Castor CDMS Study

Case Report Forms

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Visits

Screening

Screening

1. Demographics

1.1 **Year of birth***

YYYY

1.2 **Gender***

- Female
- Male

If 1.2 Gender is equal to **Female** answer this question:

1.2.1 **Pregnancy***

- Yes
- No

Warning message shown if field's value is equal to **Yes**

Check if a patient can continue in the study

Information message shown if field's value is equal to **Yes**

Patient is pregnant

1.3 **Height***

Units: cm

1.4 **Weight***

Units: kg

1.5	BMI	Calculated value

1.6	**Country of origin***	This dropdown field has too many options to list here. See Option Group - Country for its options.

Screening

2. Diagnosis and medical history

2.1 **Primary renal diagnosis***

This dropdown field has too many options to list here. See Option Group - RenalDiagnosis for its options.

If **2.1 Primary renal diagnosis** is equal to **Other** answer this question:

2.1.1 **What other diagnosis***

2.2 **History of cardiovascular disease***

- ○ No
- ○ Yes
- ○ Unknown

2.3 **History of diabetes***

- ○ No
- ○ Yes
- ○ Unknown

2.4 **History of smoking***

- ○ No
- ○ Yes, former
- ○ Yes, current

If **2.4 History of smoking** is not equal to **No** answer this question:

2.4.1 Year smoking started

YYYY

If **2.4 History of smoking** is not equal to **No** answer this question:

2.4.2 Number of packs per day

Units: packs per day

Warning message shown if field's value is smaller or equal than **0**

Enter number of packs per day, i.e. more than 0

Warning message shown if field's value is greater or equal than **4**

Enter number of packs per day (not number of cigarettes, cigars etc)

2.5 **Family history of disease***

- ☐ Renal disease
- ☐ Deafness
- ☐ (Cardio)myopathy
- ☐ Encephalopathy
- ☐ Diabetes Mellitus
- ☐ Hypertension/Cardiovascular disease
- ☐ Thrombosis
- ☐ Malignancy

2.6 Record all relevant current medications
(linked Repeating Data Form: "Medication")

Created on	Name	Start date	Stop date	Dose	Units

Screening

3. Study inclusion

3.1 **Informed consent signed?***

- ○ Yes
- ○ No

If 3.1 Informed consent signed? is equal to **Yes** answer this question:

3.1.1 **Date of informed consent***

YYYY MM DD

Warning message shown if field's value is greater than **NOW**

Date of signature cannot be in the future

3.2 **Has the patient previously participated in a clinical trial?***

- ○ Yes
- ○ No

Exclusion message shown if field's value is equal to **Yes**

Previous trial participation is an exclusion criterion. You cannot proceed with data entry.

3.3 **Is the patient older than 18?***

- ○ Yes
- ○ No

3.4 Inclusion criteria met? Calculated value

Exclusion message shown if field's value is equal to **No**

Inclusion criteria are not met!

Information message shown if field's value is equal to **Yes**

Patient can be randomized. Go to the randomization tab and click randomize.

If **3.4 Inclusion criteria met?** is equal to **Yes**:

Patient can be randomized (go to 'Randomization' section)

If **3.4 Inclusion criteria met?** is equal to **Yes** answer this question:

3.4.2 Randomization allocation

Randomization

First Study Visit

First Study Visit

4. Physical exam

4.1 **Date of visit***

YYYY MM DD

Warning message shown if field's value is greater than **NOW**

Visit date cannot be in the future

4.2 Weight

Units: kg

4.3 Height

Units: cm

4.4 BMI

Calculated value

Units: kg/m^2

4.5 Heart rate

Units: Beats per minute

4.6 Blood pressure measurements - measure in all positions
(linked Repeating Data Form: "Blood pressure")

Created on	Measurement position	Systolic pressure	Diastolic pressure	Date and time of measurement

First Study Visit

5. Blood test

5.1 **Date of blood sample***

YYYY MM DD

Warning message shown if field's value is greater than **NOW**

Date is in the future, please correct

5.2 **Haemoglobin concentration***

Units: mmol/l

5.3 **Hematocrit value***

Units: l/l

5.4 **Blood white blood cell count***

Units: *10^9/L

5.5 **Blood trombocyte count***

Units: *10^9/L

5.6 **Blood urea***

Units: mmol/l

5.7 **Blood creatinine***

Units: umol/l

5.8 **Blood CRP***

Units: mg/L

5.9 **Blood glucose***

Units: mmol/L

First Study Visit

6. Concomitant medication

6.1 Concomitant medication since study inclusion

(linked Repeating Data Form: "Medication")

Created on	Name	Start date	Stop date	Dose	Units

First Study Visit

7. Adverse Events

7.1 Report Adverse Event

Add Repeating Data Button

Second Study Visit

Second Study Visit

8. Physical exam

8.1 **Date of visit***

YYYY MM DD

Warning message shown if field's value is greater than **NOW**

Visit date cannot be in the future

8.2 Weight

Units: kg

8.3 Height

Units: cm

8.4 BMI

Calculated value

Units: kg/m^2

8.5 Heart rate

Units: Beats per minute

8.6 Blood pressure measurements - measure in all positions
(linked Repeating Data Form: "Blood pressure")

Created on	Measurement position	Systolic pressure	Diastolic pressure	Date and time of measurement

Second Study Visit

9. Blood test

9.1 **Date of blood sample***

YYYY MM DD

Warning message shown if field's value is greater than **NOW**

Date is in the future, please correct

9.2 **Haemoglobin concentration***

Units: mmol/l

9.3 **Hematocrit value***

Units: l/l

9.4 **Blood white blood cell count***

Units: *10^9/L

9.5 **Blood trombocyte count***

Units: *10^9/L

9.6 **Blood urea***

Units: mmol/l

9.7 **Blood creatinine***

Units: umol/l

9.8 **Blood CRP***

Units: mg/L

9.9 **Blood glucose***

Units: mmol/L

Second Study Visit

10. Concomitant medication

10.1 Concomitant medication since study inclusion
(linked Repeating Data Form: "Medication")

Created on	Name	Start date	Stop date	Dose	Units

Second Study Visit

11. Adverse Events

11.1 Report Adverse Event

Add Repeating Data Button

Follow-up

Follow-up

12. Physical exam

12.1 **Date of visit***

YYYY MM DD

12.2 Heart rate

Units: Beats per minute

12.3 Blood pressure measurements - measure in all positions
(linked Repeating Data Form: "Blood pressure")

Created on	Measurement position	Systolic pressure	Diastolic pressure	Date and time of measurement

Outcome

Outcome

13. Outcome measures

13.1 **Status***

- ○ Under follow-up
- ○ Referred back to GP
- ○ Lost to follow-up
- ○ Death

If **13.1 Status** is equal to **Death** answer this question:

13.1.1 Date of death

YYYY MM DD

Warning message shown if field's value is greater than **NOW**

Date of death is in the future!

If **13.1 Status** is equal to **Lost to follow-up** answer this question:

13.1.2 Date lost to follow-up

YYYY MM DD

Warning message shown if field's value is greater than **NOW**

Date is in the future!

If **13.1 Status** is equal to **Lost to follow-up** answer this question:

13.1.3 Reason for lost to follow-up

Repeating Data

Unscheduled visit

Unscheduled visit

1. Physical exam

1.1 **Type of visit***

- ○ in-patient admission
- ○ out-patient visit
- ○ admission to day-care

1.2 **Date of visit***

YYYY MM DD

1.3 Body weight

Units: kg

1.4 Systolic blood pressure in mmHg

Units: mmHg

1.5 Diastolic blood pressure in mmHg

Units: mmHg

1.6 Heart rate

Units: Beats per minute

1.7 Report Adverse Event

Add Repeating Data Button

Unscheduled visit

2. Laboratory

2.1 Date of blood sample

YYYY MM DD

2.2 Haemoglobin concentration

Units: mmol/l

2.3 Hematocrit value

Units: l/l

2.4 Blood white blood cell count

Units: *10^9/L

2.5 Blood trombocyte count

Units: *10^9/L

2.6 Blood urea

Units: mmol/l

2.7 Blood creatinine

Units: umol/l

2.8 Blood CRP

Units: mg/L

2.9 Blood glucose	Units: mmol/L
2.10 Report Adverse Event	Add Repeating Data Button

Medication

Medication

1. Medication

1.1	**Name***	This dropdown field has too many options to list here. See Option Group - med_class_dropdown for its options.
1.2	**Start date***	YYYY MM DD
1.3	**Stop date***	YYYY MM DD
1.4	**Dose***	
1.5	**Units***	○ Unknown ○ ug/day ○ mg/day ○ g/day ○ ug/week ○ mg/week ○ g/week

Pregnancy

Pregnancy

1. Pregnancy

1.1 **Date***

YYYY MM DD

Adverse event

Adverse event

1. Event details

1.1 **Describe the adverse event***

1.2 **Start date of adverse event***

YYYY MM DD

Warning message shown if field's value is greater than **NOW**

This date is in the future

1.3 **Stop date of AE***

YYYY MM DD

1.4 **Severity***

- ○ Mild
- ○ Moderate
- ○ Severe
- ○ Life-threatening

1.5 **Relationship to intervention***

- ○ Not related
- ○ Unlikely related
- ○ Possibly related
- ○ Probably related
- ○ Definitely related

1.6 **Action taken regarding intervention***

- ○ None
- ○ Dose modification
- ○ Medical intervention
- ○ Hospitalization
- ○ Intervention discontinued
- ○ Other

1.7 **Outcome of AE***

- ○ Resolved
- ○ Recovered with minor sequelae
- ○ Recovered with major sequelae
- ○ Ongoing / continuing treatment
- ○ Condition worsening
- ○ Death
- ○ Unknown

1.8 **Expected?***

- ○ Yes
- ○ No

1.9 **Serious Adverse Event?***

- ○ Yes
- ○ No

Blood pressure

Blood pressure

1. BP measurements

1.1 **Measurement position***

- ○ Lying down
- ○ Sitting
- ○ Standing

1.2 **Systolic pressure***

1.3 **Diastolic pressure***

1.4 **Date and time of measurement***

YYYY MM DD HH MM

Surveys

Generalised Anxiety Disorder Questionnaire (GAD-7)

Generalised Anxiety Disorder Questionnaire (GAD-7)

1. GAD-7

Over the last 2 weeks, how often have you been bothered by any of the following problems?

1.1 **Feeling nervous, anxious or on edge?***
- ○ Not at all
- ○ Several days
- ○ More than half the days
- ○ Nearly every day

1.2 **Not being able to stop or control worrying?***
- ○ Not at all
- ○ Several days
- ○ More than half the days
- ○ Nearly every day

1.3 **Worrying too much about different things?***
- ○ Not at all
- ○ Several days
- ○ More than half the days
- ○ Nearly every day

1.4 **Trouble relaxing?***
- ○ Not at all
- ○ Several days
- ○ More than half the days
- ○ Nearly every day

1.5 **Being so restless that it is hard to sit still?***
- ○ Not at all
- ○ Several days
- ○ More than half the days
- ○ Nearly every day

1.6 **Becoming easily annoyed or irritable?***
- ○ Not at all
- ○ Several days
- ○ More than half the days
- ○ Nearly every day

1.7 **Feeling afraid as if something awful might happen?***

- ○ Not at all
- ○ Several days
- ○ More than half the days
- ○ Nearly every day

Short Form Health Survey SF-36

Short Form Health Survey SF-36

1. SF 36

1.1 **In general, would you say your health is***

- ○ Excellent
- ○ Very good
- ○ Good
- ○ Fair
- ○ Poor

1.2 **Compared to one year ago, how would your rate your health in general now?***

- ○ Much better now than one year ago
- ○ Somewhat better now than one year ago
- ○ About the same
- ○ Somewhat worse now than one year ago
- ○ Much worse now than one year ago

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

1.3 **Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports***

- ○ Yes, limited a lot
- ○ Yes, limited a little
- ○ No, not limited at all

1.4 **Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf***

- ○ Yes, limited a lot
- ○ Yes, limited a little
- ○ No, not limited at all

1.5 **Lifting or carrying groceries***

- ○ Yes, limited a lot
- ○ Yes, limited a little
- ○ No, not limited at all

1.6 **Climbing several flights of stairs***

- ○ Yes, limited a lot
- ○ Yes, limited a little
- ○ No, not limited at all

1.7 **Climbing one flight of stairs***
- ○ Yes, limited a lot
- ○ Yes, limited a little
- ○ No, not limited at all

1.8 **Bending, kneeling, or stooping***
- ○ Yes, limited a lot
- ○ Yes, limited a little
- ○ No, not limited at all

1.9 **Walking more than a mile***
- ○ Yes, limited a lot
- ○ Yes, limited a little
- ○ No, not limited at all

1.10 **Walking several blocks***
- ○ Yes, limited a lot
- ○ Yes, limited a little
- ○ No, not limited at all

1.11 **Walking one block***
- ○ Yes, limited a lot
- ○ Yes, limited a little
- ○ No, not limited at all

1.12 **Bathing or dressing yourself***
- ○ Yes, limited a lot
- ○ Yes, limited a little
- ○ No, not limited at all

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

1.13 **Cut down the amount of time you spent on work or other activities***
- ○ Yes
- ○ No

1.14 **Accomplished less than you would like***
- ○ Yes
- ○ No

1.15 **Were limited in the kind of work or other activities***

- ○ Yes
- ○ No

1.16 **Had difficulty performing the work or other activities (for example, it took extra effort)***

- ○ Yes
- ○ No

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

1.17 **Cut down the amount of time you spent on work or other activities***

- ○ Yes
- ○ No

1.18 **Accomplished less than you would like***

- ○ Yes
- ○ No

1.19 **Didn't do work or other activities as carefully as usual***

- ○ Yes
- ○ No

1.20 **During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?***

- ○ Not at all
- ○ Slightly
- ○ Moderately
- ○ Quite a bit
- ○ Extremely

1.21 **How much bodily pain have you had during the past 4 weeks?***

- ○ None
- ○ Very mild
- ○ Mild
- ○ Moderate
- ○ Severe
- ○ Very severe

1.22 **During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?***

- ○ Not at all
- ○ A little bit
- ○ Moderately
- ○ Quite a bit
- ○ Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

1.23 **Did you feel full of pep?***

- ○ All of the time
- ○ Most of the time
- ○ A good bit of the time
- ○ Some of the time
- ○ A little of the time
- ○ None of the time

1.24 **Have you been a very nervous person?***

- ○ All of the time
- ○ Most of the time
- ○ A good bit of the time
- ○ Some of the time
- ○ A little of the time
- ○ None of the time

1.25 **Have you felt so down in the dumps that nothing could cheer you up?***

- ○ All of the time
- ○ Most of the time
- ○ A good bit of the time
- ○ Some of the time
- ○ A little of the time
- ○ None of the time

1.26 **Have you felt calm and peaceful?***

- ○ All of the time
- ○ Most of the time
- ○ A good bit of the time
- ○ Some of the time
- ○ A little of the time
- ○ None of the time

1.27 **Did you have a lot of energy?***

- ○ All of the time
- ○ Most of the time
- ○ A good bit of the time
- ○ Some of the time
- ○ A little of the time
- ○ None of the time

1.28 **Have you felt downhearted and blue?***

- ○ All of the time
- ○ Most of the time
- ○ A good bit of the time
- ○ Some of the time
- ○ A little of the time
- ○ None of the time

1.29 **Did you feel worn out?***

- ○ All of the time
- ○ Most of the time
- ○ A good bit of the time
- ○ Some of the time
- ○ A little of the time
- ○ None of the time

1.30 **Have you been a happy person?***

- ○ All of the time
- ○ Most of the time
- ○ A good bit of the time
- ○ Some of the time
- ○ A little of the time
- ○ None of the time

1.31 **Did you feel tired?***

- ○ All of the time
- ○ Most of the time
- ○ A good bit of the time
- ○ Some of the time
- ○ A little of the time
- ○ None of the time

1.32 **During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc)?***

- ○ All of the time
- ○ Most of the time
- ○ Some of the time
- ○ A little of the time
- ○ None of the time

How true or false is each of the following statements for you?

1.33 **I seem to get sick a little easier than other people***

- ○ Definitely true
- ○ Mostly true
- ○ Don't know
- ○ Mostly false
- ○ Definitely false

1.34 **I am healthy as anybody I know***

- ○ Definitely true
- ○ Mostly true
- ○ Don't know
- ○ Mostly false
- ○ Definitely false

1.35 **I expect my health to get worse***

- ○ Definitely true
- ○ Mostly true
- ○ Don't know
- ○ Mostly false
- ○ Definitely false

1.36 **My health is excellent***

- ○ Definitely true
- ○ Mostly true
- ○ Don't know
- ○ Mostly false
- ○ Definitely false

Option Groups

Country

- Afghanistan
- Albania
- Algeria
- Andorra
- Angola
- Antigua and Barbuda
- Argentina
- Armenia
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bhutan
- Bolivia
- Bosnia and Herzegovina
- Botswana
- Brazil
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cabo Verde
- Cambodia
- Cameroon
- Canada
- Central African Republic
- Chad
- Chile
- China
- Colombia
- Comoros
- Democratic Republic of the Congo
- Republic of the Congo
- Costa Rica
- Cote d Ivoire
- Croatia
- Cuba
- Cyprus
- Czech Republic
- Denmark
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Ethiopia

- Fiji
- Finland
- France
- Gabon
- Gambia
- Georgia
- Germany
- Ghana
- Greece
- Grenada
- Guatemala
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Honduras
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Israel
- Italy
- Jamaica
- Japan
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Libya
- Liechtenstein
- Lithuania
- Luxembourg
- Macedonia
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Mauritania
- Mauritius
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Morocco
- Mozambique
- Myanmar (Burma)
- Namibia

- Nauru
- Nepal
- Netherlands
- New Zealand
- Nicaragua
- Niger
- Nigeria
- North Korea
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Poland
- Portugal
- Qatar
- Romania
- Russia
- Rwanda
- Saint Kitts and Nevis
- Saint Lucia
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- Sao Tome and Principe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Swaziland
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- Timor-Leste
- Togo
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Tuvalu

- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States of America
- Uruguay
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Yemen
- Zambia
- Zimbabwe

med_class_dropdown

- ACE inhibitor (ACEi)
- Angiotensin receptor blocker (ARB)
- Loop diuretics
- Anti-aldosterone diurectics
- Thiazide diuretics
- Other diurectics
- Lipid lowering drugs
- Anti-platelets
- Anti-coagulants
- Prednisolone (oral administration)
- Methylprednisolone (IV pulse therapy)
- Cyclophosphamide
- Cyclosporin A
- Tacrolimus
- Mycofenolate Mofetil (MMF)
- Azathioprine
- Chloorambucil
- Rituximab
- Oral anti-diabetics
- Insulin s.c.
- Anti-Blyss (belumimab)
- ACTH
- Ofatumumab
- NSAID
- Eculizumab
- Bortezomib
- Daratumumab
- IVIG
- Electrolyte supplements
- Other antihypertensives
- Proton pump inhibitors (PPIs)
- Other medication

RenalDiagnosis

- Kidney stones
- Nephrotic syndrome
- Minimal change nephropathy
- Focal glomerulosclerosis
- Membranous nephropathy
- IgA nephropathy
- Henoch Schonlein Purpura/ IgA vasculitis
- Glomerulonephritis
- Glomerulopathy
- Lupus nephritis
- Diabetic nephropathy
- Cast nephropathy

- M. Alport
- Fanconi
- Other