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Clifford A. Hudis, MD,
FACP, FASCO

2318 Mill Road, Suite 800
Alexandria, VA 22314
T: 571.483.1300
F: 571.366.9530
www.asco.org

Via Electronic Submission

February 5, 2019

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

Subject: Framework for a Real-World Evidence Program – (Docket No. FDA-2018-N-4000)

Dear Dr. Gottlieb:

The American Society of Clinical Oncology (ASCO) appreciates the opportunity to provide input on the U.S. Food and Drug Administration's (FDA's) Framework for a Real-World Evidence (RWE) Program to help support the approval of a new indication or to meet post-approval study requirements. ASCO represents nearly 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO members are committed to ensuring that evidence-based practice for the prevention, diagnosis, and treatment of cancer are available to all Americans. ASCO supports major quality initiatives that enhance performance measurement and improvement, clinical practice guidelines, big data analytics, and the value of cancer care.

ASCO appreciates the FDA's efforts to develop a framework for the development of what will clearly be a multifaceted RWE Program. We generally support the FDA plans as outlined in the framework, but we are concerned that the framework may be overly conservative in its assessment of how real-world data (RWD) and RWE could fundamentally transform the way we conduct "traditional" **and** "hybrid" clinical trials. We encourage the FDA to strengthen the framework with a vision for how health information technology (HIT) could be harnessed to dramatically change the clinical research landscape. As the framework notes, we appreciate that the Agency has made "stakeholder engagement a key aspect of its RWE Program." (page 27) We urge the FDA to increase its call-to-action to bring HIT product developers

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working with RWD into the discussion about how to transform traditional and pragmatic clinical trials. If HIT products (including, but not limited to electronic health records) would promote collection of RWD at the point of care that is research-ready, clinician researchers could spend more of their time in patient and trial participant interactions and less of their time on transcription between the medical record and research data capture systems. FDA could bring together clinical- and research-related HIT developers together to promote interoperability and avoid duplication of data-entry effort. This is the sort of vision that would make busy clinicians much more excited about participating in clinical research and learning from every patient they treat.

Clinical trials are essential for improving the safety, efficacy, and effectiveness of healthcare delivery, but – just as in clinical care – we have not designed our HIT systems (both clinical care and research systems) to be interoperable and therefore make research easier. As a result, we have a research system that is reliant on human-duplication of information from EHR to electronic-capture for research. Busy clinicians are disincentivized from involvement in research because of the added risk and administrative requirements. Enhanced integration of research into routine clinical care delivery is essential to make it easier for clinician investigators and patients to be involved in the research process. The framework misses the opportunity to create this vision.

Two changes to the framework would help address this concern:

- **Include “Efficacy” in the RWE Program** – As FDA notes, the 21st Century Cures Act directed the FDA to issue the framework to describe how the Agency would use RWE for regulatory decisionmaking. New approvals and supplemental indications are generally described as a demonstration of safety and “efficacy,” while post-market research generally examines the effectiveness of a product as compared with other treatments. The framework states that use of RWD will “focus on exploring the potential of RWD/RWE to support regulatory decisions about product effectiveness.” (page 13) While the framework integrates examples of FDA’s use of RWE for drug product approvals, we are concerned that limiting the discussion to “product effectiveness” and not “efficacy” may cause unintended confusion.
- **Integrate RWD into Definition of Traditional Clinical Trials** – The framework notes that the FDA has issued several guidance documents on use of electronic source data in traditional clinical trials. ASCO applauds this work but is concerned that the framework’s discussion of “traditional clinical trials” includes transcription of data from routine medical records, rather than electronically captured data from and EHR.



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The framework seems to be anchored in human transcription, rather than improving clinical data at the source in order to promote human-informed, automated processes. We appreciate that considerable work is required to standardize and structure EHR data to make it useful for research. The FDA is uniquely poised to inspire HIT developers to work with the research community to join FDA’s vision for improvement of clinical trials.

We also have additional comments and suggestions for areas needing more clarification or that would benefit from specific examples.

Definitions of Real-World Data and Real-World Evidence

While we support the definitions of RWE and real-world data (RWD) provided in the framework, we would like to request that FDA consider a few additions to the list of examples of RWD sources. Two additional potentially useful sources of RWD are pharmacy databases, for example prescription refills, and social media. Data collected from pharmacy databases, particularly refill information, can be used in observational research studies to assess the effectiveness and tolerability of interventions by providing a measure of patient adherence to oral therapies. The framework discusses FDA’s use of pharmacy databases in the context of pharmacoepidemiologic queries and studies, but not related to hybrid trials and observational studies. In addition, social media as a source obviously provides patient perspectives on topics such as adverse events, non-adherence, and quality of life.

Clinical Trials and Observational Studies Covered by the RWE Program

The framework attempts to distinguish among trial designs and studies that will be covered under the RWE Program. As noted above, we believe RWD – particularly if it is improved through standardization and structurization – has the ability to make “traditional” clinical trials more efficient and to imbue quality by design. We are concerned that the framework may be creating artificial distinctions between use of RWD in “traditional” and “hybrid” clinical trials – based on current HIT limitations. If RWD were improved at the point of clinical collection, we might have more confidence in its use in “traditional clinical trials.” We are also concerned that the framework may create the false impression that hybrid trial designs and pragmatic clinical trials generate less reliable data. The framework notes that:

“FDA will consider these hybrid trial designs to have the potential to generate RWE. Clinical trial designs can also include some elements



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that more closely resemble routine clinical practice, which are sometimes described as “pragmatic” elements. These pragmatic clinical trials often rely on RWD and have the potential to generate RWE.” (page 6)

Further in the document, the framework notes that pragmatic clinical trials employ “broader inclusion/exclusion criteria and streamlined data collection.” ASCO is concerned that these references apply only to hybrid clinical trials. We appreciate the Agency making it clear that “evidence from traditional clinical trials will not be considered RWE.” (page 5) We are concerned, however, that the Agency may be creating an impression that pragmatic clinical trials and RWD are less reliable. We understand the framework clarifies that there is not a single definition of a traditional clinical trial and that trials vary considerably in design and conduct. However, it will be important for stakeholders to clearly understand what types of trials will not be considered RWE.

Observational Studies Using RWD to Generate RWE

The framework notes several challenges in the use of observational studies and a caution in accepting observational studies in support of effectiveness decisions. The framework specifically discusses examples of divergence in findings between randomized trials and observational studies. ASCO understands the limitations of observational studies to generate definitive evidence; however, we believe the RWE Program should be clear about in which situations observational data will be accepted to inform RWE.

Supporting FDA’s Regulatory Decisions of Effectiveness

The RWE framework notes a long history of FDA using RWE to monitor and evaluate the safety of products in a post-market setting. The document mentions limited instances where FDA has accepted RWE to support drug product approvals, primarily in the setting of oncology and rare diseases. The framework notes that the supportive RWE has consisted of data on historical response rates drawn from chart reviews, expanded access, and other practice settings. ASCO suggests that the framework should give specific examples of these types of data and briefly describe how the FDA utilized this data for regulatory decision-making.

Randomized Controlled Trials Integrated into Health Care Systems

The framework notes that clinical trials can be integrated into the health care system and can include some pragmatic elements. Additionally, trial integration should facilitate collection of outcomes and serious adverse events



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using RWD. The characteristics these trials share is the use of outcomes that have less diagnostic variability, which may be well captured in RWD sources. ASCO suggests the RWE Program include a few more examples in addition to the ones already in the framework of what those types of outcomes are, specifically in the oncology setting.

Using Trials or Studies with RWD/RWE for Effectiveness Decisions

The FDA's RWE Program will evaluate the potential use of RWE to support changes to labeling about drug product effectiveness, including adding or modifying an indication, such as a change in dose, dose regimen, or route of administration; adding a new population; or adding comparative effectiveness or safety information. The three-part approach suggested in the framework includes whether the study conduct meets FDA regulatory requirements, citing study monitoring and data collection as examples. However, ASCO suggests that using study monitoring as one of the program's components will be a challenge, since there is typically little study monitoring done in the "real world." We recommend that if study monitoring is one of the considerations, the RWE program should incorporate concepts like risk-based monitoring, which the FDA has embraced through its guidance to for industry (OMB Control No. 0910-0733). ASCO has found this type of approach to be very effective and efficient in its Targeted Agent and Profiling Utilization Registry (TAPUR™) Study (www.TAPUR.org).

Additionally, the framework acknowledges the need for appropriate data standards, and the importance of developing data standards to maximize the utility of RWD. ASCO agrees that to work with RWD across multiple sources, data will need to be put into a common format, sometimes referred to as a common data model (CDM), with common representation (terminologies, vocabularies, coding schemes). In the FDA's efforts to identify relevant standards and methodologies for collection and analysis of RWD, we suggest clarification of whether the Agency is proposing the use or modification of an existing CDM or creating a new data model. ASCO believes the use of an existing CDM (e.g., the PCORnet Common Data Model), with or without extensions, may be better for the RWE Program.

In general, the lack of data standards presents a problem even beyond the contemplation of their use in the RWE framework. This is especially true in specialty fields such as oncology. In response, ASCO is actively working on the "mCODE™" project, an effort designed to result in a parsimonious set of consensus-developed oncology data elements necessary for critical information exchange between EHRs, for clinical care, quality reporting, and



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other use cases. It is possible that the results of these efforts could feed into the RWE framework over time, helping to establish agreed-upon data elements for oncology.

Assessing Data Reliability (Data Accrual and Data Assurance) and Relevance

ASCO agrees that the strength of RWE submitted in support of a regulatory decision depends on the clinical study methodology and the reliability (data accrual) and data quality control (data assurance) and relevance of the underlying data. The framework highlights that the reliability assessment includes checking the laboratory data for completeness, consistency, and trends over time, including the use of reporting standards such as the Logical Observation Identifiers, Names, and Codes (LOINC) system. ASCO appreciates that the framework provides this level of detail, thus making the FDA's expectations in this area very clear.

FDA intends to adapt the approach of reliability and relevance assessments to evaluate sources of RWD used to generate RWE of drug and device product effectiveness, recognizing that the specific elements to consider will likely differ by RWD type and the type of research for which the data are intended. ASCO believes this is important in that commonly used efficacy endpoints will generally not be collected as rigorously in RWD as in a clinical trial. In particular, response and progression events are assessed using Response Evaluation Criteria in Solid Tumors (RECIST) or other formal response criteria in clinical trials, but that is not typically the case in clinical practice. We are eager to work with the FDA and research community to develop and employ clinical outcome standards in EHRs that could also be applied to develop RWE in a research context. In addition, we encourage the FDA to provide some clarifications on the Agency's expectations for data validity with respect to efficacy endpoints.

Data Standards — Appropriate Data Standards for Integration and Submission to FDA

Along with other activities under FDA's RWE Program, the framework suggests FDA will assess the data standards and implementation strategies required to use RWD/RWE. A few of the activities proposed include review of existing RWD/RWE-driven work, both internally and with external stakeholders; and collaboration with internal and external stakeholders to adapt or develop standards and implementation strategies. ASCO suggests the FDA clarifies whether these activities will be driven by one of the existing standards-developing organizations in health care (e.g. HL7) or will this be driven more organically with an internal and external stakeholder collaboration.



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Stakeholder Engagement

ASCO appreciates that the framework clearly states that the FDA is making stakeholder engagement a key aspect of the RWE Program. The document notes that if RWD and RWE are to be effectively leveraged for public health purposes, there will need to be shared learning and collaboration across clinicians, patients, health care systems, pharmaceutical companies, and regulators. ASCO believes it would be helpful for the FDA to clarify both the types of stakeholder engagement that would be most useful going forward and the structure of such collaborations (e.g. formal contract; series of public comments; or loose coalition of stakeholders united by a set of principles facilitated by the community or if preferable by FDA.)

Appendix: Demonstration Projects

ASCO greatly appreciates the FDA's partnership with CancerLinQ® (CLQ), ASCO's big data, health technology platform, and its mention in the appendix for current demonstration projects. The framework notes that FDA and CLQ will be using real-world, aggregated, de-identified patient care data from oncology practices to look at a variety of issues related to the appropriate use of newly approved therapies. The current collaboration focuses on the use of checkpoint inhibitor drugs across all malignancies. By working with these data to explore questions around the use of new oncologic agents, FDA will better understand how to evaluate the relevance and quality of these data.

Additionally, we would like to take this opportunity to highlight the impact of the ASCO-Friends of Cancer Research-FDA clinical trial eligibility criteria recommendations to promote greater patient participation in cancer clinical trials. Broadening eligibility criteria will also maximize the generalizability of clinical trial results and assist sponsors in designing more representative trials. We are concerned about the potential unintended impression that the framework may create that these "broader inclusion/exclusion criteria and streamlined data collection" (page 19) apply only to hybrid studies and not to traditional clinical trials. The application of our recommendations will certainly differ based on the phase of research and development and knowledge about the investigational agent. The general concept to minimize unnecessary exclusions, however, applies to each and every human study. Narrowly defined trial populations potentially limit the ability to understand the therapy's benefit-risk profile across the broad patient population who may ultimately receive the intervention in the post-market setting.



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We look forward to working with you and your staff as you further develop the RWE Program. ASCO continues to work towards efficiently leveraging practice data to improve both quality of care and understanding of the safety, efficacy, and effectiveness of new therapies and standards of care. Standardizing and validating RWD to establish a usable and interoperable RWE framework will require active engagement across the research and clinical care landscape. Thank you for the opportunity to comment on this initial framework for the FDA's RWE Program. Please contact Shimere Williams Sherwood at Shimere.Sherwood@asco.org with any questions and for further discussions.

Sincerely,

Monica M. Bertagnolli, MD, FACS, FASCO
President, American Society of Clinical Oncology