available data for similar products or other treatments for the disorder or similar disorders.

- What are challenges and strategies/opportunities with interpreting efficacy data from individual patients (including expanded access) and small groups of patients? What opportunities are there in leveraging prior and/or collective experiences?
- What strategies can be utilized to accumulate and interpret safety data in personalized/individualized CGTs?
- For genetic disorders with clear genotype-phenotype associations for disease manifestations or severity, what opportunities are there for tailoring treatments and study design to specific genotypes/phenotypes?

D. Additional Questions To Consider

- What additional major scientific challenges to advance the development of individualized CGTs should be considered?
- What existing best practices or scientific approaches should be leveraged to address any of these challenges? Are there specific opportunities for collaborations to advance the development of individualized CGTs?
- Are there specific areas where flexibility in regulatory approaches would improve the feasibility of developing and commercializing individualized CGTs?

III. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. President's Council of Advisors on Science and Technology, ''Priorities for Personalized Medicine,'' September 2008.
2. FDA, ''Focus Area: Individualized Therapeutics and Precision Medicine,'' 2022. Available at *https://www.fda.gov/science-research/focus-areas-regulatory-science-report/focus-area-individualized-therapeutics-and-precision-medicine.*
3. Marks, P. and C. Witten, ''Toward a New Framework for the Development of Individualized Therapies,'' *Gene Therapy,* 28:615–617, 2021.
4. FDA, ''Facilitating End-to-End Development of Individualized Therapeutics'' (Public Workshop) (March 3, 2020). Available at *https://fda.yorkcast.com/webcast/Catalog/Mobile/FolderPresentation/6d6af3ca61754c3c869f7f556bbede9e21/4174764f-a52d-4503-893d-0b8bc35e1da7/b9c6ac08f3d040eba768ef43befb498f1d/.*
5. Fritah, H., R. Rovelli, C.L. Chiang, and C.L. Kandalaft, ''The Current Clinical Landscape of Personalized Cancer Vaccines,'' *Cancer Treatment Reviews,* 106:102383, 2022.
6. FDA, ''OTP Events, Meetings, and Workshop,'' (2023). Available at *https://www.fda.gov/news-events/otp-events-meetings-and-workshops.*

Dated: September 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20452 Filed 9–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3550]

Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies; Guidance for Industry, Investigators, and Institutional Review Boards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies.'' This guidance recommends approaches that sponsors of clinical trials of medical products can consider when there is a major disruption to clinical trial conduct and operations due to disasters or public health emergencies, which can include but are not limited to hurricanes, earthquakes, military conflicts, infectious disease outbreaks, or bioterrorist attacks. The appendix to this guidance further explains those approaches by providing answers to questions that the Agency has received about conducting clinical trials during major disruptions.

DATES: The announcement of the guidance is published in the **Federal Register** on September 21, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–3550 for ''Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993, 301 796–2500, *CDEROMP@fda.hhs.gov*; Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Soma Kalb, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 301–796–6359.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry, investigators, and institutional review boards entitled ''Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies.'' Disasters and public health emergencies (PHEs) have the potential to cause major disruptions in the conduct of clinical trials for medical products. Such events can include, but are not limited to, weather events, military conflicts, infectious disease outbreaks, and bioterrorist attacks. The purpose of the guidance is to provide general considerations to assist sponsors, investigators, and institutional review boards in assuring the safety of trial participants, maintaining compliance with good clinical practice, and minimizing risks to trial integrity during disasters and PHEs that may lead to major disruption of clinical trial conduct and operations. The appendix to the guidance further explains these general considerations in a question-and-answer format.

FDA recognizes that disasters and PHEs can cause major disruptions to the conduct of clinical trials of medical products. For example, disasters or PHEs can lead to population quarantines, trial site closures, travel limitations, interruptions to the supply chain for the investigational product, or other considerations related to the type of disaster or emergency. These challenges can create difficulties for complying with protocol-specified procedures, including administering or using the investigational product or adhering to protocol-specific visits and laboratory/diagnostic testing. This final guidance provides recommendations on how to manage major disruptions to clinical trials during disasters and PHEs to help ensure the protection of participants and the ability of clinical trials to generate evidence to support regulatory decision-making during these times.

The final guidance provides recommendations for helping to address those challenges, including, among other things, recommendations related to the safety of trial participants, whether to continue or suspend a trial, protocol amendments and deviations, study monitoring, alternative delivery of the investigational product, remote safety and endpoint assessment, informed consent, and reporting of adverse events. Some of the recommendations in this final guidance provide less burdensome approaches that can be utilized, when appropriate, in the conduct of clinical trials during major disruptions due to a disaster or PHE and that are consistent with public health. For example, the guidance provides recommendations regarding a change to virtual, rather than in-person, clinical trial visits when necessary.

In March 2020, FDA first published the guidance for industry entitled ''Conduct of Clinical Trials of Medical Products During the COVID–19 Public Health Emergency'' (COVID–19 Conduct guidance) to support public health efforts following a declaration, under section 319 of the Public Health Service (PHS) Act (42 U.S.C. 247d), by the Secretary of Health and Human Services of a public health emergency related to Coronavirus Disease 2019 (the disease caused by SARS–CoV–2). The COVID–19 Conduct guidance focused on addressing the COVID–19 PHE.

In the **Federal Register** of March 13, 2023 (88 FR 15417), FDA listed the COVID–19-related guidance documents that would no longer be effective after the PHE declared under the PHS Act expired on May 11, 2023. The March 13, 2023, notice also listed COVID–19-related guidance documents that FDA was revising to continue in effect for 180 days after the expiration of the PHE declaration to provide a period for stakeholder transition and then would no longer be in effect, and documents that FDA was revising to continue in effect for 180 days after the expiration of the PHE declaration, during which time FDA planned to further revise the guidances with any appropriate changes based on comments received and the Agency's experience with implementation. The COVID–19 Conduct guidance was included in the latter category and was revised to remain in effect for 180 days post-expiration of the PHE declaration. FDA believes that most of the recommendations set forth in the COVID–19 Conduct guidance are applicable outside the context of the COVID–19 PHE to major disruptions to clinical trial conduct in the setting of disasters and PHEs more broadly. Consistent with what we said in the **Federal Register** of March 13, 2023, FDA is therefore issuing this revised final guidance, which supersedes the

COVID–19 Conduct guidance. FDA's revisions include broadening the guidance's scope to apply during disasters and PHEs, removing several outdated questions, clarifying recommendations regarding use of risk-based approaches for monitoring clinical investigations, clarifying recommendations concerning charging for investigational products, and making other editorial changes to improve clarity and consistency.

FDA is issuing this guidance for immediate implementation in accordance with our good guidance practices regulation (21 CFR 10.115(g)(3)) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate (see 21 CFR 10.115(g)(2) and section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i))). Specifically, we are not seeking prior comment because disasters and PHEs may occur without notice and, as we have learned from experience during the COVID–19 PHE, may rapidly cause major disruptions to clinical trial conduct. It is thus important to public health to provide guidance on approaches to assure the safety of trial participants and minimize risks to trial integrity during such major disruptions. Moreover, portions of the guidance reflect a less burdensome approach that is consistent with public health and that can be used during a disaster or PHE when appropriate. Interested parties had an opportunity to comment on the recommendations in the COVID–19 Conduct guidance, and FDA considered those comments when revising the guidance to apply those recommendations to disasters and public health emergencies more broadly. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with FDA's good guidance practices regulation (§ 10.115(g)(3)(D)).

The guidance represents the current thinking of FDA on ''Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 320 have been approved under OMB control number 0910–0630; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20474 Filed 9–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Engineered T Cell Therapies for the Treatment of HPV-Positive Cancer(s)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this Notice to Scarlet TCR, Inc. (''Scarlet''), presently headquartered in Kingston, New Jersey.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before October 6, 2023 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240) 276–5484; Email: *andy.burke@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 62/004,335 filed May 29, 2014, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–US–01];

2. PCT Patent Application No. PCT/US2015/033129 filed May 29, 2015, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–PCT–02];

3. Australian Patent No. 2015266818 issued January 16, 2020, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–AU–03];

4. Brazilian Patent Application No. BR112016027805–4 effective filing date of May 29, 2015, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–BR–04];

5. Canadian Patent Application No. 2,950,192 effective filing date of May 29, 2015, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–CA–05];

6. Chinese Patent No. ZL201580031789.X issued May 4, 2021, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–CN–06];

7. European Patent No. 3149031 issued December 18, 2019, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–EP–07];

a. Validated in: AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM and TR.

8. Israeli Patent No. 248797 issued September 1, 2021, entitled ''Anti-Human Papillomavirus 16 E7 T Cell Receptors'' [HHS Reference No. E–176–2014–0–IL–08];