

GENESISCARE CANCER CARE RESEARCH SITE PROFILE FORM

The intent of the GenesisCare Cancer Care Research Profile form is to capture site capabilities and the services that are available to the site.

1. FORM COMPLETED BY	
Full Name: Bianca Karle	Role: Clinical Trials Unit Manager
Team Email: bianca.karle@genesiscare.com	
Date Completed: 06/08/2020	

2. SITE DETAILS- <i>please complete a separate form for each site</i>	
Address: Level 1, 38 Pacific Highway	
City: St. Leonards	State: NSW
Country: Australia	Postal Code: 2065

3. SITE ADDRESS (S)		
Centre Lead:	Name: Gail Wang	Contact details: P: +61 2 8037 4100 E: gail.wang@genesiscare.com
Pharmacist:	Name: Meneka Silva Arora	Contact details: P: 0419 365 724 E: meneka.silvaarora@genesiscare.com
Physicist:	Name:	Contact details:
RT Planning Head:	Name:	Contact details:

4. SITE EXPERIENCE
Therapeutic Area: <input type="checkbox"/> Radiotherapy <input checked="" type="checkbox"/> Medical Oncology <input type="checkbox"/> Haematology <input checked="" type="checkbox"/> Theranostics
Clinical research projects phase capabilities: <input checked="" type="checkbox"/> I <input checked="" type="checkbox"/> II <input checked="" type="checkbox"/> III <input checked="" type="checkbox"/> IV <input type="checkbox"/> FTIH
Research experience: <input checked="" type="checkbox"/> Industry <input checked="" type="checkbox"/> Collaborative Group <input type="checkbox"/> Investigator Initiated
Access to Multi-disciplinary Areas: <input checked="" type="checkbox"/> Med Onc <input type="checkbox"/> Haem Onc <input type="checkbox"/> Rad Onc <input type="checkbox"/> Surg Onc <input checked="" type="checkbox"/> MDT Meetings <input type="checkbox"/> Nuclear Physician
Patient population demographic: <input type="checkbox"/> Child (see Comments) <input checked="" type="checkbox"/> Adult
Comments:

5. DOCTORS THAT WORK AT SITE (please include all Doctors that work at site)			
First Name: Sally	Last Name: Baron-Hay	Speciality: Breast, gynaecology	
Research Active: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Current GCP: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Date Completed: 27/02/2020	
First Name: Laurence	Last Name: Krieger	Speciality: Genitourinary, renal, prostate	

Research Active: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No First Name: Nick	Current GCP: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Last Name: Pavlakis	Date Completed: Speciality: Lung, mesothelium, colorectal, GI
Research Active: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No First Name: Adrian	Current GCP: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Last Name: Lee	Date Completed: 27/02/2020 Speciality: Neuro, head/neck, genitourinary
Research Active: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No First Name: Stephen	Current GCP: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Last Name: Clarke	Date Completed: 27/02/2020 Speciality: Thoracic, GI, neuroendocrine, mesothelioma, lung, Cancer Unknown Primary
Research Active: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No First Name: David	Current GCP: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Last Name: Chan	Date Completed: 27/02/2020 Speciality: GI, neuroendocrine
Research Active: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No First Name: Connie	Current GCP: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Last Name: Diakos	Date Completed: 18/09/2019 Speciality: Hepatobiliary, pancreatic, GI, gynaecological
Research Active: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No First Name: Tristan	Current GCP: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Last Name: Barnes	Date Completed: 27/02/2020 Speciality: Lung, breast
Research Active: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No First Name:	Current GCP: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Last Name:	Date Completed: 27/02/2020

6. STATE BASED RESEARCH MANAGER DETAILS	
First name: Bianca	Last name: Karle
Contact number: +61 409 591 206	Contact email: bianca.karle@genesiscare.com

7. CLINICAL RESEAERCH COORDINATORS ON SITE		
First name: Cathy	Last name: Xu	Days on Site: 4
First name: Helen	Last name: Leslie	Days on Site: 4-5 (rotating)
First name: Libby	Last name: Emmett	Days on Site: 4-5 (rotating)
First name:	Last name:	Days on Site:
First name:	Last name:	Days on Site:

8. CURRENT RESEARCH:
How many clinical research projects are currently open at this site? 18
How many clinical research projects are closed in active follow up at site? 21
How many Principal Investigators currently on site? 6
Current number of active clinical research project patients: 26

9. FACILITIES AT SITE		
On Site Pathology:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> *No
<i>* if no is service available locally</i>	<input type="checkbox"/> No	<input type="checkbox"/> Yes <i>if so</i> NAME: Douglas Hanley Moir
On Site Pharmacy:	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> *No
<i>* if no is service available locally</i>	<input type="checkbox"/> No	<input type="checkbox"/> Yes <i>if so</i> NAME: Compounding Facility: BAXTER
On Site Radiology:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> *No
<i>* if no is service available locally</i>	<input type="checkbox"/> No	<input type="checkbox"/> Yes <i>if so</i> NAME: North Shore Radiology
Overnight bed stays:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> *No
<i>* if no is service available locally</i>	<input type="checkbox"/> No	<input type="checkbox"/> Yes <i>if so</i> NAME:
On Site Nuclear Medicine:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> *No
<i>* if no is service available locally</i>	<input type="checkbox"/> No	<input type="checkbox"/> Yes <i>if so</i> NAME: North Shore Radiology
On Site Treatment Chairs	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> *No
<i>* if no is service available locally</i>	<input type="checkbox"/> No	<input type="checkbox"/> Yes <i>if so</i> NAME:
On Site Lab – freezers & centrifuges:	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> *No
<i>* if no is service available locally</i>	<input type="checkbox"/> No	<input type="checkbox"/> Yes <i>if so</i> NAME:
On Site ECG capabilities:	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> *No
<i>* if no is service available locally</i>	<input type="checkbox"/> No	<input type="checkbox"/> Yes <i>if so</i> NAME:

10. ETHICAL COMMITTEE REVIEW PROCESS		
Does the site require you to submit through their local HREC/Governance		
HREC (only)	<input type="checkbox"/> NO	<input type="checkbox"/> Yes*
Governance	<input type="checkbox"/> NO	<input type="checkbox"/> Yes
HREC/Governance	<input type="checkbox"/> NO	<input checked="" type="checkbox"/> Yes
 <i>*if yes please complete.</i>		
Ethics committee name: Bellberry Limited		
Address: 123 Glen Osmond Road		
City:	Eastwood	State: South Australia
Country: Australia		Postal Code: 5063
Ethics committee registration number (if applicable): N/A		
Ethics committee type:	<input type="checkbox"/>	<input checked="" type="checkbox"/> Central/acts as local

Process for obtaining ethical approval (list steps in sequential or parallel order with dependent actions clearly outlined):

- create submission with unique study ID
- site specific PICFs required for submission
- IB submission required completed within the last year
- submit all documents after PI review

Ethics committee meeting schedule/frequency:

Timeframe required for submitting documents in advance to ethics committee review:

Timeframe following ethics committee review which approvals are confirmed: 1-4 weeks depending on nature of amendments. Initial approvals may take up to

Does your local Ethics committee require payment of any fees ahead of submission or prior to the release of the final approval documents: Yes No

If yes, specify:

Local Governance Requirements

Does your local service provided i.e. overnight bed facilities require Departmental Approvals?

Yes No

If yes, specify:

Contract Information

Does your site require local contract information that differs from standard? Yes No

If yes, specify:

11. FACILITIES AND EQUIPMENT

LOCAL PATHOLOGY LAB: (please copy for multiple labs used)

Name: Douglass Hanly Moir

Details: 14 Giffnock Avenue, Macquarie Park, NSW 2113; P: (02) 9855 5222

Accreditation: GLP CLIA CAP ISO Other: NATA, RCPA, NPAAC

Does the study staff that prepares or transports dangerous goods have training that meets IATA International Air Transport Association: Yes No

Is Calibration of equipment done routinely: Yes No

Are records and calibration frequency available: Yes No

IMAGING DEPARTMENT: (please copy for multiple departments used)

Name: North Shore Radiology and Nuclear Medicine

Details: 38 Pacific Highway, St Leonards, NSW 2065; P: (02) 9468 1900, F: (02) 9438 4697

Accreditation: GLP DIAS HDAA QIP CLIA CAP ISO Other: NATA

CT SPECT/CT PET/CT MRI X-RAY NUC MED ECHO MAMMOGRAM Other: Ultrasound, fluroscopy

(Please refer to GenesisCare Imaging Capabilities Qualification Form)

Is Calibration of equipment done routinely: Yes No
 Are records and calibration frequency available: Yes

EQUIPMENT- FRIDGE & FREEZERS

Do you have access to non-frost-free freezers for biological sample storage: Yes No
 Do you have access to refrigerators for biological sample storage: Yes No
 Is there temperature monitoring for refrigerators: Yes No
 Is there temperature monitoring for freezers: Yes No
 Are records maintained and available: Yes No
 Is there a back-up plan for a power outage of refrigerators and freezers: Yes No
 Is the equipment alarmed for out of range for refrigerators and freezers: Yes No
 Is Calibration of equipment done routinely: Yes No
 Are records and calibration frequency available: Yes No

SITE CAPABILITIES

Does the site have access to an ECG: Yes No
 Do you have: External phone lines International phone lines (toll free number only)
(Please refer to the Cardiac Monitoring form for machine setup requirements)

Computer Capabilities

Do you have access to a dedicated computers for the research studies: Yes No
 What is your current browser and adobe version: Google Chrome, Adobe DC Version 2019.010.20064
 Does your site have internal firewalls: Yes No
 Does your site have high speed internet access: Yes No
 Does your site have wireless internet capabilities: Yes No

ONSITE PROCESSING

PK/PD capability:

Does the site have a centrifuge for process lab samples: Yes No
 Does the site have refrigerated centrifuge for processing lab samples: Yes No
 Lab hours to accommodate PK/PD studies beyond (Monday to Friday, 8am to 4:30pm): Yes No
 Is your site open on weekends: Yes No
 Are you able to admit research subjects to an in-patient setting for research purposes: Yes No

Storage Facilities:

Is the onsite patient record storage secured to protect patient privacy: Yes No
 Are the archiving facilities on site: Yes No, if offsite provide name and location information:
 Facility Name: Grace Archiving & Records Mgmt
 Facility Location: Sydney

Contact site for all archiving information.

Is there storage area on site for study related materials, ex. Lab kits or other items: Yes No

12. RADIOTHERAPY EQUIPMENT - N/A

Treatment Techniques/ Technology	
IMRT	<input type="checkbox"/> Yes <input type="checkbox"/> No
VMAT	<input type="checkbox"/> Yes <input type="checkbox"/> No
Tomotherapy	<input type="checkbox"/> Yes <input type="checkbox"/> No
MRI-Linac	<input type="checkbox"/> Yes <input type="checkbox"/> No
Brachytherapy	<input type="checkbox"/> Yes <input type="checkbox"/> No
4DCT	<input type="checkbox"/> Yes <input type="checkbox"/> No
Deep Inspiration Breath hold (DIBH/ABC)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Adaptive radiotherapy	<input type="checkbox"/> Yes <input type="checkbox"/> No
Stereotactic Radiosurgery (SRS)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Stereotactic Ablative Body Radiotherapy (SABR)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Specify SABR sites (e.g Prostate, Spine, lung):	
CT (planning)	
Manufacturer	
Model	
Planning System 1	
Manufacturer (e.g Elekta)	
Model/ Software version (e.g Pinnacle V9.0)	
Used for (e.g IMRT/VMAT/3DCRT/Electron)	
Planning System 2	
Manufacturer	
Model/ Software version	
Used for	
Planning System 3	
Manufacturer	
Model/ Software version	
Used for	
Treatment Machine 1	
Name	
Manufacturer	
Model	
Treatment couch (standard, hexapod etc)	
Beam energies	
Dose rate	

Imaging capabilities (CBCT, MV, Exactrac etc)	
Imaging action threshold (0mm, 2mm etc)	

13. INVESTIGATIONAL PRODUCT (IP)	
Ship to address:	
Attention: Baxter Healthcare Pty Ltd	
Address Line 1: 1 Baxter Drive	
Address Line 2:	
Address Line 3:	
City: Old Toongabbie	State: New South Wales
Country: Australia	Postal Code: 2146
Primary IP site contact:	
First name: Katharine	Last name: Forsyth
Role: Clinical Trials Pharmacist	
Phone: +61 2 9848 1480	Fax:
Email: sydneyclinicaltrials@baxter.com ; katharine.forsyth@baxter.com	
Storage location the same as the shipping address:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Infusion capability:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Is the IP storage area secured with controlled access:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Is the temperature monitoring available for the following:	
<input checked="" type="checkbox"/> Room temperature	<input checked="" type="checkbox"/> Refrigerator
	<input checked="" type="checkbox"/> Freezer
Details of temperature device capabilities (i.e. min/max), frequency for monitoring: Min, max, remote excursion notification via email and SMS	
Is the temperature monitoring alarmed in the event that there is an excursion:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Is there backup plan in the event of a power outage or equipment failure:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Is your site adequately staffed to perform both blinded and un-blinded roles, in case un-blinded drug monitoring is required:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<u>Destruction of IP</u>	
Does your site have the capability to destroy IP on site/arranged directly via sub-contractor: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Does your site have a written SOP/policy/procedure for IP destruction: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

14. QUESTION SPECIFIC TO CONTROLLED SUBSTANCES	
Does the site have the regulatory required licenses or registrations to receive, store, dispense and return controlled substances as required by local law:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
The storage facility for controlled substances is securely constructed with restricted access to prevent theft or diversion:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Radio labelled IP capability: at North Shore Radiology site	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Does your site have the capability to destroy IP on site for controlled substances:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

15. SOURCE DOCUMENTATION/CRFS/SITE MONITORING	
Source documents: <input type="checkbox"/> Paper <input type="checkbox"/> Electronic <input checked="" type="checkbox"/> Both	

Access limitations/requirements for the electronic medical records: Restricted access for trial monitoring

Will monitors have access to:

Phone Fax Copy machine Internet access

What electronic data systems has your staff used for clinical research projects:

Inform Medidata Rave Oracle Openclinica Bioclinica
 Other

16. Please provide any other additional comments that may relate to your site: