**.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place.

BIO appreciates the opportunity to provide comments to the Office of Management and Budget (OMB) request for feedback on the Federal Interagency Technical Working Groups (WG) initial proposals on Race and Ethnicity Standards for revising OMB's 1997 Statistical Policy Directive No. 15 (SPD-15) titled *Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity*.¹ The goal of SPD-15 was to ensure the comparability of race and ethnicity across Federal datasets and to maximize the quality of the data by ensuring the format, language, and procedures for information collection were consistent and based on rigorous evidence.

BIO supports OMB's efforts to improve the efficiency and effectiveness of the statistical system to ensure the integrity, objectivity, impartiality, utility, and confidentiality of the information collected for statistical purposes. As outlined by the Federal Register Notice (FRN), there were several key concerns identified with the use of separate race and

¹ [62 FR 58723](https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf) (Oct. 20, 1997), available at <https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf>.

ethnicity questions which often confused respondents. The FRN further elaborates that the decennial census and American Community Survey (ACS) found the combination of race and ethnicity questions to reduce confusion, resulting in a decrease in incorrect reporting by respondents. For example, combined questions for race and ethnicity decreased respondents selecting *Some Other Race (SOR)* as their identifying category, allowing for more accurate data collection. Further the categories developed represented a sociopolitical design to allow for self-reported or observed collection of information on the race and ethnicity of major groups of population in the U.S. delinked to biologic or genetic traits.

BIO acknowledges and appreciates OMB's continued efforts, specifically OMB convening the WG for the purpose of developing recommendations on topics including but not limited to:

- Whether the minimum reporting categories should be changed and how to best address detailed race and ethnicity groups in the standards;
- Whether updates should be made to the question format, terminology, and wording of the questions, as well as the instructions for respondents and associated guidance; and
- Whether guidance for the collection and reporting of race and ethnicity data can be improved, including in instances when self-identification is not possible.

BIO is also supportive of the WG's approach and outreach initiatives to further develop the recommendations for identifying the needs and uses of the collected data. BIO provides overarching recommendations for improving OMB's Race and Ethnicity Statistical Standards that could support efforts to enhance diversification in clinical trial studies during the drug development and post-market safety surveillance activities. BIO provides General Comments in addition to Specific Comments for those sections that are relevant and of priority for BIO and its member companies.

GENERAL COMMENTS

Applicability to Medical Product Development

In the research and development phase of a new drug product, it is critical to understand the prevalence of the disease in different patient populations. In order to make a comprehensive and accurate assessment of the safety and efficacy of the drug product, it is essential to enroll different patient populations. BIO member companies rely heavily on OMB's race and ethnicity statistical standards to design the epidemiological study protocols and conduct global clinical trials to bring safe and effective new life-saving and life-sustaining drug products to market to increase access to patients who need them. BIO

believes the updates to OMB's race and ethnicity statistical standards can help facilitate a better drug development paradigm that aligns with the evolving demographic landscape.

Recently, the Food and Drug Administration (FDA) published draft guidance entitled, "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials" to improve representation in clinical trials given that certain populations are "frequently underrepresented in biomedical research despite having a disproportionate disease burden for certain diseases relative to their proportional representation in the general population." Additionally, the 2022 Omnibus, provides a number of provisions to further support improving representation in clinical trials. Hence, the OMB Race and Ethnicity Statistical Standards are a core component to the biopharmaceutical industry in designing epidemiological studies and setting enrollment goals for clinical trials to develop new drugs for all patients.

BIO recommends that OMB continue to engage with regulators, sponsors, patients, physicians/practitioners, community groups, among other stakeholders in the drug development ecosystem to update and improve upon the race and ethnicity statistical standards.

Clarity on Public Law

For the section titled Collecting and Reporting Data for Multiracial/Ethnic Population, Bullet Number 12 states, "***All racial and ethnic categories should adhere to public law. All racial and ethnic categories, both established and potential, should be reviewed and constructed in a manner that adheres to public law.***" BIO believes the use of "public law" in this context is vague and ambiguous. Public law could be interpreted as any local, state, or federal law. BIO recommends that "public law" be replaced with "**relevant federal law**" to clarify and better define the scope to represent the standards at the federal level.

"Middle Eastern or North African" (MENA) Considerations

BIO agrees with the rationale to add "Middle Eastern and/or North African" (MENA) as a new minimum main category. Since MENA is not a federally recognized minority community, researchers interested in studying these illnesses cannot apply for and receive grants from the Federal Office of Minority Health. This is highlighted on the following website: Race and Ethnicity Flexibilities (whitehouse.gov). Further consideration should be given to addressing this concern so that the patients represented in this patient population are not excluded in participating nor denied access to available resources.

Combining Race and Ethnicity

The proposal to combine race and ethnicity is understandable, as they are sometimes used interchangeably and given the global complexities of clinical research, can result in confusion. The final proposal for collecting race and ethnicity data should allow for

capturing the multiple categories, recognizing respondents may identify as multiracial (choose multiple) as well as bi-ethnic. The ability to select multiple categories should be enabled as a default setting accompanied by well-implemented instructional text such as “Mark All That Apply” or “Select All That Apply”. Lastly, it may also be helpful to include an “unknown” category if the individual does not know the answer.

The allowance of subcategories of all racial groups could be informative in certain analytic frameworks. These changes would allow for more nuanced and granular assessments from an epidemiological perspective, and they would align with current Clinical Data Interchange Standards Consortium (CDISC) Clinical Data Acquisition Standards Harmonization (CDASH)/CT guidance. Hence, OMB should consider having definitions of each racial and/or ethnic category inclusive of all continents of origin (i.e., Australia is a continent that is missing with a history of aboriginal descendants).

BIO recommends that OMB continue to engage with stakeholders to ensure the updates are relevant, current, and meaningful for stakeholders involved in providing and collecting this data.

SPECIFIC COMMENTS

1. COLLECT RACE AND ETHNICITY INFORMATION USING ONE COMBINED QUESTION

1a. Please provide links or references to relevant studies that examine or test any impacts of collecting race and ethnicity information using separate questions compared to a combined question.

BIO Response: BIO recommends the following links to relevant studies that examine the impact of collecting race and ethnicity information in different formats.

- [Updated Guidance on the Reporting of Race and Ethnicity in Medical and Science Journals](#)
- [Race and ethnicity reporting for clinical trials in clinicaltrials.gov and publications](#)

1b. To what extent would a combined race and ethnicity question that allows for the selection of one or more categories impact people's ability to self-report all aspects of their identity?

BIO Response: Self-reported data is important in capturing how individuals self-identify. However, the current approach may limit self-reporting due to pigeonholing (i.e., forcing people to associate with limited categories they do not

identify with). Hence, the combination of race and ethnicity with an option to select multiple categories could address this concern. Additionally, providing a clear explanation of why the information is important and how it will be used should be considered to increase the respondent's trust in providing more accurate information.

1c. If a combined race and ethnicity question is implemented, what suggestions do you have for addressing challenges for data collection, processing, analysis, and reporting of data?

BIO Response: If a combined "Race and Ethnicity" questions is adopted, it will be critical to clearly define the terminology used to ensure complete understanding by the respondent to elicit an accurate and meaningful response. It will also be important to conduct an impact assessment across the drug development enterprise to accept, adopt and implement this change. This will require both internal and external collaboration.

1d. What other challenges should we be aware of that respondents or agencies might face in converting their surveys and forms to a one question format from the current two-question format?

BIO Response: The primary concern opposed to combining race and ethnicity is the dilution of the collected information, as noted in the FRN. Further, the current mapping to the CDISC Study Data Tabulation Model (SDTM) and Controlled Terminology would be impacted by the combined collection.

2. ADD "MIDDLE EASTERN OR NORTH AFRICAN" (MENA) AS A NEW MINIMUM CATEGORY

2a. Given the particular context of answering questionnaires in the U.S. (e.g., decennial census, Federal surveys, public benefit forms), is the term "Middle Eastern or North African (MENA)" likely to continue to be understood and accepted by those in this community? Further, would the term be consistently understood and acceptable among those with different experiences, *i.e.*, those born in the U.S., those who immigrated but have lived for an extensive period of time in the U.S., and those who have more recently immigrated to the U.S.?

BIO Response: BIO recommends including individuals of Middle Eastern descent and North African descent as bundled subgroups that rollup into the MENA category. In addition, the terms must be consistently understood and accepted among those with different experiences. BIO believes the challenge with the

addition of the American category in some (African American) but not others (Asian American) as the standard label for minimum categories creates an inconsistency in the definition of the race and ethnicity categories.

Another key challenge with respect to global clinical trials is that sponsors need the ability to combine more granular categories into more general categories to achieve proper enrollment goals. A sponsor may be able to achieve the enrollment goals for a geographical group but not in all cases.

2b. Do these proposed nationality and ethnic group examples adequately represent the MENA category? If not, what characteristics or group examples would make the definition more representative?

BIO Response: BIO recommends OMB consider referencing the United Nations Children’s Fund (UNICEF) and other organizations that align with OMB’s categorical definition of MENA.

3. REQUIRE THE COLLECTION OF DETAILED RACE AND ETHNICITY CATEGORIES BY DEFAULT

3a. Is the example design seen in *Figure 2* inclusive such that all individuals are represented?

BIO Response: In the U.S., most individuals are captured by the minimum categories as proposed in Figure 2 (with the caveat that search-as-you-type ontologies are the best way to represent the more detailed categories). However, BIO recommends OMB consider the points below in updating the labeling changes to be more inclusive:

1. Latino -> Latine or Latino or Latinx
 - While latine is a gender-neutral term that may be acceptable to some, it may not be accepted by all in the relevant community.
 - Latinx is a gender-neutral term (inclusive of trans individuals) that has been the default term in common use that includes Latino/Latina.
2. Black or African American -> Black or African
 - The term African American remains a relevant option in the U.S. However, there are additionally more inclusive terms commonly used today, including the term Black, which includes African American with long-term American ancestral lineages, as well as

African Americans with more recent American ancestry or nationality.

- Recognizing that the current OMB definition for Black or African American includes “Negro”, outside of the US, this term may be accepted by relevant communities. Hence, this should be explained in the definition. Also, the use of the term in the US is antiquated. It was announced in 2013 that this word would be dropped from the US census and multiple surveys. The US army also made a similar decision in 2014 to its equal opportunity policy. Additionally, in 2016 a modernization of terms relating to minorities act was signed to congress to remove this term from multiple existing laws.
- Another consideration could be to have Black as the default term and use additional modifiers such as African, Caribbean, or Latin for use in appropriate local contexts only as Black subgroups. Use of the terms Black or African may be problematic since Black persons may not identify their heritage as African.

3. American Indian or Alaska Native -> Indigenous

- The use of the term indigenous is suggested only when discussing race in the global contexts, where Aboriginals and other First Peoples also fall under this umbrella.
- Indigenous, if used, should include additional clarification of location of origin.

4. Native Hawaiian or Pacific Islander -> Pacific Islander

- The use of the term Pacific Islander is suggested only when discussion of race in the global context, as Native Hawaiian are by default Pacific Islanders (thereby making this less U.S.-centric).

To consolidate and harmonize information across the globe, it is important to standardize these categories. BIO suggests that every global continent be mentioned in the definitions of new race categories. We also recommend emphasizing the importance of avoiding the uninformative and pejorative term ‘Other’. When data is collected and the numbers are low such that they must be grouped into a “catch-all” category, we suggest consideration of the following categories to be used: “Other races”, “Other ethnicities”, or “Not Listed”. Lastly, BIO recommends continued engagement of stakeholders such as patients,

sponsors, regulators, and others through workshops and/or other forums to ensure that the categories are inclusive and represent all individuals.

3b. The example design seen in *Figure 2* collects additional detail primarily by country of origin. What other potential types of detail would create useful data or help respondents to identify themselves?

BIO Response: It could be helpful to state "Southeast Asian" in addition to "Asian." BIO recommends the following revision to Figure 2: "**ASIAN OR SOUTHEAST ASIAN** – *Provide details below.*"

Collecting information by country of origin may not always align with how individuals view their racial and ethnic background. For example, as a category, country of origin applied to countries with large black populations could mask groups such as Afro-Cuban or Black-Dominican. Race and ethnicity data are proxies for estimating the social conditions and systemic influences experienced by the members of the group. Country of origin will provide insight into political determinants of health, (i.e., availability of vaccines, and medicines, health care delivery system, etc.) as well as some sense of environmental conditions/exposures. Providing a free text option under detailed race may not be suitable for analysis and reporting purposes. BIO recommends including language to this effect in the updates made.

BIO recommends that OMB consider engaging with relevant stakeholders to further discuss collecting this information using 'descent' in establishing racial and ethnic categories over collecting information based on country of origin. While collecting information by *descent* is one approach to establish racial and ethnic categories, it may not be how an individual self-reports or identifies. For drug development, it will be important to balance the need for hereditary/genotype related demography questions compared to the socio-influence of race/ethnicity on disease burden, which can be different across conditions, e.g., HIV compared to Crohn's disease.

Also, as race and ethnicity data are sensitive personal identifiable information (PII), BIO recommends updating the example to be inclusive but to avoid capturing data which is not used for analysis and reporting. This makes it clear that the data collected has an evident scientific and ethical rationale for its collection.

3c. Some Federal information collections are able to use open-ended write-in fields to collect detailed racial and ethnic responses, while some collections must use a residual closed-ended category (e.g., "Another Asian Group"). What are the impacts of using a

closed-ended category without collecting further detail through open-ended written responses?

BIO Response: There are several best practices under SPD-15 that should be considered. In the 2020 Census, a combination of checkboxes and additional write-in response field options allowed respondents to provide detailed information for each of the race and ethnicity categories. While the 2020 Census collected very detailed race and ethnicity data, its coding operation was burdensome. Therefore, the Coding library should be in place for as many cases as possible beforehand to frontload operational efficiencies.

While closed ended questions may result in our ability to collect better data, we still need an “Other Race”, “Other Ethnicity” category. BIO recommends narrowing the number of people who may feel compelled to use the “Other Race”, “Other Ethnicity” category option through our library. Analytic techniques like artificial intelligence (AI) with cluster free-text specifications of the “Other Race” and “Other Ethnicity” category can be leveraged to appropriately sort or recategorize to enhance the library for future entries.

3d. What should agencies consider when weighing the benefits and burdens of collecting or providing more granular data than the minimum categories?

BIO Response: As clinical trials become increasingly more global in nature, BIO recommends the various agencies consider how the granular information will roll up to fit into larger categories.

3e. Is it appropriate for agencies to collect detailed data even though those data may not be published or may require combining multiple years of data due to small sample sizes?

BIO Response: If this data is not collected, we will not know where small sample sizes exist. It may be more harmful not to consider it at all rather than acknowledge that progress will be incremental until meaningful extrapolations can be achieved. BIO recommends providing a clear explanation of the potential use of the data over time to better inform drug development.

3f. What guidance should be included in SPD 15 or elsewhere to help agencies identify different collection and tabulation options for more disaggregated data than the minimum categories? Should the standards establish a preferred approach to collecting additional detail within the minimum categories, or encourage agencies to collect additional information while granting flexibility as to the kind of information and level of detail?

BIO Response: BIO believes it will be important to be flexible given the different needs of various agencies. One model that could be considered is to establish an ontology or comprehensive coding library for race and ethnicity that would allow for the detail and flexibility that agencies will need.

3h. What techniques are recommended for collecting or providing detailed race and ethnicity data for categories with smaller population sizes within the U.S.?

BIO Response: It may be useful to develop an ontology and have an “Other Race” and “Other Ethnicity” option. One could then leverage analytical approaches like AI to analyze the “Other Race” and “Other Ethnicity” option and any open-ended responses.

4. UPDATE TERMINOLOGY IN SPD 15

4a. What term (such as “transnational”) should be used to describe people who identify with groups that cross national borders (e.g., “Bantu,” “Hmong,” or “Roma”)?

BIO Response: While “transnational” has been used to refer to these groups, the concern with the term is that it can also refer to groups that have crossed and linked across nations. For example, certain Arab groups in Dearborn, Michigan are referred to as transnational communities since they still maintain strong links with their home nations, and not necessarily because their groups cross national borders. Transnational also has implications of going from point A to point B, rather than the convergence of many different nations in a single group’s identity.

For this reason and to better align with other terminology proposed throughout, BIO recommends using “multinational” to reflect the multitudinous composition of nationalities that are absorbed in these singular groups.

4a, 1. If a combined race and ethnicity question is implemented, what term should be used for respondents who select more than one category? For example, is the preferred term “multiracial,” “multiethnic,” or something else?

4a, 2. Please refer to *Section D, Previously Tested Definitions of Minimum Categories*. Are these draft definitions:

- i. Comprehensive in coverage of all racial and ethnic identities within the U.S.?**
- ii. Using equivalent criteria?**

iii. Reflective of meaningful distinctions?

iv. Easy to understand?

v. Respectful of how people refer to themselves?

Please suggest any alternative language that you feel would improve the definitions.

BIO Response: The terms multiracial and multiethnic would likely be the standard to follow. Both terms have separate meanings which are built upon the stem words “race” and “ethnicity”.

The virgule (/) is understood to mean “and/or,” therefore it should be utilized to reflect multiethnic/racial. It is important to note that this is different than saying “race/ethnicity” which implies we are asking about one and/or the other, when we are truly asking about both. In these cases, we are saying that someone can be multiethnic and/or multiracial, so it would be acceptable.

4b. As seen in *Figure 2*, based on the Working Group's initial proposal, the question stem asks, “What is your race or ethnicity?” Do you prefer a different question stem such as: “What is your race and/or ethnicity?”, “What is your race/ethnicity?”, “How do you identify?”, etc.? If so, please explain.

BIO Response: The current phrasing of the question “How do you identify” can be interpreted to mean a vast spectrum of things (i.e., age, sex, race, ethnicity, etc.). By asking “What is your race or ethnicity?” it creates a false dichotomy in a question where there is not one. The question should be asking for both race and ethnicity if we are combining them in one question. Therefore, BIO recommends the following questions for consideration:

- How do you identify (both) racially and ethnically?
- What is (both) your race and ethnicity?

Both questions allow the respondent to consider the concept of race **and** ethnicity instead of race **or** ethnicity.

5. GUIDANCE IS NECESSARY TO IMPLEMENT SPD 15 REVISIONS ON FEDERAL INFORMATION COLLECTIONS

5c. What guidance on bridging should be provided for agencies to implement potential revisions to SPD 15?

BIO Response: Bridging impacts aggregation of the data. BIO recommends OMB consider approaches to adequately bridge between past datasets and the new subsequent ones to follow (for tracking and analytics). Standard algorithms for converting past data into the new format should be issued by OMB so the data over time can be analyzed within an agency and across agencies in a consistent manner. Additional considerations will need to be reviewed for the CDISC compliance validation checks to either allow for “Multi-Race” as a Race value with the requirement for more than one subsequent Race collected, or the introduction of more than one Race variable (RACE1, RACE2...etc.) in the Demography dataset.

5d. How should race and ethnicity be collected when some method other than respondent self-identification is necessary (e.g., by proxy or observation)?

BIO Response: While different from "proxy or observation", the data collected by caregivers or parents for pediatric or patient focused drug development (PFDD) studies is important. BIO recommends OMB engage with stakeholders such as regulators, sponsors, patient groups, and others to discuss best approaches in collecting the data recognizing the potential limitations of proxy and observation. It is also important to note that clinical trial site and staff training for this new data collection is imperative.

6. COMMENTS ON ANY ADDITIONAL TOPICS AND FUTURE RESEARCH

6a. SPD 15 does not dictate the order in which the minimum categories should be displayed on Federal information collections. Agencies generally order alphabetically or by population size; however, both approaches have received criticism. What order, alphabetical or by population size, do you prefer and why? Or what alternative approach would you recommend?

BIO Response: Alphabetical is always preferred since it is static and independent. Just because there are more people of a certain category does not mean that category should take precedence. BIO recommends alphabetical order.

6b. The current minimum categories are termed:

- **American Indian or Alaska Native**
- **Asian**
- **Black or African American**

- **Hispanic or Latino**
- **Native Hawaiian or Other Pacific Islander**
- **White**

Do you have suggestions for different terms for any of these categories?

BIO Response: BIO recommends OMB consider the points below in updating the labeling changes to be more inclusive:

1. Latino -> Latine or Latino or Latinx
 - While latine is a gender-neutral term that may be acceptable to some, it may not be accepted by all in the relevant community.
 - Latinx is a gender-neutral term (inclusive of trans individuals) that has been the default term in common use that includes Latino/Latina.
2. Black or African American -> Black or African
 - The term African American remains a relevant option in the U.S. However, there are additionally more inclusive terms commonly used today, including the term Black, which includes African American with long-term American ancestral lineages, as well as African Americans with more recent American ancestry or nationality.
 - Recognizing that the current OMB definition for Black or African American includes “Negro”, outside of the US, this term may be accepted by relevant communities. Hence, this should be explained in the definition. Also, the use of the term in the US is fairly antiquated. It was announced in 2013 that this word would be dropped from the US census and multiple surveys. The US army also made a similar decision in 2014 to its equal opportunity policy. Additionally, in 2016 a modernization of terms relating to minorities act was signed to congress to remove this term from multiple existing laws.
 - Another consideration could be to have Black as the default term and use additional modifiers such as African, Caribbean, or Latin for use in appropriate local contexts only as Black subgroups. Use of the terms Black or African may be problematic since Black persons may not identify their heritage as African.

3. American Indian or Alaska Native -> Indigenous

- The use of the term indigenous is suggested only when discussing race in the global contexts, where Aboriginals and other First Peoples also fall under this umbrella.
- Indigenous, if used, should include additional clarification of location of origin.

4. Native Hawaiian or Pacific Islander -> Pacific Islander

- The use of the term Pacific Islander is suggested only when discussion of race in the global context, as Native Hawaiian are by default Pacific Islanders (thereby making this less U.S.-centric).

6c. How can Federal surveys or forms collect data related to descent from enslaved peoples originally from the African continent? For example, when collecting and coding responses, what term best describes this population group (e.g., is the preferred term “American Descendants of Slavery,” “American Freedmen,” or something else)? How should this group be defined?

BIO Response: Both terms, “American Descendants of Slavery” and “American Freedman” are insensitive terms and could be interpreted by other racial groups that endured servitude as excluding. BIO recommends OMB engage the appropriate communities and stakeholders to further discuss and determine best practices for collecting such information.

Should it be collected as a detailed group within the “Black or African American” minimum category, or through a separate question or other approach?

BIO Response: The ability to aggregate country of origin data is an important factor in drug development. Since the collection of data related to descent from enslaved peoples would be a new dimension not related to country of origin, BIO recommends this information to be collected separately.

6d. The proposals in this FRN represent the Working Group's initial suggestions for revisions to SPD 15 to improve the accuracy and usefulness of Federal race and ethnicity data. The Working Group and OMB welcome comments and suggestions on any other ways that SPD 15 could be revised to produce more accurate and useful race and ethnicity data.

BIO Response: Patients enroll in clinical trials with multiple interrelated backgrounds with unique needs. While BIO applauds OMB for the revision to race and ethnicity statistical standards, we encourage the Office to continue to consider how intersectionality may be captured to better reflect the complexity within race and ethnicity. For example, the health impacts of a given black participant may be further affected by access barriers, such as existing disability or by the sociocultural impacts of their transgender identity or LGBT sexual identity. In the context of clinical research, race and ethnicity is only one factor for ensuring drug products are sufficiently developed to meet the needs of the population as a whole. BIO urges that the categorical revisions expand upon the requirements around race and ethnicity to be inclusive of marginalized demographics such as sexual orientation, gender identity, socioeconomic status, disability status, geographic location, etc.

Sincerely,

/s/

Camelia Thompson, Ph.D.
Senior Director, Science & Regulatory Policy
Biotechnology Innovation Organization

/s/

Leslie Harden, Pharm.D.
Director, Science & Regulatory Policy
Biotechnology Innovation Organization