Bristol Myers Squibb™

June 2, 2020

RE: Clinical Trials CA047-004, CC-90009-AML-002, CC-90010-GBM-002, CC-90011-PCA-001, CC-94676-PCA-001, CC-98633-MM-001, CC-99282-CLL-001, CV019-010, CV023-005, IM026-027, IM039-004, JCAR017-FOL-001 and RPM-CART-001

Dear Investigator,

I appreciate your continued interest and willingness to participate in Bristol Myers Squibb (BMS) research at such a difficult time. The past several months have been very challenging for patients and for investigative sites due to the added burden COVID-19 has placed on researchers like you.

I would like to describe conditions for site initiation for new BMS clinical trials including healthy volunteer studies. You may have previously received letters from Samit Hirawat, M.D., Chief Medical Officer, Global Drug Development at BMS, dated March 19, 2020 and April 9, 2020, which provided BMS' position on initiation of new studies or new study sites as well as enrollment and treatment guidelines for active studies and study sites in light of the COVID-19 pandemic. These letters communicated that site initiations and activations for new studies were being suspended. After careful consideration, BMS has decided to resume start-up activities for the trials listed above.

When and how we begin clinical trial work at new sites requires a very thoughtful and inclusive approach with input from multiple functions at the global, country, and local level. We also appreciate that your site is experiencing its own challenges as a result of COVID-19, and we know that is a key factor to be considered. Our goal is to listen and understand your specific situation and work with you to accelerate research at your site. In order to initiate your site, we will require all of the following conditions to be met:

- Your country/state does not have restrictions on travel or commerce that would restrict the ability of BMS to safely monitor the conduct of trial activities at your site or remote access to the Electronic Health Record has been assessed and can be / has been enabled to allow for remote monitoring.

- The local/national BMS or Contract Research Organization (CRO) operational team has determined that they can safely monitor the conduct of trial activities at your site.

- Your site does not have restrictions on in-person site monitoring or remote access to the Electronic Health Record has been assessed and can be / has been enabled to allow for remote monitoring.

- Your site has no restrictions in place that would limit your ability to fully comply with the requirements of the conduct of the study. In particular, this would include your ability for participants enrolled to have all study-mandated procedures performed as defined in the protocol including physical exams, disease assessments, adverse event assessments, processing of biomarker and pharmacokinetic materials, as well as laboratory assessments and administration of trial product.

- You have determined that your site has sufficient resources to allow you to safely care for participants enrolled in the trial.
- You have determined that participation in the clinical trial does not pose an excessive or unacceptable risk on the trial participant in the unusual circumstances of the ongoing COVID-19 pandemic.
- You have a guidance/policy in place that describes preventative measures and required screening or clearances for safe participant visits to your site.
- You have a guidance/policy in place that describes the care for participants exposed to or infected with Severe Acute Respiratory Syndrome Corona Virus 2 (SARS-CoV-2), the virus that causes COVID-19, after enrollment.

When you believe that these conditions have all been met, please reach out to your BMS Study Team. They will review your assessment and verify our ability to comply with GCP and safely monitor the conduct of the trial at your site. Following our assessment, we will inform you whether we are able to schedule an initiation visit at your site.

Thank you for your continued efforts to provide care to patients during these challenging times and for your partnership in determining when it is reasonable for BMS to initiate clinical research at your site. We look forward to better times.

Sincerely,

Kathryn Owen
Senior Vice President, Global Development Operations
Bristol Myers Squibb