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**Clinical Study Report Synopsis**

Drug Substance	NA
Study Code	D081LR00003
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A cross-sectional, non-interventional, multicenter study to determine the prevalence of homologous recombination repair (HRR) gene mutations in patients with metastatic castration-resistant prostate cancer in Latin America

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**Study dates:** First subject enrolled: 20 Apr 2021  
Last subject last visit: 06 Apr 2022

**Phase of development:** Non Interventional

**International Co-ordinating Investigator:** NA

**Sponsor's Responsible Medical Officer:** **Melissa Barbieri**  
Oncology Medical Manager  
AZ CAMCAR

**Carmen Vargas**  
International Diagnostic Director  
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This study was performed in compliance with Good Clinical Practice, including the archiving of essential documents.

This submission /document contains trade secrets and confidential information, disclosure of which is prohibited without providing advance notice to AstraZeneca and opportunity to object.

### Study centre(s)

Country	Site ID	Site name
Argentina	ARG01	Fundación Estudios Clinicos
Argentina	ARG02	Instituto Alexander Fleming
Colombia	COL01	Sociedad de Oncología y Hematología del Cesar S.A.S.
Peru	PER01	Centro de Investigación Oncosalud - RCI N° 166
Costa Rica	CRC01	Instituto de Investigaciones en Ciencias Médicas (ICIMED)
Panama	PAN01	Centro Hemato Oncológico Panamá (CHOP)
Mexico	MEX02	Instituto Nacional de Cancerología (INCAN)
Mexico	MEX01	Centro Médico Nacional Siglo XXI (CMNSXXI)
Brazil	BRA01	Centro de Pesquisa Hospital Moinhos de Vento
Brazil	BRA02	Centro Paulista de Oncologia SA
Brazil	BRA03	Oncoclinicas Rio de Janeiro S.A

### Publications

A poster was presented during ASCO-GU this year

## Objectives and criteria for evaluation

**Table S1 Objectives and Endpoints**

Objectives	<< Estimand description/Endpoints >>
Primary	
Determine the prevalence of homologous recombination repair (HRR) gene mutations in participants with mCRPC in Latin America (LatAm) between February 2021 and January 2022.	To know the prevalence and type of Homologous Recombinational Repair (HRR) mutations identified in Formalin-fixed paraffin-embedded (FFPE) tissue or blood samples in patients diagnosed with metastatic castration-resistant prostate cancer (mCRPC) in the selected participants countries in LatAm.
Exploratory	
<ul style="list-style-type: none"> <li>• Describe the demographic and clinical characteristics of the mCRPC participants with HRR gene mutations in LatAm between February 2021 and January 2022.</li> <li>• Describe the association between demographic and clinical characteristics, and the prevalence of HRR gene mutations in participants with mCRPC per LatAm country between February 2021 and January 2022.</li> </ul>	

### Study design

A cross-sectional, non-interventional, multicenter study to determine the prevalence of homologous recombination repair (HRR) gene mutation in participants with metastatic castration-resistant prostate cancer in Latin American countries. The study was performed in reference centers for the attention of metastatic castration-resistant PC patients in LatAm countries (Argentina, Colombia, Costa Rica, Mexico, Panama and Peru). The study selected patients with mCRPC diagnosed between February 2021 and January 2022.

### **Target subject population and sample size**

The sample size was estimated with a confidence level of 95%, with a margin of error (MOE) of 5% and with a projected HRR mutations mCRPC prevalence of 28% according with a previous report. Based on these data, the final sample size is estimated to be 340 participants. At the end 387 patients were included.

### **Investigational product and comparator(s): dosage, mode of administration and batch numbers**

NA

### **Duration of treatment**

NA

### **Statistical methods**

Demographic information clinical and general pathological and hereditary background characteristics will be summarized using descriptive statistics. HRR gene mutation prevalence and the specific alterations for the positive cases, will be determined. The HRR gene mutation prevalence will be determined based on all the studied cases and the specific gene alterations will be determined based on the positive cases with HRR alteration. All the estimations will be performed with 95% Confidence Interval (95%CI).

### **Study population**

Study population will be the diagnosed castration-resistant metastatic prostate cancer patients in the selected countries from February 2021 and January 2022. 387 patients were included.

### **Conclusion(s)**

This was the first time that the prevalence of germline HRR gene mutations were studied in Latin American in patients with mCRPC and the results found in this multinational study showed rates ranging between 8% to 12%, which differ from previous publications in other regions of the world. With these results we have a better understanding of the genetic characteristics for classification and appropriate therapeutic decisions in Latin American prostate cancer patients.

The first results showed that 25 subjects from the total (6.6%) had HRR germline mutation, being BRCA2 the most prevalence (16%). More data analysis is on progress.