I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment.” This draft guidance provides recommendations to sponsors regarding the development of drugs regulated by CDER and CBER for the adjuvant treatment of renal cell carcinoma. The draft guidance includes recommendations regarding eligibility criteria, choice of comparator, followup imaging assessments, determination of disease recurrence, analyses of disease-free survival (DFS), and interpretation of trial results. Although FDA may consider endpoints other than DFS for the adjuvant treatment of renal cell carcinoma, this guidance is focused on clinical trials with DFS as the primary efficacy endpoint.

Adjuvant renal cell carcinoma clinical trials are an active area of research. There is significant variability in the design, conduct, and analysis of these trials, including the eligibility criteria, radiological disease assessments, the definition of disease recurrence, and the date used to define the DFS endpoint in these trials. Consistency in these aspects within and across trials may facilitate interpretation of trial results. These issues were discussed at an FDA-National Cancer Institute public workshop held on November 28, 2017. This draft guidance provides recommendations on these issues to facilitate adjuvant renal cell carcinoma clinical trials.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Renal Cell Carcinoma: Developing Drugs and Biologics for Adjuvant Treatment.” 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 of 1995

This draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under 0910–0338.

III. Electronic Access

Justification: The purpose of these cooperative agreements is to save lives, prevent HIV infections, and accelerate progress toward achieving HIV/AIDS epidemic control in more than 50 countries around the world. Recipients have completed certain project activities, but evaluation and transition to scale-up has been interrupted by the COVID–19 pandemic and associated country-specific restrictions. This notice extends the current project period for HRSA–15–021, Quality Improvement Capacity for Impact Project, by one year until September 29, 2021, to ensure the orderly conclusion of these projects while facilitating virtual stakeholder engagement during the COVID–19 pandemic.


SUMMARY: In accordance with the Federal Advisory Committee Act, HHS is hereby giving notice that the Council on Graduate Medical Education (COGME) has been rechartered. The effective date of the renewed charter is September 30, 2020.

FOR FURTHER INFORMATION CONTACT: Shane Rogers, Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA. Anyone requesting information may reach Mr. Rogers by mail at 5600 Fishers Lane, 15N142, Rockville, Maryland 20857; by phone at 301–443–5260; or by email at S Rogers@hrsa.gov

SUPPLEMENTARY INFORMATION: COGME makes recommendations to the Secretary of HHS (Secretary) and Congress on matters specified by section 762 of Title VII of the Public Health Service (PHS) Act. Issues addressed by COGME include (1) the supply and distribution of physicians in the United States; (2) current and future shortages or excesses of physicians in medical and surgical specialties and subspecialties; (3) issues relating to foreign medical school graduates; (4) appropriate federal policies with respect to the matters specified in (1), (2), and (3) above, including policies concerning changes in the financing of undergraduate and graduate medical education (GME) programs and changes in the types of medical education training in GME programs; (5) appropriate efforts to be carried out by hospitals, schools of medicine, schools of osteopathic medicine, and accrediting bodies with respect to the matters specified in (1), (2), and (3) above, including efforts for changes in undergraduate and GME programs; and (6) deficiencies in, and needs for improvements in, existing databases concerning the supply and distribution of, and postgraduate training programs for, physicians in the United States and steps that should be taken to eliminate those deficiencies. Not later than September 30, 2023, and not less than every 5 years thereafter, COGME shall submit a report with recommendations to the Secretary, and to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Additionally, COGME encourages entities providing GME to conduct activities to voluntarily achieve the recommendations of COGME; and develops, publishes, and implements performance measures, develops and publishes guidelines for longitudinal evaluations, and recommends appropriation levels for certain programs under Title VII of the PHS Act.

The renewed charter for COGME was approved on September 30, 2020, which will also stand as the filing date. Recharter of the COGME gives authorization for the Council to operate until September 30, 2022.

A copy of the COGME charter is available on the COGME website at https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/graduate-medical-edu/cogme-charter.pdf. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is http://www.facadatabase.gov/.

Maria G. Button, Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Recharter for the Council on Graduate Medical Education

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of recharter.

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**TABLE 1—RECIPIENTS AND AWARD AMOUNTS**

<table>
<thead>
<tr>
<th>Grant number</th>
<th>Award recipient name</th>
<th>Extension length</th>
<th>Award amount</th>
</tr>
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<tbody>
<tr>
<td>UCSF–U1NHAA3422 ........................................</td>
<td>The Regents of the University of California San Francisco.</td>
<td>1 Year</td>
<td>$4,000,000</td>
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<tr>
<td>ICAP–U1NHAA28555 ........................................</td>
<td>Trustees of Columbia University in the City of New York.</td>
<td>1 Year</td>
<td>2,000,000</td>
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