

**Pre-medical Cancer Immunotherapy  
Network for Canine Trials**

**PRECINCT**

**Case Report Forms**

**V1.0.20180918**

# PRECINCT

## Adverse Events

Subject ID: \_\_\_\_\_

Subject Name: \_\_\_\_\_

AE # \_\_\_\_\_

Event Term (based on VCOG-CTCAE) \_\_\_\_\_

If Other, specify \_\_\_\_\_

Grade  1  2  3  4  5

Attribution to study treatment

- Unrelated
- Unlikely
- Possible
- Probable
- Definite

Outcome

- Recovered
- Recovered with sequelae
- Death
- Unknown
- Not recovered

Action taken/Treatment

- No action taken
- Study treatment adjusted
- Treatment initiated
- Hospitalization/prolonged hospitalization
- Withdrawn from study
- Unknown

Start Date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)

Stop Date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)

# PRECINCT

## Death Form

Subject ID: \_\_\_\_\_

Subject Name: \_\_\_\_\_

Date of Death \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)

- Primary cause of death
- Disease progression
  - Adverse event
  - Euthanasia
  - Other

If Other, specify \_\_\_\_\_

- Was a necropsy performed?
- Yes
  - No
  - Unknown

Date of necropsy \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)

Upload Necropsy Report

# PRECINCT

## Demographics

Subject ID: \_\_\_\_\_

Subject First Name: \_\_\_\_\_

Subject First Name \_\_\_\_\_

Age, Years \_\_\_\_\_

Age, Months \_\_\_\_\_

Gender  Male  Female

Is the subject intact or neutered?  Intact  Neutered

Breed \_\_\_\_\_

Date of first study visit \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ (mm-dd-yyyy)

Weight in kg \_\_\_\_\_ . \_\_\_\_\_

Was owner consented?  Yes  No

Date of consent \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ (mm-dd-yyyy)

Was eligibility confirmed?  Yes  No

Was an exception given?  Yes  No

- Choose all that apply
- Compassionate use
  - Investigator decision
  - Other

If Other, specify \_\_\_\_\_

# PRECINCT

## Follow Up

Subject ID: \_\_\_\_\_

Subject Name: \_\_\_\_\_

Date of follow up \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)

Weight in kg \_\_\_\_\_ . \_\_\_\_\_

### Target Lesions

Target lesion 1 measured  Yes  No

If No, reason  Surgical resection

Other

If Other, specify \_\_\_\_\_

Target lesion 1 location \_\_\_\_\_

Target lesion 1 longest diameter in mm \_\_\_\_\_

Target lesion 2 measured  Yes  No  N/A

If No, reason  Surgical resection

Other

If Other, specify \_\_\_\_\_

Target lesion 2 location \_\_\_\_\_

Target lesion 2 longest diameter in mm \_\_\_\_\_

Target lesion 3 measured  Yes  No  N/A

If No, reason  Surgical resection

Other

If Other, specify \_\_\_\_\_

Target lesion 3 location \_\_\_\_\_

Target lesion 3 longest diameter in mm \_\_\_\_\_

# PRECINCT

## Follow Up

Subject ID: \_\_\_\_\_

Subject Name: \_\_\_\_\_

Target lesion 4 measured

Yes     No     N/A

If No, reason

Surgical resection

Other

If Other, specify

\_\_\_\_\_

Target lesion 4 location

\_\_\_\_\_

Target lesion 4 longest diameter in mm \_\_\_\_\_

Target lesion 5 measured

Yes     No     N/A

If No, reason

Surgical resection

Other

If Other, specify

\_\_\_\_\_

Target lesion 5 location

\_\_\_\_\_

Target lesion 5 longest diameter in mm \_\_\_\_\_

Best response

Complete Response (CR)

Partial Response (PR)

Stable Disease (SD)

Progressive Disease (PD)

Response criteria

Standard RECIST

IR-RECIST

Other

If Other, specify

\_\_\_\_\_

Primary Diagnosis

- B-cell lymphoma
- T-cell lymphoma
- Glioma
- Osteosarcoma (OSA)
- Melanoma
- Other

If Other, specify

\_\_\_\_\_

WHO Stage

- I
- II
- III
- IV
- V

Sub-stage (if lymphoma)

- A
- B
- N/A

Date of diagnosis

\_\_\_\_/\_\_\_\_/\_\_\_\_ (mm-dd-yyyy)

Method of diagnosis  
(check all that apply)

- Aspirate
- Biopsy
- Imaging
- None

If aspirate or biopsy  
(check all that apply)

- Histopathology
- Cytology
- Immunophenotyping

**Target Lesions**

Target lesion 1 measured

- Yes
- No

If No, reason

- Surgical resection

- Other

If Other, specify

\_\_\_\_\_

Target lesion 1 location

\_\_\_\_\_

Target lesion 1 longest diameter in mm

\_\_\_\_\_

Target lesion 2 measured

- Yes
- No
- N/A

If No, reason

- Surgical resection

- Other

If Other, specify

\_\_\_\_\_

Target lesion 2 location

\_\_\_\_\_

Target lesion 2 longest diameter in mm

\_\_\_\_\_

# PRECINCT

## Medical History

Subject ID: \_\_\_\_\_

Subject Name: \_\_\_\_\_

Target lesion 3 measured

Yes     No     N/A

If No, reason

Surgical resection

Other

If Other, specify

\_\_\_\_\_

Target lesion 3 location

\_\_\_\_\_

Target lesion 3 longest diameter in mm \_\_\_\_\_

Target lesion 4 measured

Yes     No     N/A

If No, reason

Surgical resection

Other

If Other, specify

\_\_\_\_\_

Target lesion 4 location

\_\_\_\_\_

Target lesion 4 longest diameter in mm \_\_\_\_\_

Target lesion 5 measured

Yes     No     N/A

If No, reason

Surgical resection

Other

If Other, specify

\_\_\_\_\_

Target lesion 5 location

\_\_\_\_\_

Target lesion 5 longest diameter in mm \_\_\_\_\_



Survey Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ (mm-dd-yyyy)

For all questions, answer on the following scale:

- 1 = Strongly Disagree  
2 = Mostly Disagree  
3 = Neither Agree nor Disagree  
4 = Mostly Agree  
5 = Strongly Agree

**Happiness**

1. My pet wants to play  1  2  3  4  5
2. My pet responds to my presence  1  2  3  4  5
3. My pet enjoys life  1  2  3  4  5

**Mental Status**

4. My pet has more good days than bad days  1  2  3  4  5
5. My pet sleeps more, is awake less  1  2  3  4  5
6. My pet seems dull or depressed, not alert  1  2  3  4  5

**Pain**

7. My pet is in pain  1  2  3  4  5
8. My pet pants frequently, even at rest  1  2  3  4  5
9. My pet shakes or trembles occasionally  1  2  3  4  5

**Appetite**

10. My pet eats the usual amount of food  1  2  3  4  5
11. My pet acts nauseous or vomits  1  2  3  4  5
12. My pet eats treats/snacks  1  2  3  4  5

**Hygiene**

13. My pet keeps him/herself clean  1  2  3  4  5
14. My pet smells like urine or has skin irritation  1  2  3  4  5
15. My pet's hair is greasy, matted, rough looking  1  2  3  4  5

1 = Strongly Disagree  
2 = Mostly Disagree  
3 = Neither Agree nor Disagree  
4 = Mostly Agree  
5 = Strongly Agree

**Water Intake (Hydration)**

- 16. My pet drinks adequately  1  2  3  4  5
- 17. My pet has diarrhea  1  2  3  4  5
- 18. My pet is urinating a normal amount  1  2  3  4  5

**Mobility**

- 19. My pet moves normally  1  2  3  4  5
- 20. My pet lays in one place all day long  1  2  3  4  5
- 21. My pet is as active as he/she has been  1  2  3  4  5

**General Health**

- 22. General health compared to last evaluation  1  2  3  4  5
- 23. General health compared to initial diagnosis of cancer  1  2  3  4  5

24. Current quality of life Very Poor Excellent

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(Place a mark on the scale above)

# PRECINCT

## Specimen Collection

Subject ID: \_\_\_\_\_

Subject Name: \_\_\_\_\_

Date of specimen \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)

Location \_\_\_\_\_

If Other, specify \_\_\_\_\_

Type of specimen (choose one)

- Serum
- Plasma
- Urine
- CSF
- PBMCs
- Cell pellet
- TILs
- Tissue
- Other

Specify other specimen \_\_\_\_\_

Method of preservation

(for Tissue, TILs, PBMCs, and Other)

- FFPE
- Flash Frozen
- OCT
- RNA later (extraction)
- Other viable cell suspension

Specify cell suspension method \_\_\_\_\_

Indicate SOP # used to collect specimen \_\_\_\_\_

Time point

- Pre-treatment
- Post-treatment

Study \_\_\_\_\_

# PRECINCT

## Study Stop

Subject ID: \_\_\_\_\_

Subject Name: \_\_\_\_\_

Date of study stop \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm/dd/yyyy)

Did the subject complete the study?  Yes  No

Reason for withdrawal from study  
(choose all that apply)

- Subject withdrawn due to disease progression/relapse
- Subject withdrawn due to developing an unrelated medical or surgical condition
- Owner non-compliance
- Adverse event (complete AE form if not done)
- Lost to follow up
- Owner request
- Investigator judgment
- Death (complete Death form)
- Other

If Other, specify

\_\_\_\_\_

Date of Progression/Relapse \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm/dd/yyyy)

Adverse Event number \_\_\_\_\_

Best response at time of withdrawal

- Complete Response (CR)
- Partial Response (PR)
- Stable Disease (SD)
- Progressive Disease (PD)

Response criteria

- Standard RECIST
- IR-RECIST
- Other

If Other, specify

\_\_\_\_\_

# PRECINCT

## Cancer Treatments

Subject ID: \_\_\_\_\_

Subject Name: \_\_\_\_\_

Surgical resection

Yes  No

Date of surgical resection \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)

Radiation

Yes  No

Start date of radiation \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)

Stop date of radiation \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)

Chemotherapy

Yes  No

Start date of chemotherapy \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)

Stop date of chemotherapy \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)

Other Cancer Treatment 1

Yes  No

If Other, specify \_\_\_\_\_

Date of treatment \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)

Other Cancer Treatment 2

Yes  No

If Other, specify \_\_\_\_\_

Date of treatment \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)

Other Cancer Treatment 3

Yes  No

If Other, specify \_\_\_\_\_

Date of treatment \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm-dd-yyyy)