U.S. FOOD & DRUG ADMINISTRATION

OFFICE OF WOMEN'S HEALTH

Research Impact and Outcomes Framework

GUIDE TO DEVELOPING AN ORGANIZATIONAL IMPACT AND OUTCOMES MEASUREMENT TOOL FOR PROGRAM ASSESSMENT AND REPORTING

FDA

Office of Women's Health

Research Impact and Outcomes Framework

Guide to Developing an Organizational Impact and Outcomes Measurement Tool for Program Assessment and Reporting

April 2018

FDA Office of Women's Health Research Impact and Outcomes (RIO) Framework

Table of Contents

Executive Summary 1

Introduction 3

OWH Research and Development 4

Research Opportunities 5

Project Background 6

Summary of Impact Frameworks for Biomedical and Health Research 7

Getting Started: Developing an Impact and Outcomes Framework 8

Adaptability and Implementation of the Framework 9

Development and Adaptation of the OWH Research Impact and Outcomes Framework 10

OWH Metrics by Impact Area 14

OWH Impact Spectrum with Aligned Metrics 16

Implementation: OWH Application of the Framework 20

OWH RIO Framework Model. 22

Future Applications: Gap Analysis 26

Conclusion 27

References 29

Appendix A: Brief Review of Impact Frameworks for Biomedical and Health Research 30

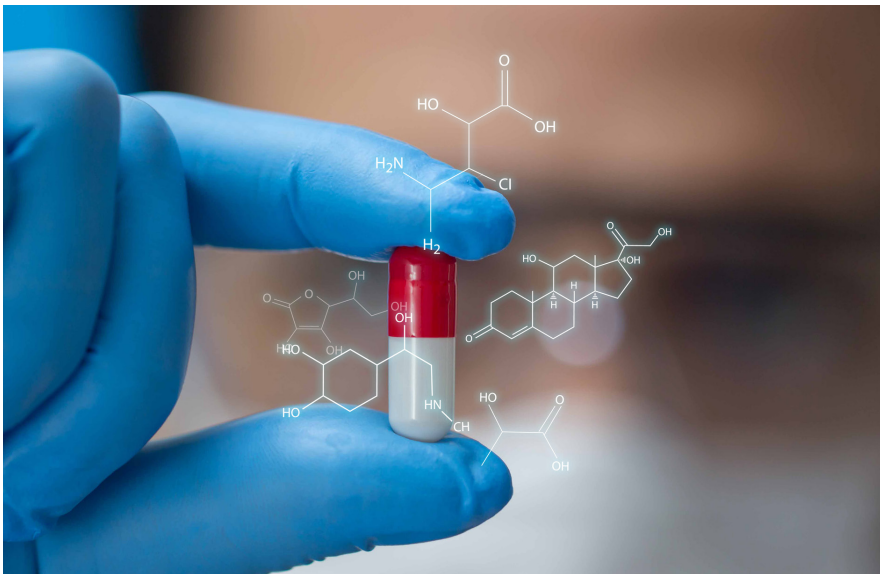
Appendix B: Glossary of Terms 31

Appendix C: OWH Framework in Outline Format 32

Acknowledgements 35

Executive Summary

The U.S. Food and Drug Administration (FDA) is a regulatory agency that works to protect the public's health through evidence-based regulatory science. Research is conducted at the FDA to assess the toxicity, safety, efficacy, quality, and performance of FDA-regulated products. This research advances science and technology, promotes innovation in and security of human and veterinary drugs, biological products, medical devices, the food supply, cosmetics, products that emit radiation, and tobacco products. Within the FDA, the Office of Women's Health (OWH) was established in 1994 to promote and advance the health of women through policy, science, and outreach, as well as to advocate for the inclusion and sex-gender analysis of women in clinical trials. The OWH established the Research and Development program to fulfill the office's mission through the following activities:



- Advancing the evaluation of sex-based differences in safety and efficacy of FDA regulated products
- Conducting research on health conditions and diseases that solely or disproportionately affect women
- Tracking the participation of women and special populations in clinical studies and improving demographic subset analyses
- Advancing scientific knowledge through advanced professional training and education in subpopulation analysis and women's health

Executive Summary (continued)

In the past 22 years (1994-2017), over $40 million in research funding has been provided, supporting 371 projects total.

The Research and Development program accomplishes its goals largely through its intramural research project, which addresses knowledge gaps in regulatory science pertaining to sex differences and health conditions unique to women. In the past 22 years (1994-2017), over $40 million in research funding has been awarded, supporting 371 total projects. Members of the Office of Women's Health working with the intramural research project identified the need to create a Framework for identifying the impact and outcomes of OWH-funded research as they pertain to the OWH mission. This resulted in the inception of the diverse intra-agency collaboration called the Research Impact and Outcomes Subcommittee (RIOSc). The members were invited from the OWH Research Steering Committee. The RIOSc recommended development of an Impact Framework, not solely for the Office of Women's Health, but one that could be flexible for other organizational use as well.

The RIOSc met approximately twice monthly for 1-2 hours over a nine-month period. After reviewing the Framework's development process, six essential steps were identified for guiding organizations in the creation of an Impact Framework that would effectively assess the processes, progress, and impact of their programs. This report represents a guide for creating an Impact Framework that aligns with an organization's mission and provides a detailed case study of the development of the Office of Women's Health Impact Framework and Application Model.

Introduction

The U.S. Food and Drug Administration (FDA) Office of Women's Health (OWH) was established in 1994 by Congressional mandate. The mission of the Office is to "promote and advance the health of women through policy, science, and outreach, and to advocate for the participation of women in clinical trials and for sex, gender, and subpopulation analyses." OWH does not have regulatory authority and is positioned within the Office of the Commissioner at FDA. Thus, OWH is uniquely situated to coordinate and fund cross-Agency research projects that span a broad range of product areas. Additionally, OWH advances its mission through strategic collaborations with several stakeholders (Figure 1).

FDA	Federal Government	External
• FDA Centers and Offices • Women's Health Research Steering Committee • OWH Center Liaisons • Research Programs across FDA • FDA Reviewers • FDA Researcher Staff	• Congress • HHS Office of Women's Health • HHS Coordinating Committee for Women's Health • NIH Office of Research on Women's Health • Other Federal Agencies	• Women • Healthcare Consumers • Women's Health Advocacy Groups • Disease Groups • Medical Associations • Universities and Research Institutions • Regulated Industry • Media • Health Professionals

Figure 1: OWH Stakeholders

OWH is composed of three program areas: 1) Research and Development (R&D); 2) Medical Initiatives and Scientific Engagement (MI&SE); and 3) Outreach and Communications. The R&D program administers and supports research grants to facilitate FDA regulatory decision-making by addressing knowledge gaps in regulatory science pertaining to sex differences and health conditions unique to women (see below). The MI&SE program promotes the Office's mission through medical and scientific education using diverse platforms, including distance-learning webinars, collaborations with professional organizations, presentations at national meetings, and internal (FDA) scientific lectures. In addition, MI&SE engages external professional organizations to disseminate the scholarly works of OWH and the expertise of FDA staff at national and international meetings. The Outreach and Communications program conducts national consumer awareness campaigns and develops health education materials to promote women's health. Recent initiatives of the Outreach and Communications program include the Use Medicines Wisely Campaign, the Pink Ribbon Sunday Mammography Awareness Initiative, the College Women's Campaign, and the Diverse Women in Clinical Trials Initiative in collaboration with the NIH Office of Research on Women's Health. These three OWH program areas collaborate across initiatives to synergize and enhance program impact.

The R&D program administers and supports research grants to facilitate FDA regulatory decision-making by addressing knowledge gaps in regulatory science pertaining to sex differences and health conditions unique to women.

OWH Research and Development

The OWH Research Impact and Outcomes (RIO) Framework was developed to strategically assess the impact of OWH-funded research. The R&D program funds intramural research projects to address knowledge gaps in regulatory science pertaining to sex differences and health conditions unique to women. Over the past 22 years (1994-2017), the Office has awarded over $36 million in intramural funding and over $4 million in extramural funding. (Since 2007, OWH has funded intramural research only.) Since 1994, 371 projects have been funded by the Office. The allocation of funded projects across the diseases and conditions in women's health is presented in Figure 2.

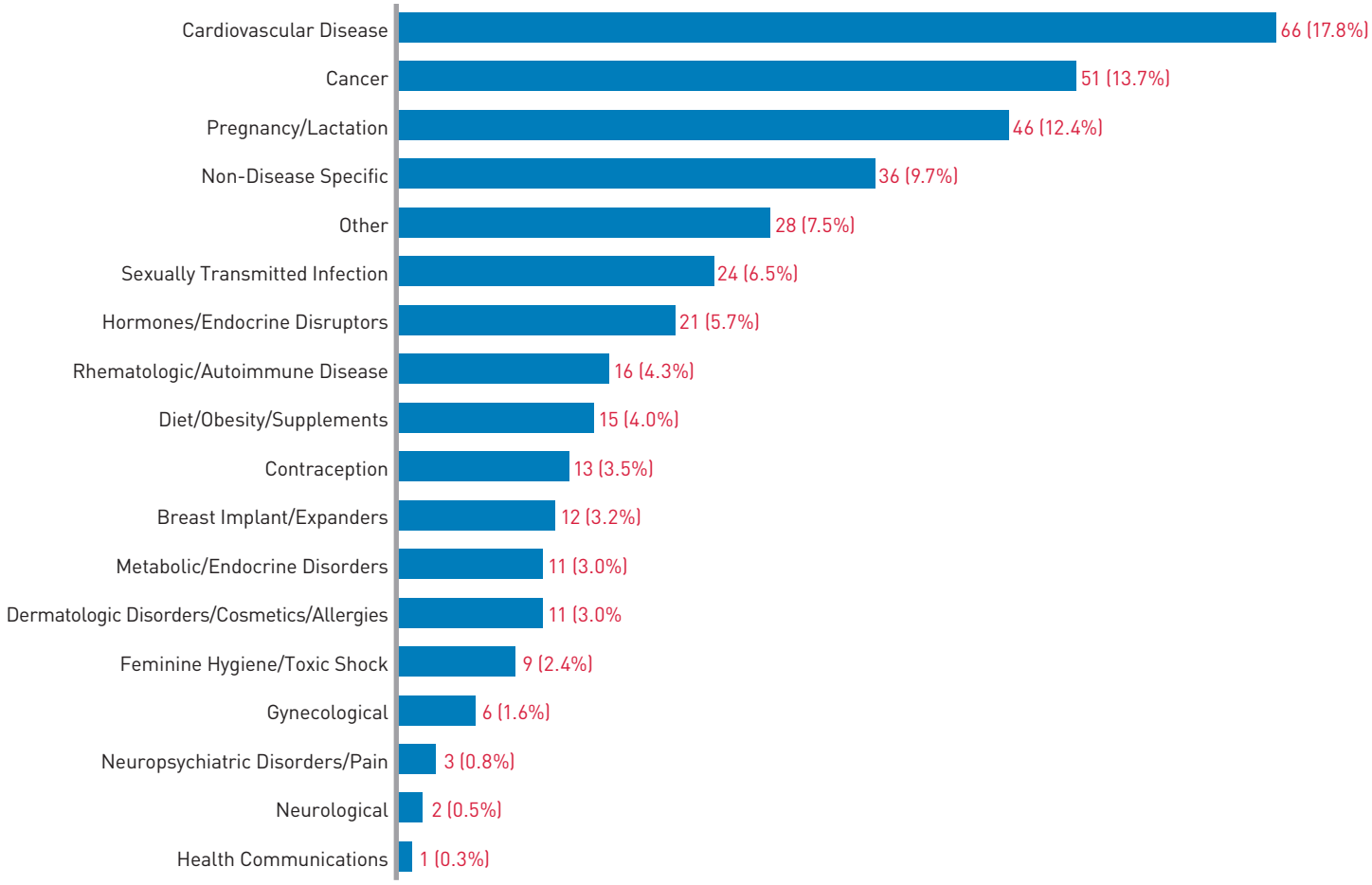


Figure 2. Number and Percentage of OWH-Funded Projects by Diseases and Conditions in Women's Health, 1994-2017 [Total Number of Projects: 371]

Research Opportunities

Opportunities to fund research relevant to sex and gender-specific women's health exist throughout the phases of product development (Figure 3). Proposals in the discovery phase have promising innovative potential. Research in the pre-clinical phase includes in vitro, in vivo, and in silico studies and simulation testing (e.g., to assess the potential for sex differences in pharmacokinetics). FDA does not conduct clinical trials to evaluate the safety and efficacy of products to support marketing applications. However, the Agency has regulations, policies, and procedures in place to ensure that clinical trial participants reflect the intended use population and that data are analyzed by pertinent subgroups. As a result, OWH has funded reviews exploring the participation of women in clinical trials in specific therapeutic areas to assess FDA's compliance with these regulations and policies. Research in the post-marketing phase can include epidemiological surveillance studies to detect a safety signal among women, as well as (systematic) review and meta-analysis of clinical trial results and the scientific literature to understand potential sex/gender differences.

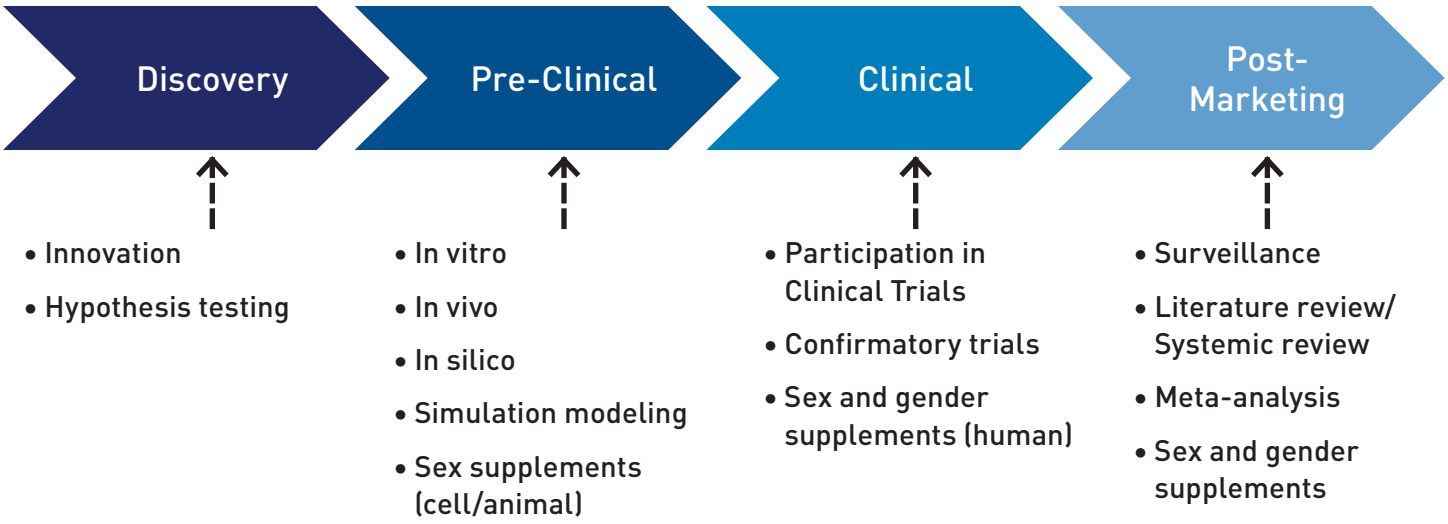


Figure 3. Opportunities for OWH-Funded Research Along the Product Development Life Cycle

Project Background

The purpose of the Impact Framework, as pertaining to the R&D division of FDA OWH, is to recognize the breadth of contributions a given research proposal is likely to make, or has made, toward advancing the OWH mission.

The Women's Health Research Roadmap (FDA Office of Women's Health 2015) established the need for a formal Women's Health Research Steering Committee, composed of scientists across the Agency. Members of the Office of Women's Health identified the need to create a Framework with which to identify the impact and outcomes of OWH-funded research. These members requested the Women's Health Research Steering Committee to participate voluntarily in this endeavor, forming the Research Impact and Outcomes Subcommittee (RIOSc). Several FDA Centers and Offices, as well as a diversity of research interests and scientific backgrounds, were represented on RIOSc (Figure 4).

The purpose of the Impact Framework, as it pertains to the R&D division of FDA OWH, is to recognize the breadth of contributions a given research proposal is likely to make, or has made, toward advancing the OWH mission. The desired application of the Framework is to strategically assess the impact and outcomes of OWH-funded research. Specifically, the Framework was designed for potential application in the contexts of proposal review, final report evaluation, portfolio impact, and gap analyses. The actual implementation and utilization of the Framework should be adapted to the unique context and needs of the users.

Office of the Commissioner

- National Center for Toxicological Research: Beverly Lyn-Cook, PhD, MS
- Office of Women's Health: Marjorie Jenkins, MD, MEdHP; Ruth Geller, MHS; Michelle Luo, MD, PhD

Office of Foods and Veterinary Medicine

- Center for Food Safety and Applied Nutrition: Beverly Wolpert, PhD, MS; Cary Parker, MPH
- Center for Veterinary Medicine: Cecilia Aguila, DVM

Office of Global Regulatory Operations and Policy

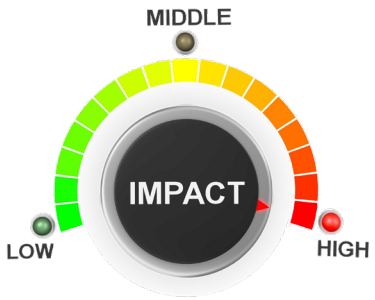
- Office of Regulatory Affairs: Marilyn Khanna, PhD

Office of Medical Products and Tobacco

- Center for Biologics Evaluation and Research: Carolyn Wilson, PhD
- Center for Devices and Radiological Health: Heather Benz, PhD
- Center for Drug Evaluation and Research: Ruth Barratt, PhD, DVM
- Center for Tobacco Products: Ami Bahde, MPH

Figure 4. Members of the Research Impact and Outcomes Subcommittee (RIOSc)

Summary of Impact Frameworks for Biomedical and Health Research



Recent years have seen increasing interest in evaluating the impact and outcomes of research. We reviewed the literature to find relevant examples of frameworks for assessing the impact of biomedical and population health research. Examples were selected from academic, government, and non-profit contexts. The Payback Framework by Buxton and Hanney (1996) is a landmark publication, and incorporates both a logic model and a multidimensional categorization of impact. The Canadian Academy of Health Sciences Making an Impact Framework builds on the Payback Framework and provides an array of proposed metrics. The Institute of Medicine Degrees of Impact Framework is a high-level overview focusing on the impact of research dissemination. The Centers for Disease Control and Prevention Science Impact Framework is an adaptation and extension of the Degrees of Impact Framework for the context of government public health activities (not strictly limited to research). Further description of these frameworks is provided in Appendix A.

Getting Started: Developing an Impact and Outcomes Framework

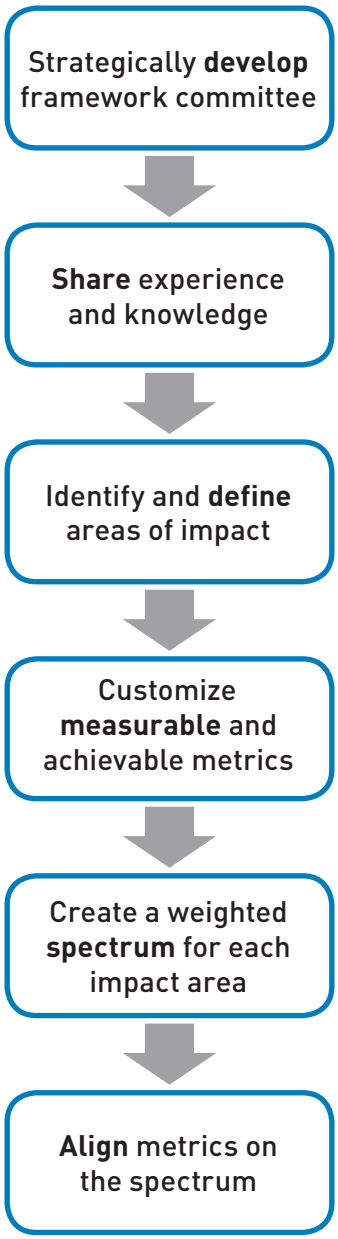


Figure 5. Six Steps for the Development of a Research Impact and Outcomes Framework

The research impact and outcomes framework development process starts with the strategic creation of a representative framework committee. A successful group facilitates productive discussions and encourages varying perspectives. The key to creating this successful committee is having a diverse representation from all stakeholders within your organization. This includes but is not limited to individuals with expertise within their own environment in evaluating research, those involved in research, and team members who have experience in creating research and program analysis models.

After selecting representative committee members, the next step is to meet and share knowledge and experience. This includes highlighting the mission statement, position, and roles and responsibilities of each organization. Understanding these factors establishes an important foundation and facilitates the process of identifying and defining framework impact areas. The committee members should decide on 2-4 impact areas that reflect on the mission statement and represent organizational needs. Impact is defined by the framework committee as that which creates an effect on, change or benefit to the economy, society, culture, public policy or services, health, the environment or quality of life, beyond academia. It is imperative that the framework committee comprehensively define each impact area before moving forward. Well-defined impact areas will make subsequent discussions about metric development more efficient.

After impact areas have been identified and defined, each committee member should critically review each area independently to develop metrics that will measure impact. The metrics must be achievable and measurable qualitatively and/or quantitatively. Metrics should be specific to the work of the organization and clearly support the impact area they measure. The subcommittee recognized that some metrics could be used prospectively and/or retrospectively when evaluating a project. The prospective metrics will be utilized to select proposals for funding with the highest potential impact. Retrospective metrics will be utilized to evaluate and report the impact of completed projects. Metrics should be designed to cover outcomes internal and external to the organization and should measure a range of impact. It is important to note that every metric may not apply to each project.

Finally, the committee should develop a spectrum of impact for each impact area in order of increasing impact. Each metric should align on a different section of the spectrum. Metrics placed on the far left of (or far down on) the spectrum, measure low or baseline impact, and metrics placed on the far right of (or far up on) the spectrum, measure higher impact. Placing the metrics along a continuum of impact, from low to high, enhances the applicability of the framework and facilitates a clean evaluation of research proposals and progress within the organization.

Adaptability and Implementation of the Framework

As discussed, the purpose of the Framework is to recognize the breadth of contributions a project is likely to make, or has made, toward advancing the organization's mission. The Framework facilitates the categorization of past, current, and future projects to determine an organization's project funding direction, otherwise known as an Impact Analysis. Reviewing past projects for historical impact and ongoing evaluations of current and potential opportunities can be utilized to guide mission-directed funding decisions. Potential applications in the research funding process include proposal review, progress report evaluation, and final report evaluation. Prospective utilization in the research funding process could entail using the framework to score the proposals. After funded research has been executed, the Framework can be applied to measure research impact and outcomes.

Many options exist for implementation. The Framework can be used to qualitatively describe the breadth of impact, beyond publications and citations. Alternatively, more quantitative approaches can be developed, such as developing a scoring system to grade projects as low, medium, or high impact. This analysis could remain an internal metric, or it could serve as the basis for portfolio impact and gap analyses (see Appendix B for discussion of impact analysis, gap analysis, and key performance indicators). The Framework could also be utilized to adjust the content requested in grant applications, progress reports, and final reports, for the purposes of measuring the metrics.

The design of the Framework allows for flexibility in its implementation. The scoring of projects and the weighting of metrics and impact areas are up to the discretion of the users and may differ by context. For example, in the context of proposal review, the users may choose to assign increased weight to metrics in the impact areas pertaining to scientific advancement (Significance & Alignment and Innovation). Alternatively, for a retrospective review of the policy influence of OWH-funded research, the user could limit the scope of analysis to the Advocacy impact area.

The metrics are intended to provide broad coverage corresponding to OWH priorities. As such, any given proposal is not expected to fulfill every metric. Indeed, there may be some proposals that do not meet any metrics within an Impact Area. This would not necessarily result in the rejection of such a proposal. However, if any metrics are deemed mandatory for a project to be funded, this decision could be incorporated into the scoring algorithm.

The Framework facilitates the categorization of past, current, and future projects to determine an organization's project funding direction, otherwise known as an Impact Analysis.

Development and Adaptation of the *OWH Research Impact and Outcomes Framework*

The RIOSc met on an approximately twice-monthly basis for 1-2 hour meetings between July 2016 and March 2017, for a total 23.5 hours of in-person meetings. Outside of group meetings, the OWH committee members contributed approximately 32 hours of foundational and preparatory work. Additionally, committee members contributed approximately 10 hours of work outside of meetings. The process began with a review of the literature, as well as previous work within FDA, on the topic of evaluating the impact and outcomes of funded research. RIOSc defined impact areas, metrics for evaluation, and a spectrum of impact within each impact area. Feedback was sought and incorporated from the OWH R&D program and the RIOSc (Figure 6).

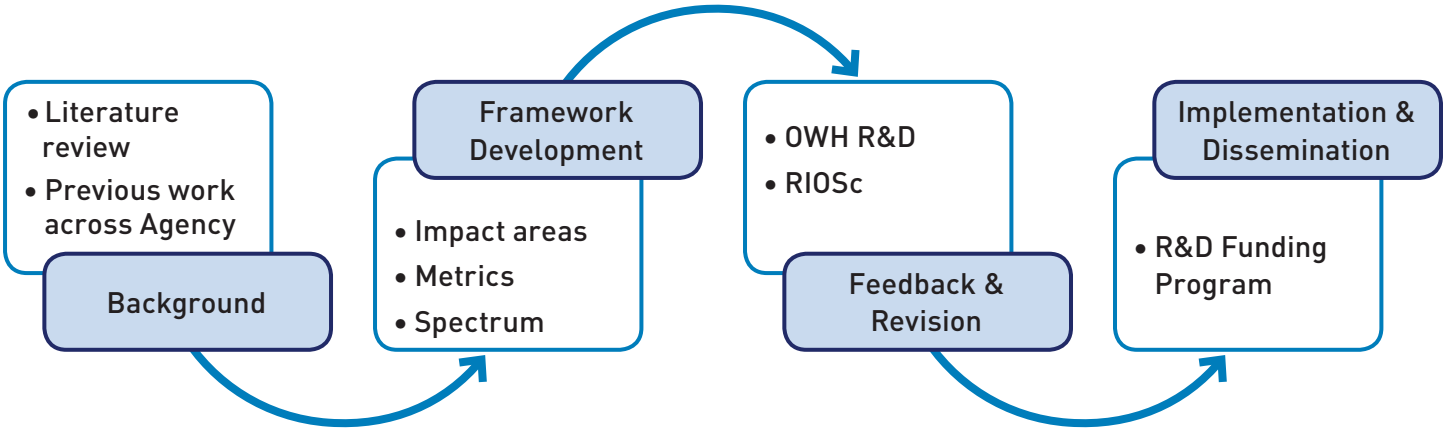


Figure 6. Development of the OWH Research Impact Framework

Development and Adaptation of the OWH Research Impact and Outcomes Framework (continued)

Impact areas driven by the OWH Mission Statement and corresponding definitions were developed through discussion. RIOSc first defined the desired impact areas, guided by the mission of the Office. Next, the subcommittee developed a list of indicators that could be used to measure impact in each desired area. Finally, a three-level spectrum was developed for each impact area, in order of increasing impact (Figure 7).

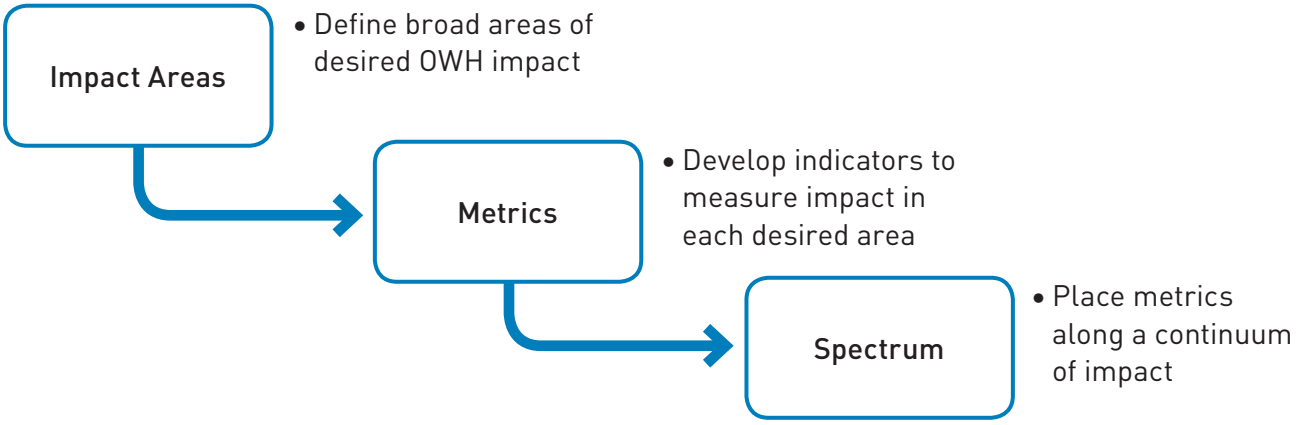


Figure 7. Development of Key Elements of the Research Impact Framework

Development and Adaptation of the OWH Research Impact and Outcomes Framework (continued)

The impact areas reflect the multifaceted nature of the OWH Mission: Engagement and Advocacy are oriented toward the dissemination and communication of scientific advances in women's health, whereas Significance & Alignment and Innovation speak to the substantive scientific impact of research outcomes.

The OWH Mission Statement is to protect and advance the health of women through science, education, and outreach, which includes advocating for the participation of women in clinical trials and sex and gender subpopulation analyses. The impact areas are Engagement, Advocacy, Significance & Alignment, and Innovation; definitions are provided in Figure 8. To summarize, Engagement recognizes meaningful two-way interaction and collaboration between the researchers and relevant stakeholders. Advocacy recognizes influence of research results in the policy realm. Significance & Alignment focus on the scientific/regulatory science impact. Innovation highlights novelty and inventiveness. The impact areas reflect the multifaceted nature of the OWH Mission: Engagement and Advocacy are oriented toward the dissemination and communication of scientific advances in women's health, whereas Significance & Alignment and Innovation speak to the substantive scientific impact of research outcomes.

Engagement

- **Harnessing appropriate expertise and capabilities, attracting key players to ensure the progress of the FDA OWH mission.**

Advocacy

- **Increasing awareness to influence decisions and actions by stakeholders in regard to sex and gender-specific women's health.**

Significance & Alignment

- **Ensuring funding decisions and research outcomes advance knowledge of sex and gender-specific women's health.**

Innovation

- **Producing a new and measurable shift in the landscape of sex and gender-specific women's health.**

Figure 8. Impact Areas and Definitions

Development and Adaptation of the OWH Research Impact and Outcomes Framework (continued)

Following the development of impact areas, RIOSc developed metrics for the measurement of impact and outcomes in each area. As with the impact areas, the metrics were tailored to the specific context of FDA OWH. Close to 60 metrics were initially brainstormed over the course of several discussions; later, the selection was narrowed down to around 6-12 metrics per impact area (Figure 10). Metrics could be applied to more than one impact area.

The group ensured that metrics within each impact area provided coverage of prospective and retrospective application. Some metrics may be more appropriately applied retrospectively than prospectively, and vice versa. The RIOSc created these categories of metrics to reflect the traditional life cycle of a research project. The prospective metrics are considered prior to the start of the research when project funding is being determined. These prospective metrics aid in selecting projects which best align with OWH research, mission, and identified priority funding areas. The retrospective metrics are applied at the completion of the research project and are utilized to assess and report the impact of the project and may be used to evaluate gaps in the research portfolio (Figure 9). Measurable retrospective and prospective metric examples can be found in Table 1.

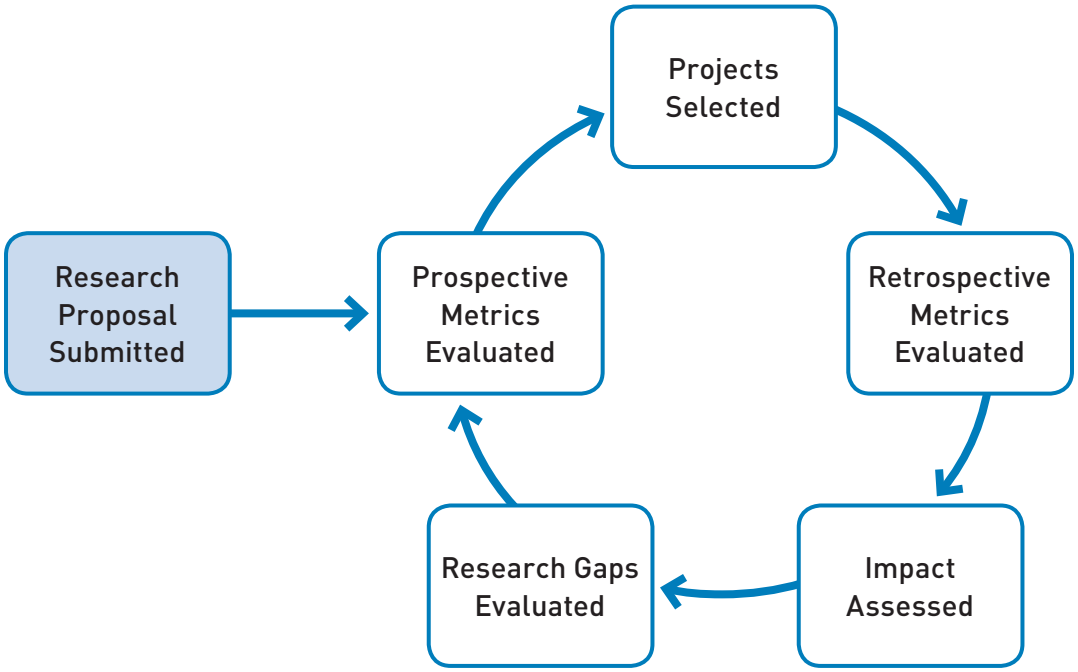


Figure 9. Prospective and Retrospective Metrics Diagram

OWH Metrics by Impact Area

Figure 10

METRICS: Engagement

EN1. Results in requests for partnership/collaboration/invitations to present or participate in relevant external research projects

EN2. Involves relevant internal content matter experts and other primary FDA stakeholders in guiding the research project

EN3. Referenced in communications from Agency leadership

EN4. Involves appropriate input from academia, industry, patient/advocacy groups, when additional expertise would enhance the feasibility, quality, or impact of the research

EN5. Involves collaborations with academia, industry, patient/advocacy groups, when additional expertise would enhance the feasibility, quality, or impact of the research

EN6. Results in interactions through social media, such as blog comments and linkages, retweets, visits to webpage

EN7. Involves scientists from more than one FDA Office or Center, when additional Center involvement would enhance the feasibility, quality, or impact of the research

EN8. Contributes to a scientific publication that is subsequently cited by others

EN9. Receives endorsement or letter of recommendation from relevant experts/stakeholders

METRICS: Advocacy

AD1. Communicated to appropriate internal stakeholders (e.g., through internal scientific seminar)

AD2. Spurs additional research activities

AD3. Contributes to a Clinical Care Guideline

AD4. Disseminated through public forum, such as national presentation or public workshop

AD5. Triggers additional sex and gender-specific women's health research by other federal agencies

AD6. Disseminated through media, including social media, press release, print media, television

AD7. Results in an increase in appropriations

OWH Metrics by Impact Area (continued)

Figure 10 (continued)

METRICS: Significance & Alignment

SA1. Includes sex and gender reporting and analysis

SA2. Results in an invitation to speak at a public forum, such as national presentation or public workshop

SA3. Changes regulatory knowledge, practice, or methodology

SA4. Aligns with OWH, Center, and FDA research priorities

SA5. Included as expert content within a Public Advisory Committee

SA6. Changes evidentiary requirements (e.g., clinical to animal or modeling studies; new endpoints; DDTs/MDDTs)

SA7. Responsive to emerging regulatory or public health issue

SA8. Results in an employee invention report or patent application

SA9. Contributes to consumer advisories, labelling, industry warnings, recalls, etc.

SA10. Addresses an unmet need in sex and gender-specific women's health

SA11. Contributes to scientific methodology that is subsequently used by others

SA12. Results in a licensing agreement

SA13. Aligns with relevant initiatives across federal agencies and globally

SA14. Facilitates development and evaluation of FDA-regulated products and practices (e.g., decreasing time/cost)

METRICS: Innovation

IN1. First-time application of an established technique/method to study sex and gender-specific women's health

IN2. Results in an employee invention report

IN3. Recognized as significantly groundbreaking (for example, resulting in a nomination for internal Center or FDA awards, or contributing toward receipt of FDA Scientific Achievement Award)

IN4. First-time interdisciplinary approach to study sex and gender-specific women's health

IN5. Results in a patent application

IN6. Results in a patent award

IN7. Results in a licensing agreement

IN8. Utilization of the licensing agreement outcome

IN9. Recognition through peer review that research has the potential for groundbreaking discovery

IN10. Recognition of the innovative results of the research through peer review

OWH Impact Spectrum with Aligned Metrics

The OWH R&D team created a spectrum of impact for each impact area. The left side of the spectrum considers low impact research proposals; these projects meet the minimal requirements of recognition and relevance, for example. The right side of the spectrum considers research proposals with higher impact; these projects often lead to an actionable change in the regulatory science field. The metrics were aligned along the spectrum to demonstrate their weight and significance (Figure 11). The Framework, spectrum of impact and aligned metrics are also presented in outline form in Appendix C.

Figure 11

SPECTRUM: Engagement

Relevant experts/stakeholders value the (proposed) work	Relevant experts/stakeholders provide resources necessary for the (proposed) work	Relevant experts/stakeholders execute and/or use the research
Recognition	**Contribution**	**Action**
EN1. Results in requests for partnership/collaboration/invitations to present or participate in relevant external research projects	**EN2.** Involves relevant internal content matter experts and other primary FDA stakeholders in guiding the research project	**EN3.** Referenced in communications from Agency leadership
EN6. Results in interactions through social media, such as blog comments and linkages, retweets, visits to webpage	**EN4.** Involves appropriate input from academia, industry, patient/advocacy groups, when additional expertise would enhance the feasibility, quality, or impact of the research	**EN5.** Involves collaborations with academia, industry, patient/advocacy groups, when additional expertise would enhance the feasibility, quality, or impact of the research
EN9. Receives endorsement or letter of recommendation from relevant experts/stakeholders		**EN7.** Involves scientists from more than one FDA Office or Center, when additional Center involvement would enhance the feasibility, quality, or impact of the research
		EN8. Contributes to a scientific publication that is subsequently cited by others

OWH Impact Spectrum with Aligned Metrics (continued)

Figure 11 (continued)

SPECTRUM: Advocacy

Findings are disseminated	Findings lead to increased knowledge base for future regulatory or research activities	Findings are implemented or lead to increased capacity
Awareness	**Influence**	**Action**
AD1. Communicated to appropriate internal stakeholders (e.g., through internal scientific seminar)	**AD2.** Spurs additional research activities	**AD3.** Contributes to a Clinical Care Guideline
AD4. Disseminated through public forum, such as national presentation or public workshop	**AD5.** Triggers additional sex and gender-specific women's health research by other federal agencies	**AD7.** Results in an increase in appropriations
AD6. Disseminated through media, including social media, press release, print media, television		

OWH Impact Spectrum with Aligned Metrics (continued)

Figure 11 (continued)

SPECTRUM: Significance & Alignment

Research addresses a priority area

Relevance

SA1. Includes sex and gender reporting and analysis

SA4. Aligns with OWH, Center, and FDA research priorities

SA7. Responsive to emerging regulatory or public health issue

SA10. Addresses an unmet need in sex and gender-specific women's health

SA13. Aligns with relevant initiatives across federal agencies and globally

Research informs regulatory science and practice

Applicability

SA2. Results in an invitation to speak at a public forum, such as national presentation or public workshop

SA5. Included as expert content within a Public Advisory Committee

SA11. Contributes to scientific methodology that is subsequently used by others

Research contributes to change in regulatory science and practice

Action

SA3. Changes regulatory knowledge, practice, or methodology

SA6. Changes evidentiary requirements (e.g., clinical to animal or modeling studies; new endpoints; DDTs/MDDTs)

SA8. Results in an employee invention report or patent application

SA9. Contributes to consumer advisories, labelling, industry warnings, recalls, etc.

SA12. Results in a licensing agreement

SA14. Facilitates development and evaluation of FDA-regulated products and practices (e.g., decreasing time/cost)

OWH Impact Spectrum with Aligned Metrics (continued)

Figure 11 (continued)

SPECTRUM: Innovation

Early stages of novel investigation with recognized innovative potential

Exploration

IN1. First-time application of an established technique/method to study sex and gender-specific women's health

IN4. First-time interdisciplinary approach to study sex and gender-specific women's health

IN9. Recognition through peer review that research has the potential for groundbreaking discovery

Novel findings illuminate path toward transformation

Discovery

IN2. Results in an employee invention report

IN3. Recognized as significantly groundbreaking (for example, resulting in a nomination for internal Center or FDA awards, or contributing toward receipt of FDA Scientific Achievement Award)

IN5. Results in a patent application

IN10. Recognition of the innovative results of the research through peer review

Shifting of an existing scientific paradigm

Transformation

IN6. Results in a patent award

IN7. Results in a licensing agreement

IN8. Utilization of the licensing agreement outcome

Implementation: OWH Application of the Framework

Each year, the Office of Women's Health issues a call for quad charts for the intramural research program. A quad chart is a one-page document in which the Principal Investigator provides the project title, specific aims of the project, as well as objectives and expected outcomes of the potential research proposal. The quad charts are reviewed and ranked by the center/office that will be conducting the research. Also, the quad charts are independently reviewed and ranked by OWH to select projects for full proposal development. Prior to the implementation of the Framework, the quad charts were assessed and selected for proposal development based on the following criteria:

- Cross-Cutting Issues
- Stakeholder Interest
- FDA Mission
- OWH Roadmap Priority Area
- FDA Responsibility for Research
- Knowledge Gap in Women's Health or Sex Differences
- Hypothesis/Research Question/Objective
- Experience and Qualifications of Applicant(s)/Past Performance
- Impact

Prior to implementation of the Framework, the proposals were reviewed by scientific experts from within and outside of FDA, and assessed for funding based on the following elements:

- Hypothesis/Research Question
- Study Design/Method
- Feasibility, Relevance
- Personnel/Past Performances
- Budget

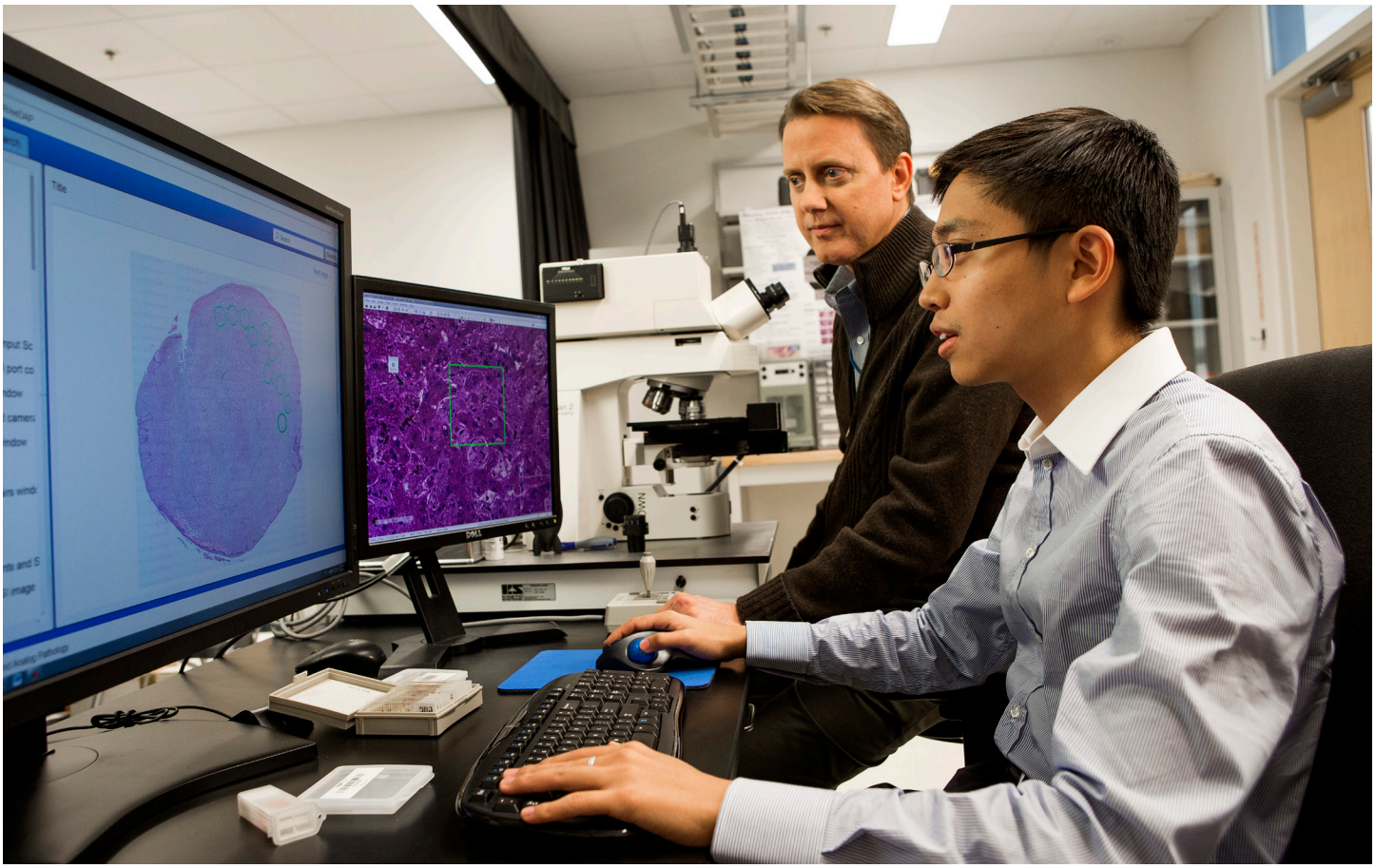
Implementation: OWH Application of the Framework (continued)

Previously, after a project was completed, an outcomes assessment was performed to determine regulatory and scientific impact based on these criteria:

- Knowledge Gap
- Disseminating Scientific Knowledge
- Regulatory Impact
- Uptake of Research
- Catalyst for Future Research.

The Research Impact and Outcomes Framework expands OWH's previous metrics to more effectively measure outcomes and impacts in the areas of: Engagement, Advocacy, Significance & Alignment, and Innovation. This Framework will be used to prospectively guide funding decisions and retrospectively assess project outcomes and impact.

For each metric, Table 1 provides examples of specific metric measurements developed by OWH R&D which may assist other organizations or groups when implementing the RIO Framework. This will be utilized by OWH R&D prospectively (e.g., Funding Selection criteria) or retrospectively (e.g., assessment of project outcome). OWH will modify its proposal review forms to ensure that the appropriate metrics are evaluated and considered in the project selection process and disseminate selection criteria to potential applicants within FDA. OWH will also revise its final report template and proactively follow-up on projects to more effectively identify and capture project outcomes and impact.



OWH RIO Framework Model

Table 1

Engagement			
Metric	**Examples of OWH Identifying Metric Measurements**	**Funding Selection Criteria (Prospective)**	**Project Outcome (Retrospective)**
EN1. Results in requests for partnership/collaboration/invitations to present or participate in relevant external research events	• Presentations and participation in scientific meetings		X
EN2. Involves relevant internal content matter experts and other primary FDA stakeholders in guiding the research project	• Subject matter experts within and outside of FDA reviewed proposal • Subject matter experts part of study team	X	
EN3. Referenced in communications from Agency leadership	• Study results in referenced communications from Agency leadership (e.g., publications, presentations and blogs)		X
EN4. Involves appropriate input from academia, industry, patient/advocacy groups, when additional expertise would enhance the feasibility, quality, or impact of the research	• External review comments and input from subject matter experts note that additional expertise enhances the research (YES or NO)	X	
EN5. Involves collaborations with academia, industry, patient/advocacy groups, when additional expertise would enhance the feasibility, quality, or impact of the research	• Collaborator on project from external stakeholder	X	
EN6. Results in interactions through social media, such as blog comments and linkages, retweets, visits to webpage	• Study results shared through social media • Study results highlighted on FDA webpages, OWH e-updates		X
EN7. Involves scientists from more than one FDA Office or Center, when additional Center involvement would enhance the feasibility, quality, or impact of the research	• Study team and collaborations with members from more than one Office or FDA Center	X	
EN8. Contributes to a scientific publication that is subsequently cited by others	• Citation count for scientific publications		X
EN9. Receives endorsement or letter of recommendation from relevant experts/stakeholders	• Endorsement or letter of recommendation from experts/stakeholders	X	X

OWH RIO Framework Model (continued)

Table 1 (continued)

Advocacy			
Metric	**Examples of OWH Identifying Metric Measurements**	**Funding Selection Criteria (Prospective)**	**Project Outcome (Retrospective)**
AD1. Communicated to appropriate internal stakeholders (e.g., through internal scientific seminar)	• Sharing research findings with appropriate Centers/Offices (e.g., internal scientific seminar, meeting with review divisions, disseminated to Senior Science Council and Women's Health Research Steering Committee)		X
AD2. Spurs additional research activities	• Use PlumX Metrics to capture research-specific social media mentions		X
AD3. Contributes to a Clinical Care Guideline	• Research produces a Clinical Care Guideline or statement		X
AD4. Disseminated through public forum, such as national presentation or public workshop	• Scientific workshops • Presentations		X
AD5. Triggers additional sex and gender-specific women's health research by other federal agencies	• Follow up on research conducted by other federal agencies		X
AD6. Disseminated through media, including social media, press release, print media, television...	• Study results disseminated through external communications		X
AD7. Result in an increase in appropriations	• Research focuses on issues prioritized by federal mandates		X

OWH RIO Framework Model (continued)

Table 1 (continued)

Significance & Alignment			
Metric	**Examples of OWH Identifying Metric Measurements**	**Funding Selection Criteria (Prospective)**	**Project Outcome (Retrospective)**
SA1. Includes sex and gender reporting and analysis	• Includes sex and gender reporting and analysis (YES or NO)	X	X
SA2. Results in an invitation to speak at a public forum, such as national presentation or public workshop	• Scientific workshops and presentations (YES or NO)		X
SA3. Changes regulatory knowledge, practice, or methodology	• Changes regulatory knowledge, practice, or methodology e.g., Guidance Documents (YES or NO)		X
SA4. Aligns with OWH, Center, and FDA research priorities	• Aligns with OWH, Center, and FDA research priorities (YES or NO)	X	
SA5. Included as expert content within a Public Advisory Committee	• Included as expert content within a Public Advisory Committee (YES or NO)		X
SA6. Changes evidentiary requirements (e.g., clinical to animal or modeling studies; new endpoints; DDTs/MDDTs)	• Changes evidentiary requirements (YES or NO)		X
SA7. Responsive to emerging regulatory or public health issue	• Responsive to emerging regulatory or public health issue (YES or NO)	X	X
SA8. Results in an employee invention report or patent application	• Results in an employee invention report or patent application (YES or NO)		X
SA9. Contributes to consumer advisories, labelling, industry warnings, recalls, etc.	• Contributes to consumer advisories, labelling, industry warnings or recalls (YES or NO)		X
SA10. Addresses an unmet need in sex and gender-specific women's health	• Addresses an unmet need in sex and gender-specific women's health (YES or NO)	X	X
SA11. Contributes to scientific methodology that is subsequently used by others	• Development of new models, new tools, and new theories • Citation count for novel scientific methodology used		X
SA12. Results in a licensing agreement	• Results in a licensing agreement (YES or NO)		X
SA13. Aligns with relevant initiatives across federal agencies and globally	• Results in collaborations with external stakeholders (YES or NO)	X	X
SA14. Facilitates development and evaluation of FDA-regulated products and practices (e.g., decreasing time/cost)	• Follow-up through progress reports and final research publication(s)	X	X

OWH RIO Framework Model (continued)

Table 1 (continued)

Innovation			
Metric	**Examples of OWH Identifying Metric Measurements**	**Funding Selection Criteria (Prospective)**	**Project Outcome (Retrospective)**
IN1. First-time application of an established technique/method to study sex and gender-specific women's health	• Development of new models, new tools, and new theories to study sex and gender	X	X
IN2. Results in an employee invention report	• Results in an employee invention report (YES or NO)		X
IN3. Research recognized as significantly groundbreaking (for example, resulting in a nomination for internal Center or FDA awards, or contributing toward receipt of FDA Scientific Achievement Award)	• Scientific awards		X
IN4. First-time interdisciplinary approach to study sex and gender-specific women's health	• First-time interdisciplinary approach to study sex and gender-specific women's health (YES or NO)	X	
IN5. Results in a patent application	• Results in a patent application (YES or NO)		X
IN6. Results in a patent award	• Results in a patent award (YES or NO)		X
IN7. Results in a licensing agreement	• Results in a licensing agreement (YES or NO)		X
IN8. Utilization of the licensing agreement outcome	• Results in a signed license report at the FDA Technology Transfer Program Office		X
IN9. Recognition through peer review that research has the potential for groundbreaking discovery	• Positive feedback indicating the potential for a groundbreaking discovery noted in peer review reports or letters to the editor	X	X
IN10. Recognition of the innovative results of the research through peer review	• Positive feedback recognizing innovative results noted in peer review reports or letters to the editor	X	X

Future Applications: Gap Analysis

A Gap Analysis utilizes Key Performance Indicators (KPIs) to determine whether a project will have an impact on an organization's mission and goals. In essence, a Gap Analysis shows where an organization is deficient in achieving the stated mission and can be completed retrospectively. The Framework metrics can be used in an Impact Analysis to help identify KPIs and establish the current state of OWH's impact. The R&D program can apply this knowledge to a Gap Analysis, and direct project funding based on the evaluation of potential project impact relative to the deficiencies in current project impact. For example, Impact on Clinical Care Guidelines is 1% of the portfolio; a KPI could be the number of funded projects that contribute to a Clinical Care Guideline to increase by 20% over the next 5 years. The Gap is 20%. Once identified, the specific process for "Closing the Gap" is developed among the team and progress is measured at specified time intervals.

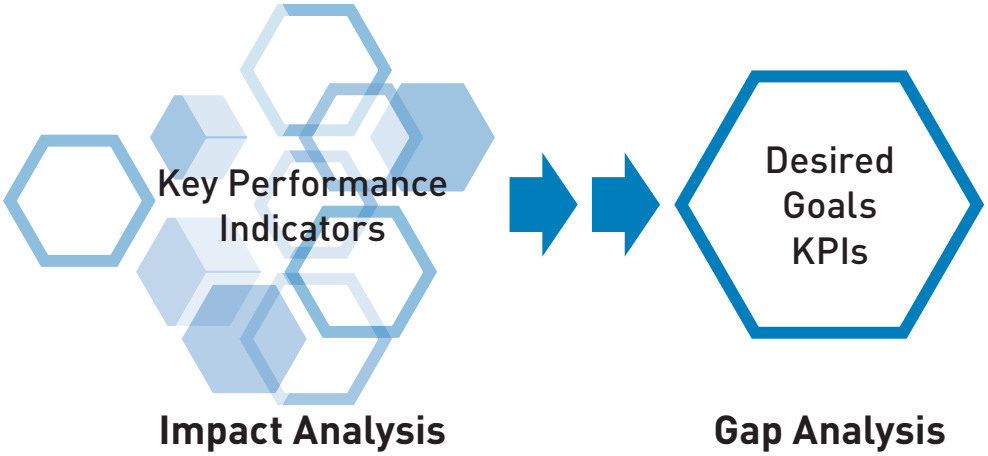


Figure 12. Process from Impact to Gap Analysis

Conclusion

The Research Impact and Outcomes Framework serves as a guide to assess the progress and Impact of an organization's mission. Specifically, this report follows extensively the development of the Office of Women's Health Research Impact and Outcomes Framework. Through a six-step process, organizations will have the ability to facilitate the development and adaptation of a Research Impact and Outcomes Framework that meets their organizational needs. Successful creation of an Impact and Outcomes Framework begins with garnering diverse expertise to form the Framework Development Committee. It further focuses on developing a foundation for the framework embedded firmly in the organizational mission. The identification of impact areas is then followed by the development of measurable metrics for each impact area, and alignment of the metrics on a spectrum to provide organization of the metrics along a continuum.

With a guide in place to assess past research and to steer future research, an organization can more effectively analyze the impact of each project and can detect gaps in their research portfolio. Although the initial intent was measurement of research impact and outcomes, due to the depth and breadth of the completed Framework, it is applicable across all OWH mission areas. Thus, a tangible tool is now available for measurement and reporting of meeting the mission in addition to planning future directions. This guide could also prove useful across a diverse array of programs and organizational environments.

References

1) Bernard Becker Medical Library. (2016, Dec. 27 2016). "Research Impact: Impact." Retrieved Mar. 21 2017, from http://beckerguides.wustl.edu/impact.

2) Buxton, M. and S. Hanney (1996). "How Can Payback from Health Services Research Be Assessed?" Journal of Health Services Research 1(1): 35-43.

3) Centers for Disease Control and Prevention Office of the Associate Director for Science. "Table 1: CDC science beyond citations - Examples of key indicators." Retrieved Mar. 22 2017, from https://www.cdc.gov/od/science/impact/pdfs/sif_indicators_examples.pdf.

4) Centers for Disease Control and Prevention Office of the Associate Director for Science. (2015, Apr. 24 2015). "About the Science Impact Project." Retrieved Mar. 22 2017, from https://www.cdc.gov/od/science/impact/about.html.

5) FDA Office of Women's Health (2015). Women's Health Research Roadmap, U.S. Food and Drug Administration. Retrieved March 22, 2017, from https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/WomensHealthResearch/UCM499322.pdf.

6) Fineberg, H. V. (2013). Presidential Address: The Institute of Medicine: What Makes It Great? Institute of Medicine Annual Meeting.

7) Hanney, S. (2013). The Payback Framework. H. E. R. Group. U.K., Brunel University.

8) Kosten, J. (2016). "A classification of the use of research indicators." Scientometrics 108(1): 457-464.

9) National Academy of Medicine. (2016). "Giving Opportunities." Retrieved Mar. 22 2017, from https://nam.edu/support-the-nam/opportunities-for-giving/.

10) National Institutes of Health. (2017). "Impact of NIH Research." Retrieved Mar. 21 2017, from https://www.nih.gov/about-nih/what-we-do/impact-nih-research.

11) Panel on Return on Investment in Health Research (2009). Making an Impact: A Preferred Framework and Indicators to Measure Returns on Investment in Health Research. Canadian Academy of Health Sciences. Ottowa, ON, Canada.

12) Penfield, T., M. J. Baker, R. Scoble and M. C. Wykes (2014). "Assessment, evaluations, and definitions of research impact: A review." Research Evaluation 23(1): 21-32.

13) Sarli, C. C., E. K. Dubinsky and K. L. Holmes (2010). "Beyond citation analysis: a model for assessment of research impact." J Med Libr Assoc 98(1): 17-23.

14) Searles, A., C. Doran, J. Attia, D. Knight, J. Wiggers, S. Deeming, J. Mattes, B. Webb, S. Hannan, R. Ling, K. Edmunds, P. Reeves and M. Nilsson (2016). "An approach to measuring and encouraging research translation and research impact." Health Res Policy Syst 14(1): 60.

15) Taylor-Powell, E., L. Jones and E. Henert. (2003, Feb. 2003). "Enhancing Program Performance with Logic Models." Retrieved Mar. 20 2017, from https://fyi.uwex.edu/programdevelopment/files/2016/03/lmcourseall.pdf.

Appendix A: Brief Review of Impact Frameworks for Biomedical and Health Research

Payback Framework

The Payback Framework, published by Buxton and Hanney in 1996, consists of two primary structures: a multidimensional categorization of impact and a logic model of processes (Buxton and Hanney 1996, Hanney 2013). The main categories of impact include the traditional academic areas of knowledge production and capacity-building for future research, as well as the wider impact areas of informing policies, improvements in population health, and broad economic benefits. The logic model envisions a research project interacting with its environment first through Research Needs Assessment and later through Dissemination. Dissemination contributes to policy decisions that ultimately impact health and wider societal impact.

Canadian Academy of Health Sciences Making an Impact Framework

The Canadian Academy of Health Sciences led an interdisciplinary project to investigate whether there is a "best method" for assessing impact of health research in Canada, and what the "best metrics" may be for assessing and improving health outcomes (Panel on Return on Investment in Health Research 2009). The Framework builds on the Payback Model (Buxton and Hanney 1996) and identifies the roles of stakeholders, including government, the public, public groups, and the healthcare industry. A logic model is presented in which research activity and results contribute to decision-making, which in turn affects health care and determinants of health. The ultimate outcomes of the logic model are improvements in population health and economic and social prosperity, which are seen to mutually reinforce one another. Accordingly, five categories of health research impacts are presented: Advancing Knowledge, Building Capacity, Informing Decision-Making, Health Impacts, and Broad Socio-economic Impacts. A "menu" of proposed metrics is presented for each category of impact. Several bibliometric indicators are proposed for Advancing Knowledge. Capacity-Building contains metrics pertaining to personnel, funding, and infrastructure. Metrics in Informing Decision-Making include use of the research in guidelines and education material, collaborations with industry, and utilization in public policy and advocacy publications. Health Impacts include epidemiological measures, such as prevalence, incidence, quality-adjusted life-years, and patient-reported outcome measures, as well as measures of social/environmental risk factors. Broad Economic and Social Impacts consist of econometric and sociological concepts, ranging as far as to include happiness and socioeconomic status.

Institute of Medicine Degrees of Impact Framework

In 2009, the Institute of Medicine established the Harvey V. Fineberg Impact Fund, in order to fund research on "controversial and complex issues that government and other institutions are not able or willing to support" (National Academy of Medicine 2016). The "Degrees of Impact Thermometer" graphic accompanied the announcement of this fund (Fineberg 2013). The "Degrees of Impact Thermometer" presents a continuum of impact, beginning with Spreading the Message; progressing through Receiving Recognition, Informing the Field, and Inspiring Action; and culminating with Effecting Change. In this framework, publication and recognition in the scientific realm occupies a lower standing, whereas outcomes such as the enactment of legislation, designation of appropriations, and policy change are found at the highest level of impact. The ultimate impact is the improvement of health outcomes.

Centers for Disease Control and Prevention Science Impact Framework

The Centers for Disease Control and Prevention (CDC) developed a Science Impact Framework to assess scientific influence of CDC activities. The framework is presented as an adaptation and extension of the Institute of Medicine Degrees of Impact Framework (Centers for Disease Control and Prevention Office of the Associate Director for Science 2015). The CDC chose to position their framework as a Science Framework rather than a Research Framework to encapsulate other important activities of the CDC, including public health guidelines and recommendations. The CDC Science Impact Framework presents five domains of influence: Disseminating Science, Creating Awareness, Catalyzing Action, Effecting Change, and Shaping the Future, with the ultimate goal of changing health outcomes. The framework does not position the domains or indications along a progression of chronology or importance, noting that "the degree of impact is not necessarily a progression." Potential measurable indicators corresponding to each domain of influence are presented (Centers for Disease Control and Prevention Office of the Associate Director for Science). Traditional indicators such as publications, presentations, and training are listed under the heading of Disseminating Science. Indicators that reach more broadly include information sharing and communications among professional societies (Creating Awareness), advocacy among government and non-government entities (Catalyzing Action), and legal/policy changes (Effecting Change). Implementation of public health programs, reduction in economic burden, and health outcomes contribute to Shaping the Future, although the Framework states that health outcomes are the ultimate goal of all 5 domains of impact.

Appendix B: Glossary of Terms

DDTs: Drug development tools

Gap Analysis: Utilizes Key Performance Indicators (KPIs) to determine whether a project will have an impact on an organization's mission and goals. In essence, a Gap Analysis shows where an organization is deficient in achieving the stated mission. A Gap Analysis cannot be performed until two things are known: the current state of an organization's impact and the KPIs that will demonstrate achievement of the mission. Once these are recognized, the evaluation of project funding can be directed through evaluation of the project impact compared to the deficiencies in current organization impact.

Impact: There is not a generally accepted definition of research impact (Bernard Becker Medical Library 2016). In general, impact refers to the long-term consequences of research (Taylor-Powell, Jones et al. 2003). NIH provides a description of the impact of NIH research that encompasses improvements in population health, advances in medicine and scientific knowledge, and economic productivity and growth (National Institutes of Health 2017). The Research Excellence Framework defines impact as "an effect on, change or benefit to the economy, society, culture, public policy or services, health, the environment or quality of life, beyond academia" (REF 2014 2012, Penfield, Baker et al. 2014).

Impact Analysis: An Impact Analysis categorizes past, current, and future projects to determine an organization's project funding direction. Impact Analysis is a tool to help establish Key Performance Indicators for the organization in a Gap Analysis. Reviewing past projects for historical impact and on-going evaluations of current and potential opportunities can be used to guide mission-directed funding decisions.

Indicator: Indicators are "specific, concrete examples that demonstrate research impact as a result

of a research finding or output" (Sarli, Dubinsky et al. 2010). They may be qualitative or quantitative (Kosten 2016).

Key Performance Indicator: A Key Performance Indicator (KPI) is a type of performance measurement used to evaluate the success of an organization or of a particular activity in which it engages. KPIs can reflect operational goals or progress toward strategic goals.

MDDTs: Medical device development tools

Metric: Metrics are quantitative measures used to assess impact. Examples include number of trained personnel recruited, number of publications, and estimated costs avoided in a disease area (Penfield, Baker et al. 2014, Searles, Doran et al. 2016). Metrics may be tailored to the feasibility of data collection to minimize overly burdensome processes (Searles, Doran et al. 2016)

Output: Research outputs are "products generated by a research study and disseminated by research investigators who discuss or interpret the findings of the research study" (Sarli, Dubinsky et al. 2010). Examples of research outputs include publications for scientific or lay audiences, algorithms, or license agreements or patients (Sarli, Dubinsky et al. 2010).

Outcome: Outcomes are measurable results of research. Unlike impact, which is generally long-term, outcomes can be measured in the short or intermediate term.

Sex and Gender-Specific Women's Health: Sex and gender-specific women's health encompasses the range of topics within women's health: sex/gender differences in conditions that affect both women and men; conditions that are more common among women; and conditions specific to female sex organs.

Appendix C: OWH Framework in Outline Format

I. Engagement: Harnessing appropriate expertise and capabilities, attracting key players to ensure the progress of the FDA OWH mission.
   a. Recognition: Relevant experts/stakeholders value the (proposed) work.
      i. Results in requests for partnership/collaboration/invitations to present or participate in relevant external research events.
      ii. Results in interactions through social media, such as blog comments and linkages, retweets, visits to webpage.
      iii. Receives endorsement or letter of recommendation from relevant experts/stakeholders.
   b. Contribution: Relevant experts/stakeholders provide resources (financial, material, intellectual) that are necessary for the (proposed) work.
      i. Involves relevant internal content matter experts and other primary FDA stakeholders in guiding the research project.
      ii. Involves appropriate input from academia, industry, patient/advocacy groups, when additional expertise would enhance the feasibility, quality, or impact of the research.
   c. Action: Relevant experts/stakeholders execute and/or use the research.
      i. Referenced in communications from Agency leadership.
      ii. Involves collaborations with academia, industry, patient/advocacy groups, when additional expertise would enhance the feasibility, quality, or impact of the research.
      iii. Involves scientists from more than one FDA Office or Center, when additional Center involvement would enhance the feasibility, quality, or impact of the research.

iv. Contributes to a scientific publication that is subsequently cited by others.

II. Advocacy: Increasing awareness to influence decisions and actions by stakeholders regarding sex and gender-specific women's health.

a. Awareness: Findings are disseminated.

i. Communicated to appropriate internal stakeholders (e.g., through internal scientific seminar).

ii. Disseminated through public forum, such as national presentation or public workshop.

iii. Disseminated through media, including social media, press release, print media, television.

b. Influence: Findings lead to increased knowledge base for future regulatory or research activities.

i. Spurs additional research activities.

ii. Triggers additional women's health research by other federal agencies.

c. Action: Findings are implemented or lead to increased capacity.

i. Contributes to a Clinical Care Guideline.

ii. Results in an increase in appropriations.

III. Significance & Alignment: Ensuring funding decisions and research outcomes advance knowledge of sex and gender-specific women's health.

a. Relevance: Research addresses a priority area.

i. Includes sex and gender reporting and analysis.

ii. Aligns with OWH, Center, and FDA Research Priorities.

iii. Responsive to emerging regulatory or public health issue.

iv. Addresses an unmet need in sex and gender-specific women's health.

v. Aligns with relevant initiatives across federal agencies and globally, particularly NIH ORWH Research Priority Areas.

b. Applicability: Research informs regulatory science and practice.

i. Results in an invitation to speak at a public forum, such as national presentation or public workshop.

ii. Included as expert content within a Public Advisory Committee.

iii. Contributes to scientific methodology that is subsequently used by others.

c. Action: Research contributes to change in regulatory science and practice.

i. Changes regulatory knowledge, practice, or methodology.

ii. Changes evidentiary requirements (e.g., clinical to animal or modeling studies; new endpoints; DDTs/MDDTs).

iii. Results in an employee invention report or patent application.

iv. Contributes to consumer advisories, labelling, industry warnings, or recalls.

v. Results in a licensing agreement.

vi. Facilitates development and evaluation of FDA-regulated products and practices (e.g., decreasing time/cost).

IV. Innovation: Producing a new and measurable shift in the landscape of sex and gender-specific women's health.

a. Exploration: Early stages of novel investigation with recognized innovative potential.

i. First-time application of an established technique/method to study sex and gender-specific women's health.

ii. First-time interdisciplinary approach to study sex and gender-specific women's health.

iii. Recognition through peer review that research has the potential for groundbreaking discovery.

b. Discovery: Novel findings illuminate path toward transformation.

i. Results in an employee invention report.

ii. Recognized as significantly groundbreaking (for example, resulting in a nomination for internal Center or FDA awards, or contributing toward receipt of FDA Scientific Achievement Award).

iii. Results in a patent application.

iv. Recognition of the innovative results of the research through peer review.

c. Transformation: Shifting of an existing scientific paradigm.

i. Results in a patent award.

ii. Results in a licensing agreement.

iii. Utilization of the licensing agreement outcome.

Acknowledgements

RIO Framework Development

The development of the framework was a collaborative effort of the Research Impact and Outcomes Subcommittee (RIOSc), consisting of physicians and scientists across Centers and Offices at the FDA. Many thanks to the following individuals:

- Marjorie Jenkins, MD, MEdHP, Office of Women's Health (Chair)
- Cecilia Aguila, DVM, Center for Veterinary Medicine
- Ami Bahde, MPH, Center for Tobacco Products
- Ruth Barratt, PhD, DVM, Center for Drug Evaluation and Research
- Heather Benz, PhD, Center for Devices and Radiological Health
- Ruth Geller, MHS, Office of Women's Health (Lead ORISE Fellow)
- Marilyn Khanna, PhD, Office of Regulatory Affairs
- Michelle Luo, MD, PhD, Office of Women's Health
- Beverly Lyn-Cook, PhD, MS, National Center for Toxicological Research
- Cary Parker, MPH, Center for Food Safety and Applied Nutrition
- Carolyn Wilson, PhD, Center for Biologics Evaluation and Research
- Beverly Wolpert, PhD, MS, Center for Food Safety and Applied Nutrition

RIO Framework OWH R&D Application Model

The Office of Women's Health Research and Development team provided valuable feedback throughout the development process and successfully created a dynamic adaptation model that will serve as exemplar for other organizations:

- Pamela Scott, PhD, MA (Lead)
- Marjorie Jenkins, MD, MEdHP (Facilitator)
- Michelle Luo, MD, PhD
- Deborah Kallgren
- Sara Robinson, MS, MLIS (ORISE Fellow)
- Dania Shafei, MS (ORISE Fellow)
- Kenneth Geh, BS (ORISE Fellow)

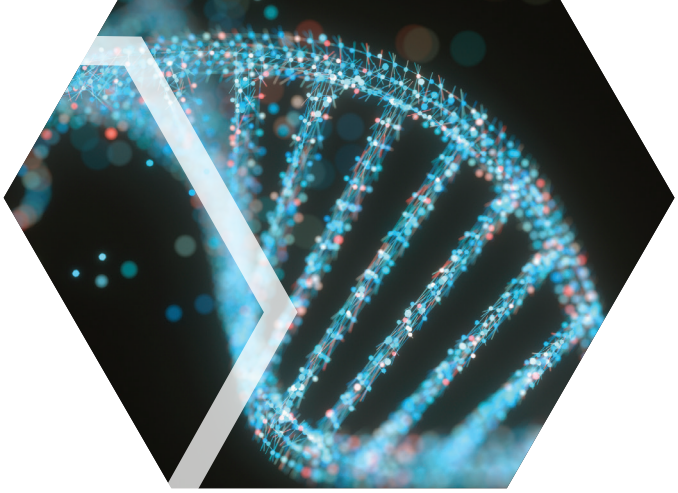
RIO Framework User Guide Development

The following individuals worked to revise and shape the final document into a practical user guide:

- Marjorie Jenkins, MD, MEdHP (Lead)
- Sara Robinson, MS, MLIS (ORISE Fellow)
- Dania Shafei, MS (ORISE Fellow)

To cite this document:

FDA Office of Women's Health (2018). Research Impact and Outcomes Framework: Guide to Developing an Organizational Impact and Outcomes Measurement Tool for Program Assessment and Reporting. U.S. Food and Drug Administration.



U.S. FOOD & DRUG
ADMINISTRATION

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

www.fda.gov/womens

APRIL 2018