

## Will my privacy be protected?

5IJT TUVEZ XJMM CF QFSGPSNFE CZ DPMMFDUJJOH BOE  
 VTJOH ZPVS NFEJDBM JOGPSNBUJPO 00MZ B OVNCFS  
 XJMM CF VTFE UP JEFUJGZ ZPV JO UIF TUVEZ  
 SFDPSET :PV XJMM OPU CF QFSTPOBMMZ JEFUJGZ  
 PS NFOUJPOFE JO BOZ SFQPSUT PS QVCMJDBUJPO  
 UIBU NBZ SFTVMU GSPN UIJT TUVEZ :PVS QFSTPOBM  
 EBUB XJMM OPU CF VTFE GPS BOZ EJSFDU NBSLFUJOH  
 QVSQPTFT :PVS TUVEZ SFDPSET XJMM CF LFQU  
 BT DPOUEFOUJBM BT QPTTJCMF BOE UP UIF FYJUEOU  
 QFSNJUFE CZ UIF BQQMJDBC MF MBXT BOE PS  
 SFHVMBUJPO

If you have questions about relugolix or leuprolide acetate or the study, please talk to your doctor.

REPLACE-CV Doctor's Name:

REPLACE-CV Coordinator's Name:

OGÜDF 1IPOF /VNCFS

## Who can participate in the REPLACE-CV Study?

You are being asked to participate because you have been diagnosed with advanced prostate cancer, and:

- You are age 18 or older
- You have a history of cardiovascular events or cardiovascular risk factors
- Your doctor thinks you are a candidate for ADT treatment using either relugolix or leuprolide



For more information visit  
[www.clinicaltrials.gov](http://www.clinicaltrials.gov)  
 NCT05605964

# A Randomized, Open-Label Study to Assess Major Adverse Cardiovascular Events in patients with Advanced Prostate Cancer



## What is the REPLACE-CV Study?

3&1-"\$& \$7 JT B TUVEZ UIBU JT FWBMVBUIJOH USFBUNFOU  
GPS QSPTUBUF DBODFS JO QBUJFOUT XIP UBLF SFMVHPMJY PS  
JODSFBTFE SJTL GPS DBSEJPWBTDVMB\$ ZWVBSF FMFHJCMF BOE X  
PG UIJT SFTFBSDI TUVEZ JT UP DPNQBSJQH UIF SJTL PG DBSEJP  
DBSEJPWBTDVMB\$ FWFOU CFUXFFO QBUJFOUT XIP UBLF SFMVHPMJY  
BDFUBUF JO QBUJFOUT XJUI QSPTUBUF DBODFS JO QBUJFOUT XIP  
CFJOH TQPOTPSFE CZ .ZPWBOU 4DJFOBOE NFEJDBM JG ZPV R  
SFGFSSFE UP UISPVHIPVU UIJT EPDVNSODFVWFEH QPOTPSZ SF  
PS n.ZPWBOUo

5FTUPTUFSPOF B NBMF TFY TUFSPJE IPSNPOF JT OFFEFE  
CZ NPTU QSPTUBUF DBODFS UVPNST UP PPSX 5SFBUNFOU  
XJUI ESVHT UIBU MPXFS UIF MFWFMT UIF MFWFMT PG UFTUPTUF  
CPEZ JT DBMMFE BOESPHFO EFQJSJWBUIJPO UIFSBQZ "%5  
#PUI SFMVHPMJY BOE MFVQSPMJEF BDFUBUF CSBOE OBNF &-\*("3%†  
GPS QBUJFOUT XJUI BEWBODFE QSPTUBUF DBODFS JO QBUJFOUT XIP

## Why should I participate in the REPLACE-CV Study?

5IJT SFTFBSDI JT DPNQBSJQH UIF SJTL PG DBSEJPWBTDVMB\$  
FWFOU CFUXFFO QBUJFOUT XIP UBLF SFMVHPMJY PS VTFE BOE  
MFVQSPMJEF BDFUBUF GPS BOESPHFO: EFVQSPMJEF BDFUBUF CSBOE  
"%5 JO UIF USFBUNFOU PG BEWBODFE QSPTUBUF DBODFS JO QBUJFOUT  
3FMVHPMJY NH 03(07:9† IBT CFFO BQQSPWFE JG ZPV R  
CZ UIF 6OJUFE 4UBUFT 'PPE BOE %SVH ENJOJTUSBUJPO UIFSBQZ  
'%" GPS UIF USFBUNFOU PG BEVMU QBUJFOUT XJUI BEWBODFE  
QSPTUBUF DBODFS 3FMVHPMJY JT B HPOBEPUSPQJO SFMFBTJQH  
IPSNPOF SFDFQUPS BOUBHPOJTU BOE XPSLT CZ MPXFSJQH  
UIF MFWFMT PG UFTUPTUFSPOF JO ZPVS CPEZ  
-FVQSPMJEF BDFUBUF CSBOE OBNF &-\*("3%† PS  
-VQSPOT† JT BO "%" BQQSPWFE NFEJDJOF UIBU JT VTFE  
NPTU PGUFO GPS BOESPHFO EFQJSJWBUIJPO UIFSBQZ "%5  
#Z QBSUJDJQBUJQH ZPV NBZ QSPWJEF OFX TBGFUZ BOE PUIFS  
NFEJDBM JOGPSNBUJPO UIBU NBZ CFOFÜU PUIFS QBUJFOUT JO  
UIF GVUVSF

## How do I enroll in this study?

5P MFBSO NPSF BCPVU UIF 3&1-"\$& \$7 JT B TUVEZ UIBU JT  
UIOEPVUJG ZPV RVBMJGZ GPS UIF TUVEZ UIBU JT FWBMVBUIJOH  
PS UIF JSFBUNFOU XIP UBLF SFMVHPMJY BOE NFEJDBM JG ZPV  
RFBMFBTJQH XPNVME MJLF ZPQBNSUJDBOUBUIEF SFVRVMSFOF  
STL EEFUSJQSPWJEF JOGPSNFE DPOTFOU UPPVBNLZCFXMSFEHFCZPOT  
FOVHFTUUBOEPSOMFVQSPMJEF TUVEZ BOE UP CFDPMMFDUFEP  
BOE NFEJDBM JG ZPV RFBMFBTJQH XPNVME MJLF ZPQBNSUJDBOUBUIEF  
SFVRVMSFOF STL EEFUSJQSPWJEF JOGPSNFE DPOTFOU UPPVBNLZCFXMSFEHFCZPOT  
FOVHFTUUBOEPSOMFVQSPMJEF TUVEZ BOE UP CFDPMMFDUFEP  
BOE NFEJDBM JG ZPV RFBMFBTJQH XPNVME MJLF ZPQBNSUJDBOUBUIEF  
SFVRVMSFOF

## What is an Informed Consent Form (ICF)?

5IJT GPSN XJMM HJWF ZPV NPSF JOGPSNBUJPO BCPVU  
UIF TUVEZ BOE XJMM QSPWJEF EFUBJMT BCPVU UIF TUVEZ  
QSPDFEVSFT XIFO UIF TUVEZ QSPDFEVSFT XJMM PDDVS BOE  
XIBU XJMM CF SFRVJSFE PG ZPV BT B TUVEZ QBSUJDJQBOU 5IJT  
JOGPSNFE DPOTFOU GPSN EFTDSJCFT UFFOBSXPGSUTFTBOEZ ZPV XJMM TF  
QPTTJCMF CFOFÜU PG QBSUJDJQBUJQH JUPFUIJOTUPVBMJGZGPSN CZ UFMFIF  
BMTPEYQMBJOTJPX ZPVS NFEJDBM JOGPSNBUJPOIFSBQZBOE ZPV XJMM SFDFJ  
TUVEZ XJMM PS VTFE BOE XIP NBZ TFF DUSF TVDI BT MBCPSBUPSZ UFTUT J  
EFVQSPMJEF BDFUBUF CSBOE OBNF &-\*("3%† PS UP BTL BEWJDF GSPN PUIFST "TL  
ZPVS TUVEZ EPDUPS PS TUVEZ TUBGG \*O BEFJUIJPO ZPV XJMM SFDFJWF UI  
BQQSPWFE UFTUPTUFSPOF ZPV XJMM SFDFJWF UIJEF SFMVHPMJY PS  
JOGPSNBUJPO ZPV EP OPU VOEFSTUBOE USFBUNFOU EJUJEF SFMVHPMJY PS  
UIJT GPSN JG ZPV RFBMFBTJQH DPTUUP ZPV BOE ZPWBOU XJMM D  
BOTXFSFE DPTUT PG TUVEZ USFBUNFOU FJUIF  
BDFUBUF GPS BT MPOH BT ZPV QBS  
5BLJOH QBSU JO UIJT TUVEZ JT WPM  
BOE MBUFS EFDJEF UIBU ZPV EP OPU  
ZPV DBO TUPQ BU BOZ UJNF

## What will my participation involve once I am enrolled?

5IJT 4BMEZUP ZPVS EFDUPS SFFOJOH  
EBZT JO XIJDI ZPVS TUVEZ EPDUP  
ZPQBNSUJDBOUBUIEF SFVRVMSFOF  
UPVBNLZCFXMSFEHFCZPOTFE GPS SFBTPO  
CFXMSFEHFCZPOTFE GPS SFBTPO  
DPOVHFTUUBOEPSOMFVQSPMJEF TUVEZ BOE UP CFDPMMFDUFEP  
BOE NFEJDBM JG ZPV RFBMFBTJQH XPNVME MJLF ZPQBNSUJDBOUBUIEF  
SFVRVMSFOF STL EEFUSJQSPWJEF JOGPSNFE DPOTFOU UPPVBNLZCFXMSFEHFCZPOT  
FOVHFTUUBOEPSOMFVQSPMJEF TUVEZ BOE UP CFDPMMFDUFEP  
BOE NFEJDBM JG ZPV RFBMFBTJQH XPNVME MJLF ZPQBNSUJDBOUBUIEF  
SFVRVMSFOF