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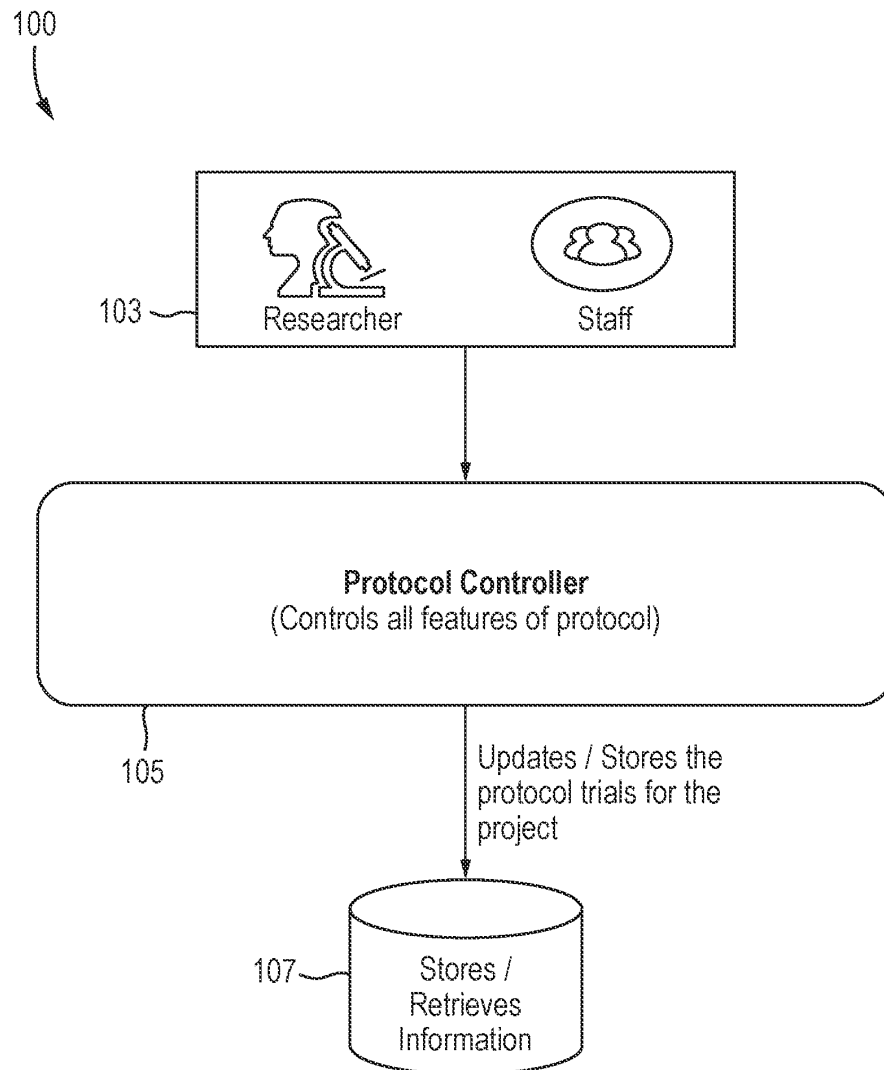


Fig. 2

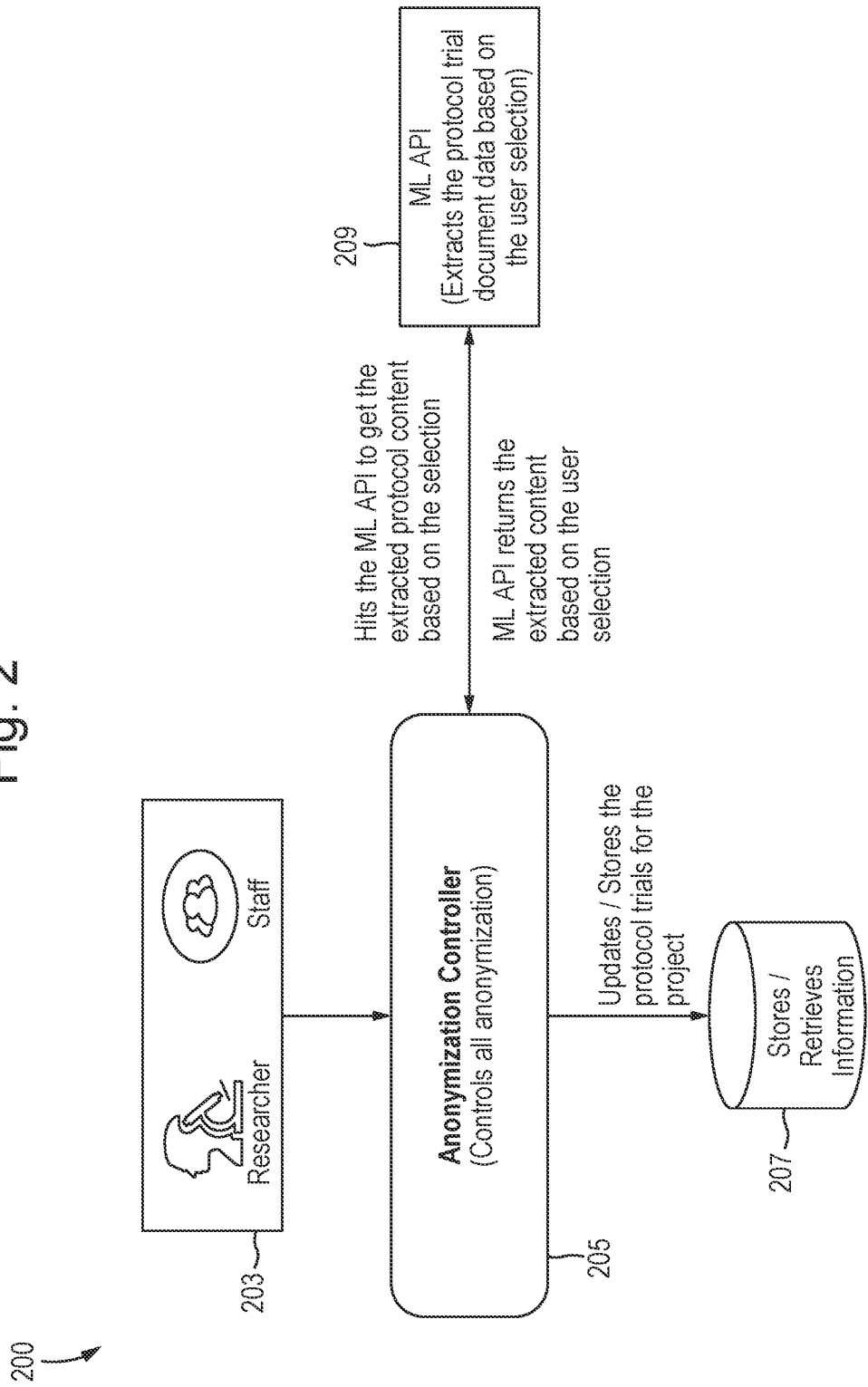


Fig. 3

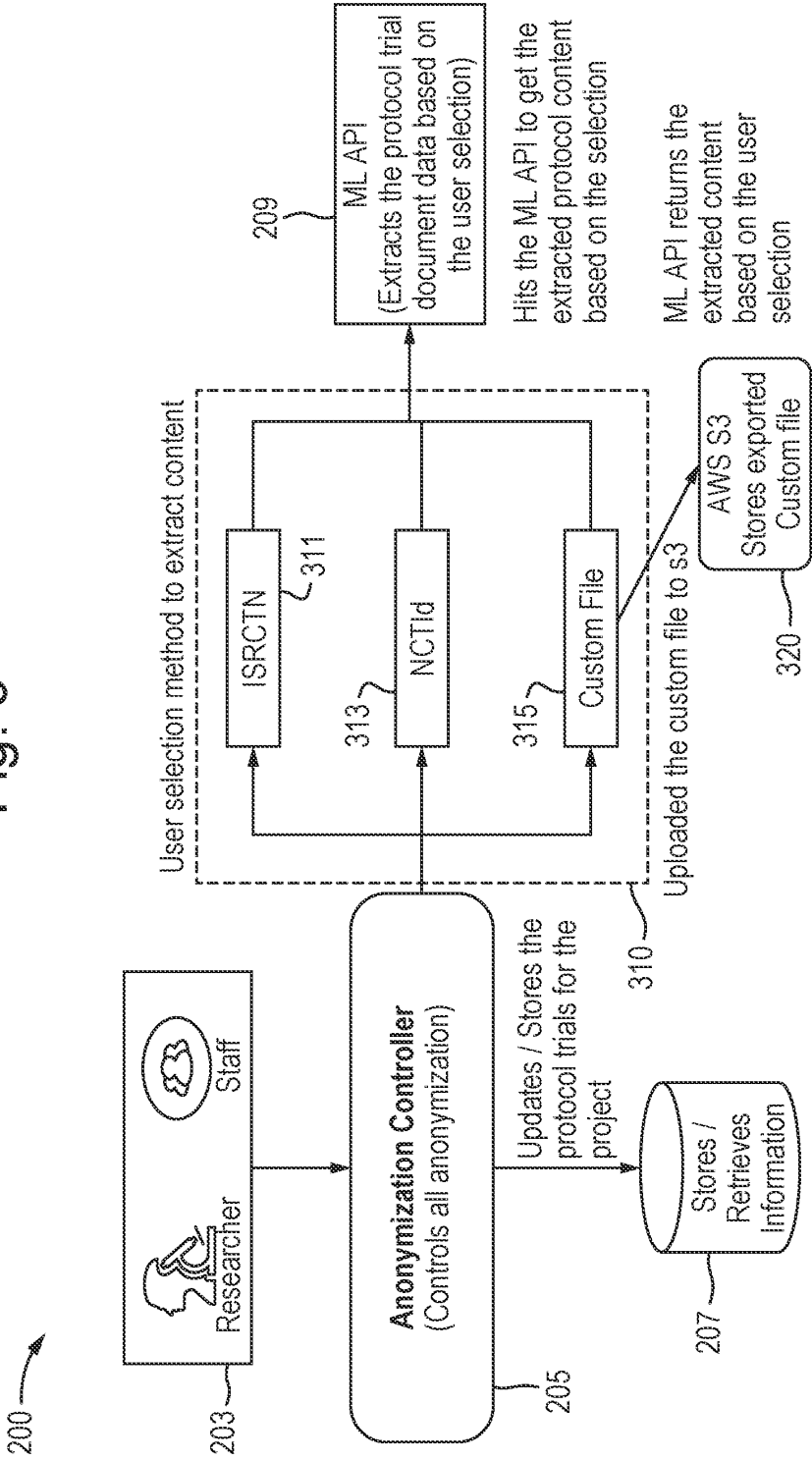


Fig. 4

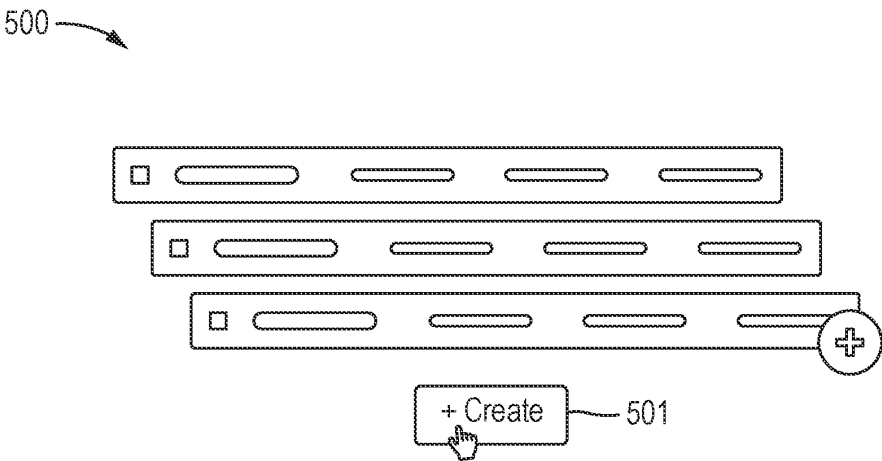


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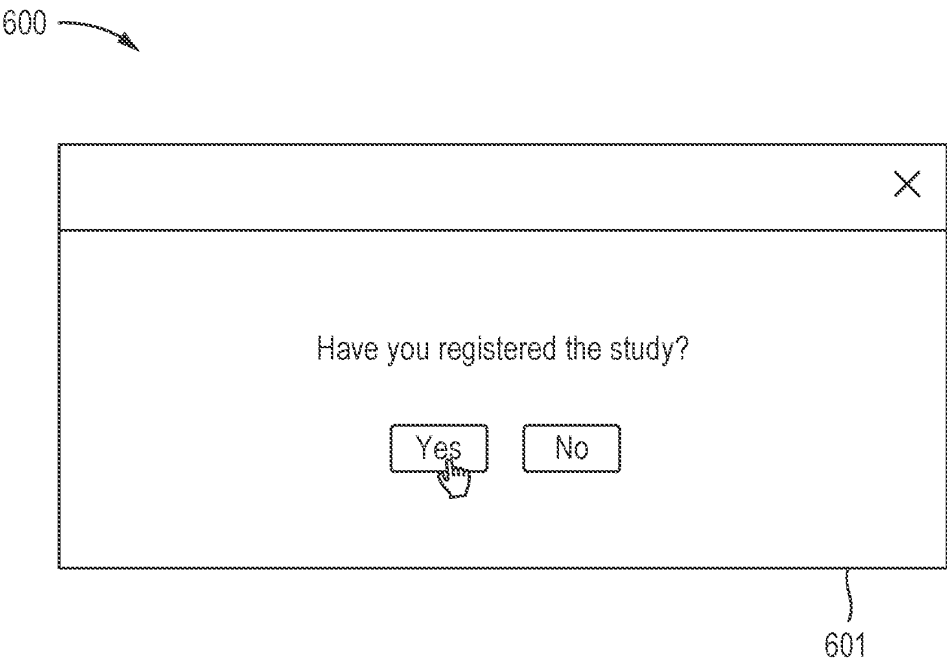


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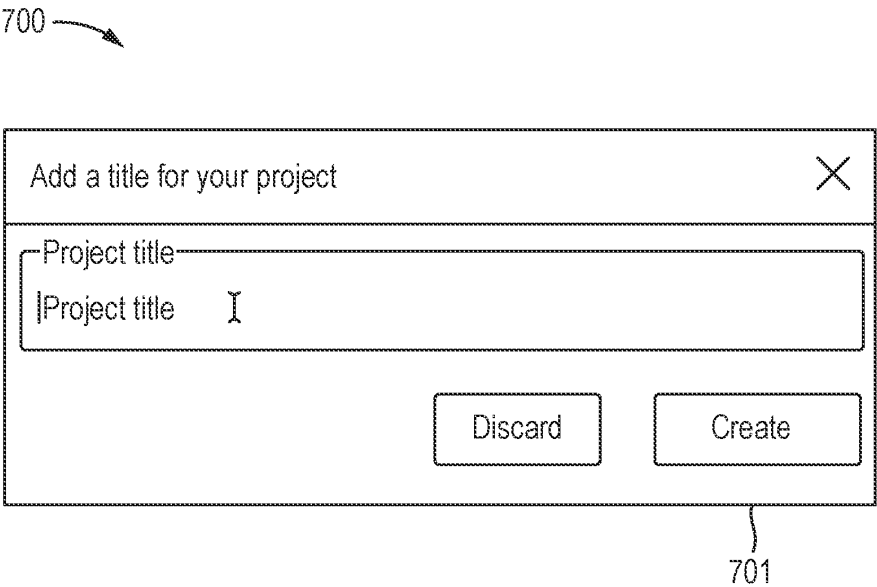


Fig. 7

800

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NCTId

ISRCTN

EUDRACT

Please select your primary registry?

Enter your register id

Done

Upload your protocol draft here
docx or pdf

Drag & Drop your file here or Browse

900

Fig. 8

Overview

Save

X

Title & Additional Identifiers:

Public Title:

Assessing the Longitudinal Cardiopulmonary and Immunological Impacts on COVID-19 Survivors Using an Cardiac MRI, IGM and IGG Multimodal

Principal Investigator:

Prof. Alan Harper

Study Location:

London, United Kingdom

Sponsor:

Celgene - Covid19 Funding Coalition

ISRCTN Id:

ISRCTN13034177

Sponsor Code:

grid.4714.6

901

Fig. 9

1000

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Assessing the Longitudinal Cardiopulmonary and Immunological Impacts on COVID-19 Survivors Using an Cardiac MRI, IGM and IGG Multimodal Approach

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1001

Fig. 10

Disease Type:	Covid19, Cardiopulmonary Disease
Study Design:	Cross-sectional and Longitudinal Cardiovascular Changes in COVID-19 Survivors
Primary Objective:	Assess the longitudinal affects of chronic immune response on the cardiovascular system in COVID-19 patients with MRI
Secondary Objective:	Longitudinal assessment of IGM and IGG level and if there is immunological changes [Time Frame: 12 months] IGG, IGM level using rapid covid antibody titre
Inclusion Criteria:	Adult individuals in the age group over 30 years, Adult individuals under 60 years old.
Exclusion Criteria:	① The Participant Group is the experimental group or cohort of participants being assessed. It is defined by the inclusion and exclusion criteria.
Investigational Medicinal Product:	Suggestion: Adults 30 - 60, 3 months post-COVID19, without cardiovascular complications prior to presenting with COVID19
Participant Group:	Adults 30 - 60, 3 months post-COVID19, without cardiovascular complications prior to presenting with CO
Total Number of Participants:	Adults 30 - 60, 3 months post-COVID19, without cardiovascular complications prior to presenting with COVID19
Study Hypothesis:	Measurement of pulmonary function changes either obstructive or restrictive also lung diffusion and if there is remaining interstitial fibrosis [Time Frame: 12 months] pulmonary function include FEV1, FVC, FEV/fvc, DLCO
Ethics Approval:	Observational Study not required

Fig. 11

1250

Participant Group:	Adults 30 - 60, 3 months post-COVID19, without cardiovascular complications prior to presenting with COVID19
Total Number of Participants:	1
Study Hypothesis:	1) Please select the intervention type from the drop-down that most accurately describes that used in your trial. Options are as follows: • Drug: A chemical substance used as a medicine and recognised in an official pharmacopeia. Examples would include antibiotics and drugs used in chemotherapy • Supplement: A product that has been developed to supplement the diet but are not in themselves considered food. Examples would include minerals, herbs and amino acids • Device: This includes instruments, apparatus, machines or implants, for example, surgical lasers, hearing aids and MRI equipment • Biological/Vaccine: Biological products used as medicines. This includes vaccines, blood and blood products, and human cells and tissues used for transplantation • Procedure/Surgery: Invasive or external procedures/therapies or external therapies used in medical treatment • Behavioural: Treatment that is designed to modify a person's behaviour. This includes behavioural therapies, group therapies and relaxation techniques • Genetic: This includes gene therapies and identification of genes or polymorphisms involved in disease • Mixed: Please select this option if multiple types of intervention are used • Other: Please select if the intervention is different to any listed above
Ethics Approval:	
Trial Setting:	
Trial Type:	1260
Condition:	Suggestion: Primary outcome measure: measurement of pulmonary function changes either obstructive or restrictive also lung diffusion and if there is remaining interstitial fibrosis [Time Frame: 12 months] pulmonary function include FEV1,FVC,FEV/fvc,DLCO
Intervention Type:	Primary outcome measure: measurement of pulmonary function changes either obstructive or restrictive also lung diffusion and if there is remaining interstitial fibrosis [Time Frame: 12 months] pulmonary function include FEV1,FVC,FEV/fvc,DLCO
Primary Outcome Measure:	Primary outcome measure: measurement of pulmonary function changes either obstructive or restrictive also lung diffusion and if there is remaining interstitial fibrosis [Time Frame: 12 months] pulmonary function include FEV1,FVC,FEV/fvc,DLCO
Secondary Outcome Measure:	Longitudinal assessment of IGM and IGG level and if there is immunological changes [Time Frame: 12 months] IGG,IGM level using rapid covid antibody titre

Fig. 12

1300

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30     study rationale and aim: Resolving the COVID-19 pandemic quickly hinges on a crucial factor:
31     how well a person's immune system remembers SARS-CoV-2, the virus behind the disease, after
32     an infection has resolved and the patient is back in good health. This phenomenon, called
33     immune memory, helps our bodies avoid reinfection by a bug persons have had before and
34     influences the potency of life-saving treatments and vaccines. Also, the new coronavirus
35     causes cardiac and pulmonary inflammation. So, our study planned to measure the
36     cardiopulmonary and immunological changes in treated COVID-19 patients. Specific objectives:
37     Measurement the duration of existence of COVID-19 IgM and IgG antibody in patient's plasma,
38     detection of cardiac changes, pulmonary radiological and functional changes after COVID-19
39     infection. This could help detection of functional impairment in COVID-19 survivors which may
40     have economic and social impact. Also, investigator will assess possible protective immune
41     response following infection which may affect vaccination schedule. Methods: One hundred RT-
42     PCR positive COVID-19 patients will be enrolled. HRCT chest, lateral flow immunoassay,
43     spirometry, DLCO and Echo will be done on after 3, 6 and 12 months of discharge.
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48     • Background and significance:

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1301

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Fig. 13

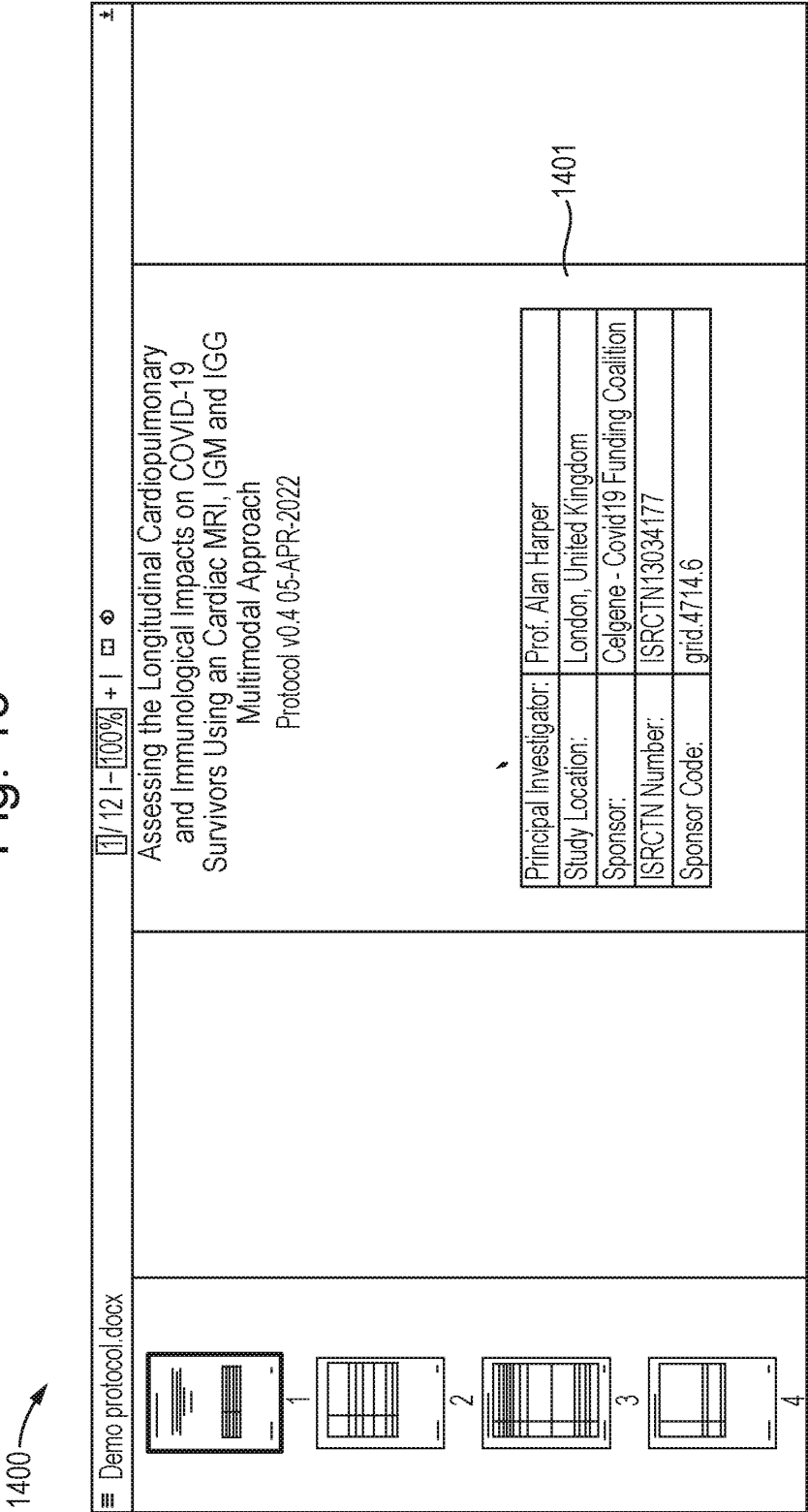


Fig. 14

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2

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involve for you. After you have read the information sheet one of our study staff will go through it with you and answer any questions you may have.

Please read this document carefully. Take time to ask as many questions as you want. The study staff will explain any words or procedures you do not understand.

1. What is the purpose of this study?

the purpose of this study is to find out whether there is a link between COVID19 infection and the levels inflammation in the heart. The study will then test whether inflammatory markers in the blood can tell us more about how COVID19 has affected the heart over time using an imaging machine called a Magnetic Resonance imaging.

2. Why have I been invited?

You have been invited to participate because you have recently been diagnosed with COVID19 and the investigator believes you may be suitable for the study. Approximately 200COVID19patients and 160 healthy 'controls' will be recruited to the trial.

3. Do I have to take part?

It is up to you to decide whether or not to participate. We will describe the study

Public Title
Assessing the Longitudinal Cardiopulmonary and Immunological Impacts on COVID-19 Survivors Using an Cardiac MRI, IGM and IGG
:: Multimodal Approach

Isrctn id
:: ISRCTN13034177

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1501

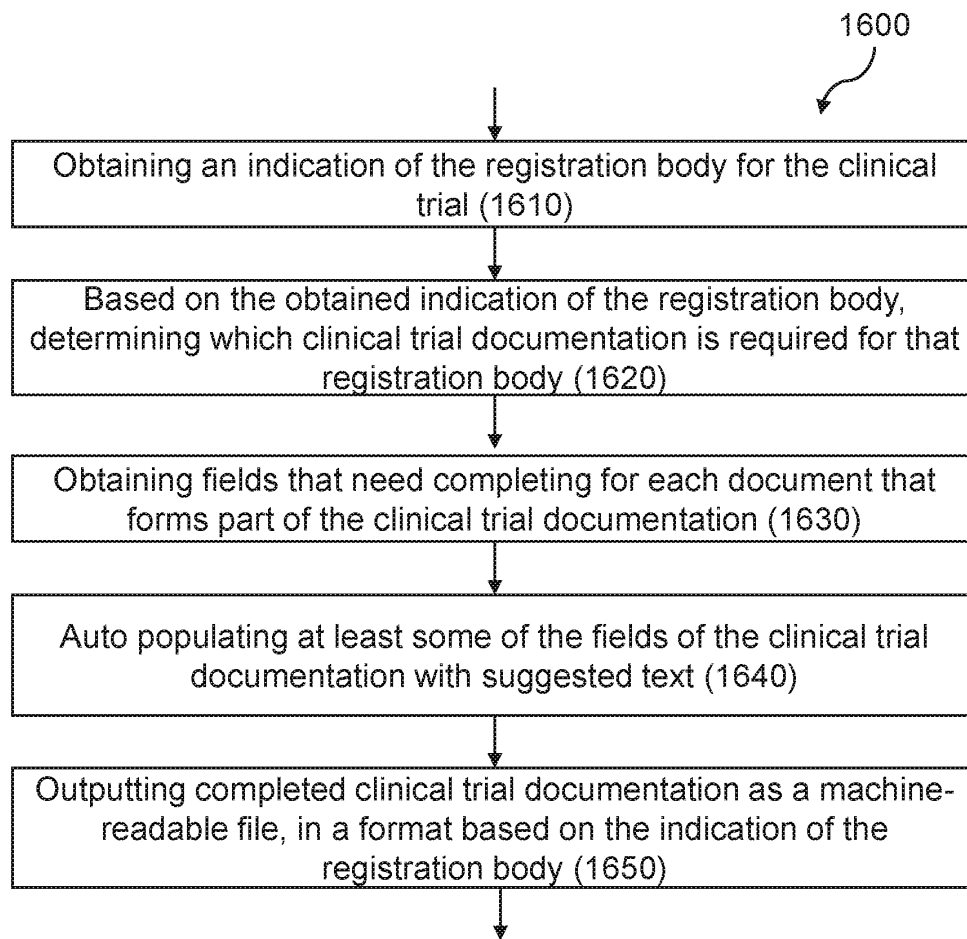


Figure 15

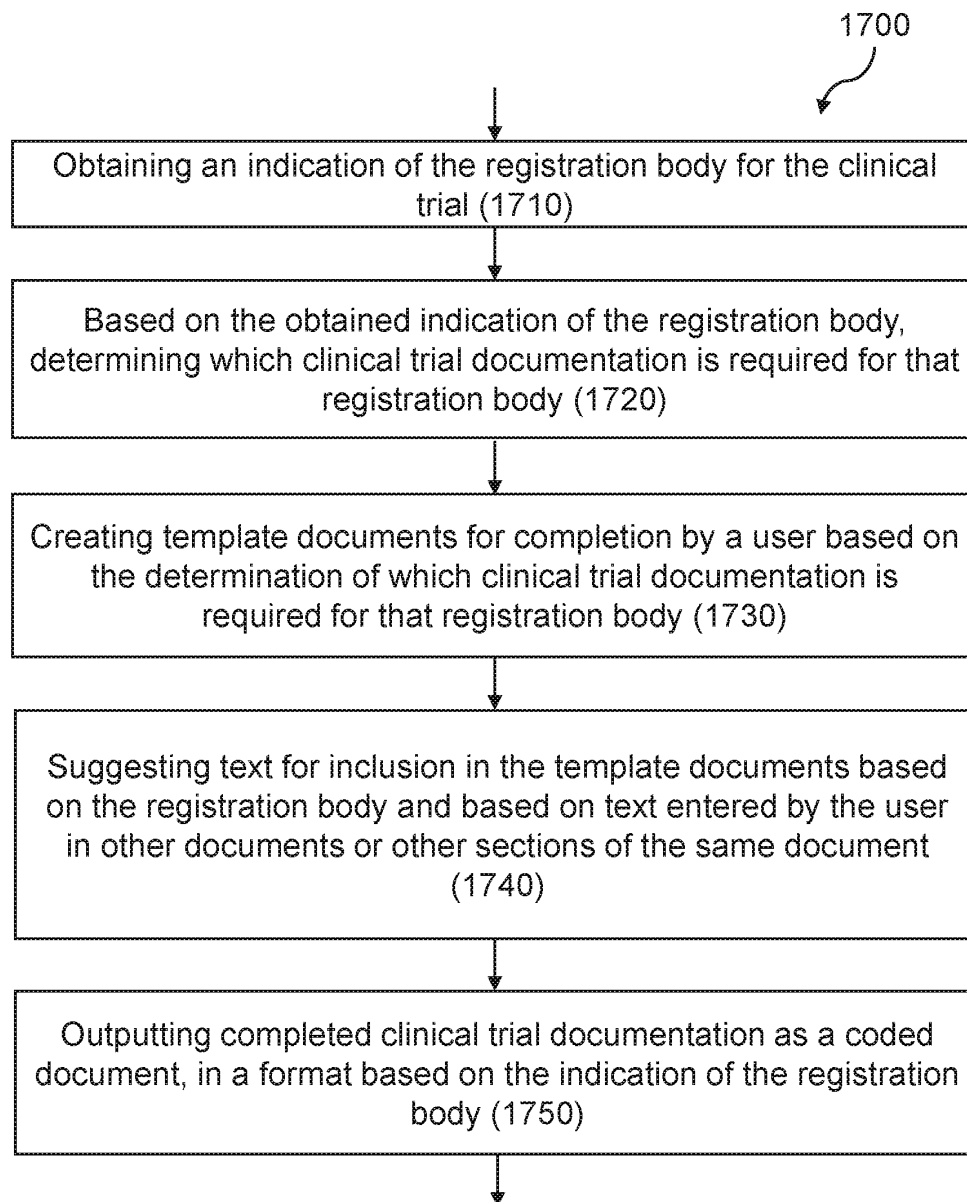


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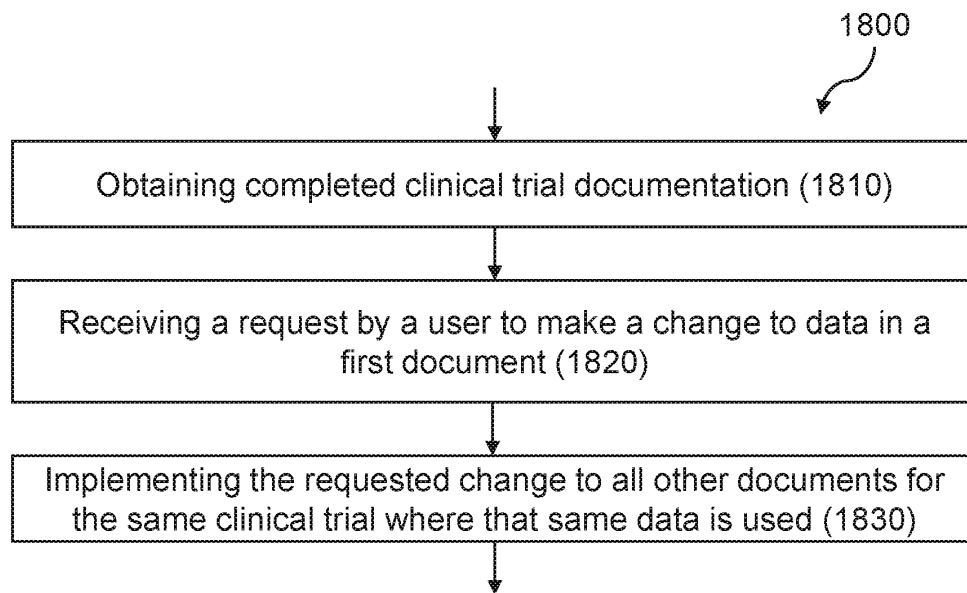


Figure 17

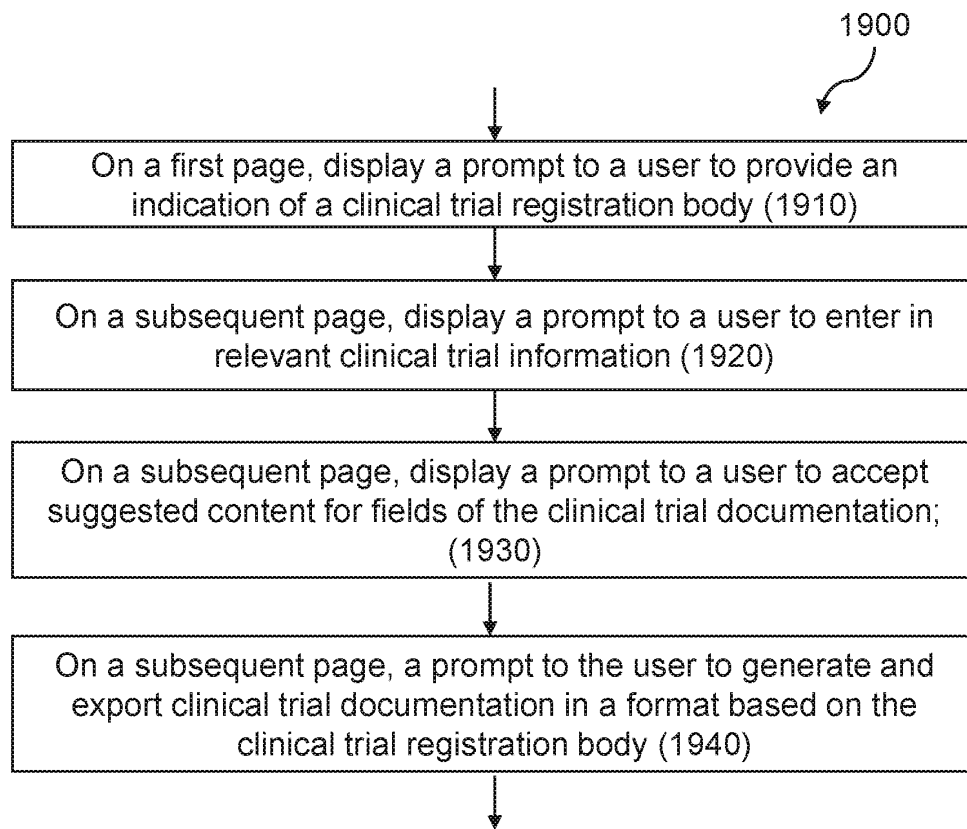


Figure 18

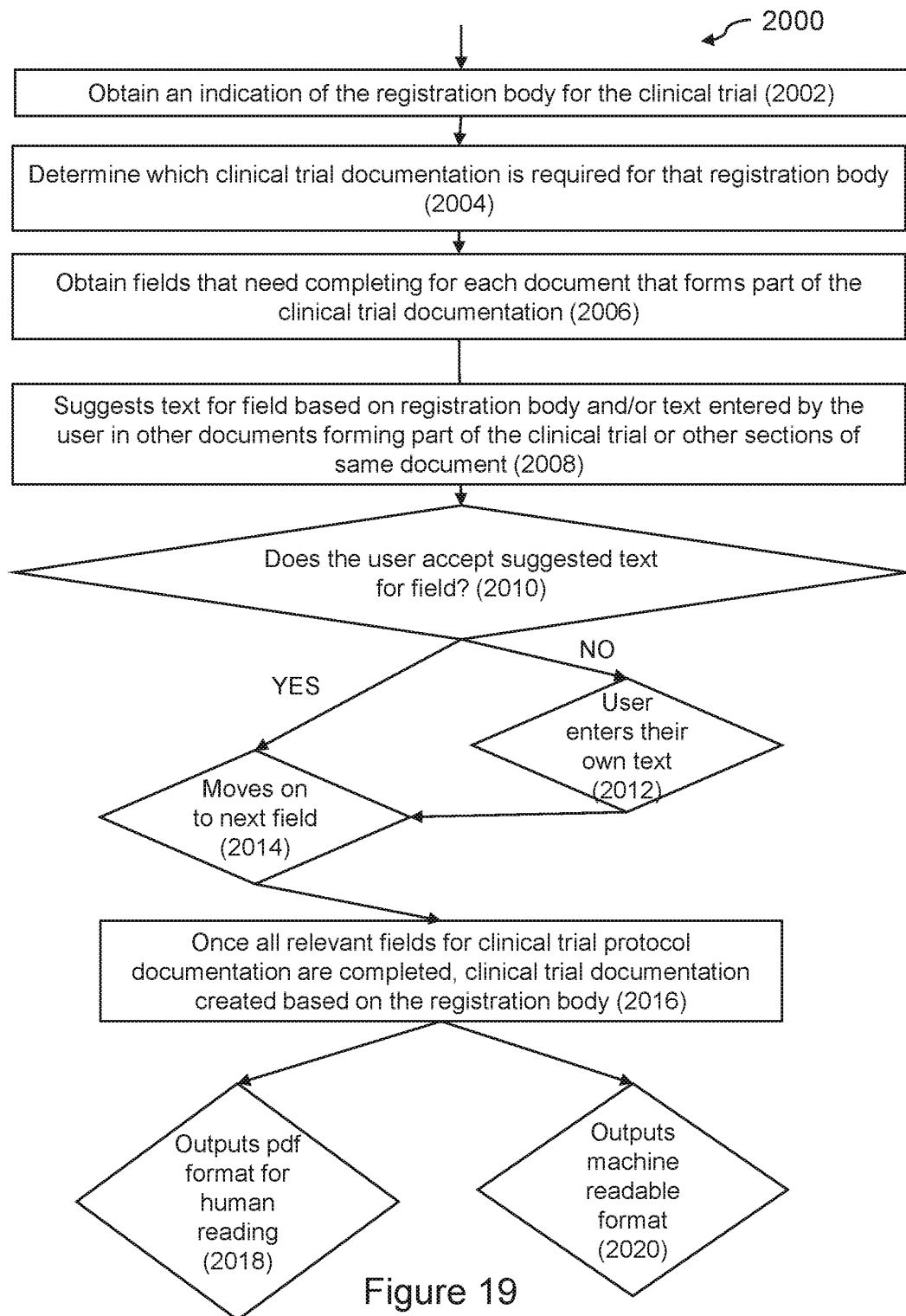


Figure 19

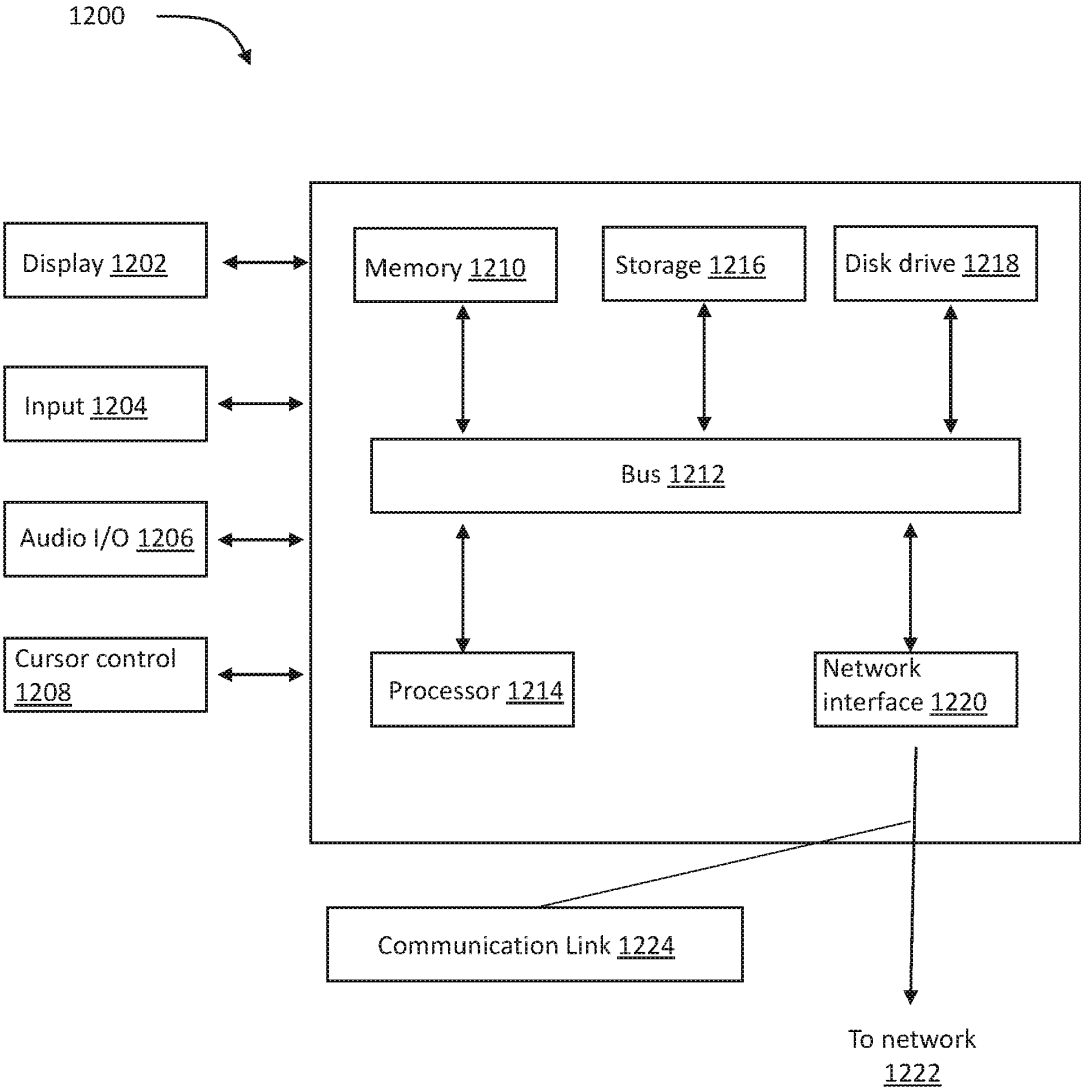


Figure 20