Supplementary Table S1. Schedule of enrolment procedures and follow-up assessments.

	Baseline	**Telephone calls**	**Follow-up visits**				
	From 30 days before vaccination to the same day of first dose administration	***7 days after immunization (after each dose)***	***Week 4 post-vaccine (second dose)***	***Week 12 post-vaccine (second dose)***	***Week 24 post-vaccine (second dose)***	***Week 36 post-vaccine (second dose)***	***Week 48 post-vaccine (second dose)***
Demographics	X						
Date of vaccination and type of vaccine	X						
rcCTD diagnosis	X						
Past medical history (year of diagnosis, cumulative organ involvement)	X						
Comorbidities	X						
Cumulative GCs dosage	X						
Number of disease flares during the past year	X						
Previous COVID-19 infection	X						
COVID-19 serology *(optional)*	(X)		(X)	(X)	(X)	(X)	(X)
Current symptoms suggestive of COVID-19	X		X	X	X	X	X
Physical exam	X		X	X	X	X	X
Lab exams (ESR, CRP, CBC, renal function, liver function)	X		X	X	X	X	X
Active organ involvement	X		X	X	X	X	X
Ongoing treatment for rcCTD	X		X	X	X	X	X
Concomitant medications	X		X	X	X	X	X
PhGA of disease activity (0-3)	X		X	X	X	X	X
PtGA of disease activity (0-3)	X		X	X	X	X	X
AEs (any type)		X	X	X	X	X	X
Early AEs		X					
PROs (SF-36, FACIT-F)	X		X	X	X	X	X
Healthcare resource utilization	X		X	X	X	X	X

Table legend: *rcCTD, rare and complex Connective Tissue Disease; GCs, glucocorticoids; ESR, erythrocyte sedimentation rate; CRP, C-reactive protein; CBC, complete blood count; PhGA, Physician Global Assessment; PtGA, Patient Global Assessment; AEs, adverse events; PROs, Patient Reported Outcomes; SF-36, 36-item Short Form Health Survey; FACIT-F, Functional Assessment of Chronic Illness Therapy – Fatigue.*

Supplementary Table S2. Definitions of serious adverse events (SAE) and adverse events of special interest (AESI).

SERIOUS ADVERSE EVENTS (SAE)

Any untoward medical occurrence that:

- results in death, or
- in the view of the investigator places the subject at immediate risk of death, or
- requires inpatient hospitalization or prolongation of existing hospitalization, or
- results in persistent or significant disability/incapacity, or
- results in congenital anomaly/birth defect

ADVERSE EVENTS OF SPECIAL INTEREST (AESI)

[adapted from https://brightoncollaboration.us/wp-content/uploads/2020/06/SPEAC_D2.3_V2.0_COVID-19_20200525_public.pdf]

Body System	**COVID-19** *(italic font identifies AESI with existing published Brighton Case Definitions)*	**Rationale for inclusion as an AESI** *(see footnote)*
Immunologic	Enhanced disease following immunization	1 formalin-inactivated measles/RSV vaccines; HIV vaccine 2 Chimeric Yellow Fever Dengue vaccine 5 mouse models SARS/MERS-CoVs
	Multisystem inflammatory syndrome in children	3, 4
Respiratory	Acute respiratory distress syndrome (ARDS)	3, 4
Cardiac	Acute cardiac injury including: • Microangiopathy • Heart failure and cardiogenic shock • Stress cardiomyopathy • Coronary artery disease • Arrhythmia • Myocarditis, pericarditis	3, 4
Hematologic	Coagulation disorder: • Deep vein thrombosis • Pulmonary embolus • Cerebrovascular stroke • Limb ischemia • Haemorrhagic disease	3, 4
Renal	Acute kidney injury	3, 4
Gastrointestinal	Liver injury	3, 4
Neurologic	*Guillain Barré Syndrome*	4
	Anosmia, ageusia	3, 4
	Meningoencephalitis	1, 4
Dermatologic	Chilblain-like lesions	3, 4
	Single organ cutaneous vasculitis	3, 4
	Erythema multiforme	3, 4

Footnote: 1. Proven association with immunization encompassing several different vaccines. 2. Proven association with vaccine that could theoretically be true for Coalition for Epidemic Preparedness Innovations (CEPI) vaccines under development. 3. Theoretical concern based on immunopathogenesis. 4. Theoretical concern related to viral replication during wild type disease. 5. Theoretical concern because it has been demonstrated in an animal model with one or more candidate vaccine platforms.

Supplementary Table S3. Definitions for disease flares.

DISEASE FLARE
At least one should be present: • increase in PhGA ≥1 from previous evaluation • increase in prednisone equivalent dosage >0.1mg/kg/day • hospitalization due to disease activity • added NSAID for disease activity • added new immunosuppressant for disease activity • new disease manifestation attributable to disease activity (physician judgment)
SEVERE DISEASE FLARE
At least one should be present: • increase in PhGA to >2.5 • increase in prednisone equivalent dosage to >0.5mg/kg/day • hospitalization due to disease activity • added cyclophosphamide, mycophenolate mofetil, biological drugs or plasmapheresis for disease activity • new severe disease manifestation attributable to disease activity (physician judgment)

Table legend: *PhGA, Physician Global Assessment; NSAID, non-steroidal anti-inflammatory drug. Adaptation from SELENA-SLEDAI Flare Index [Petri M et al. N Engl J Med 2005].*