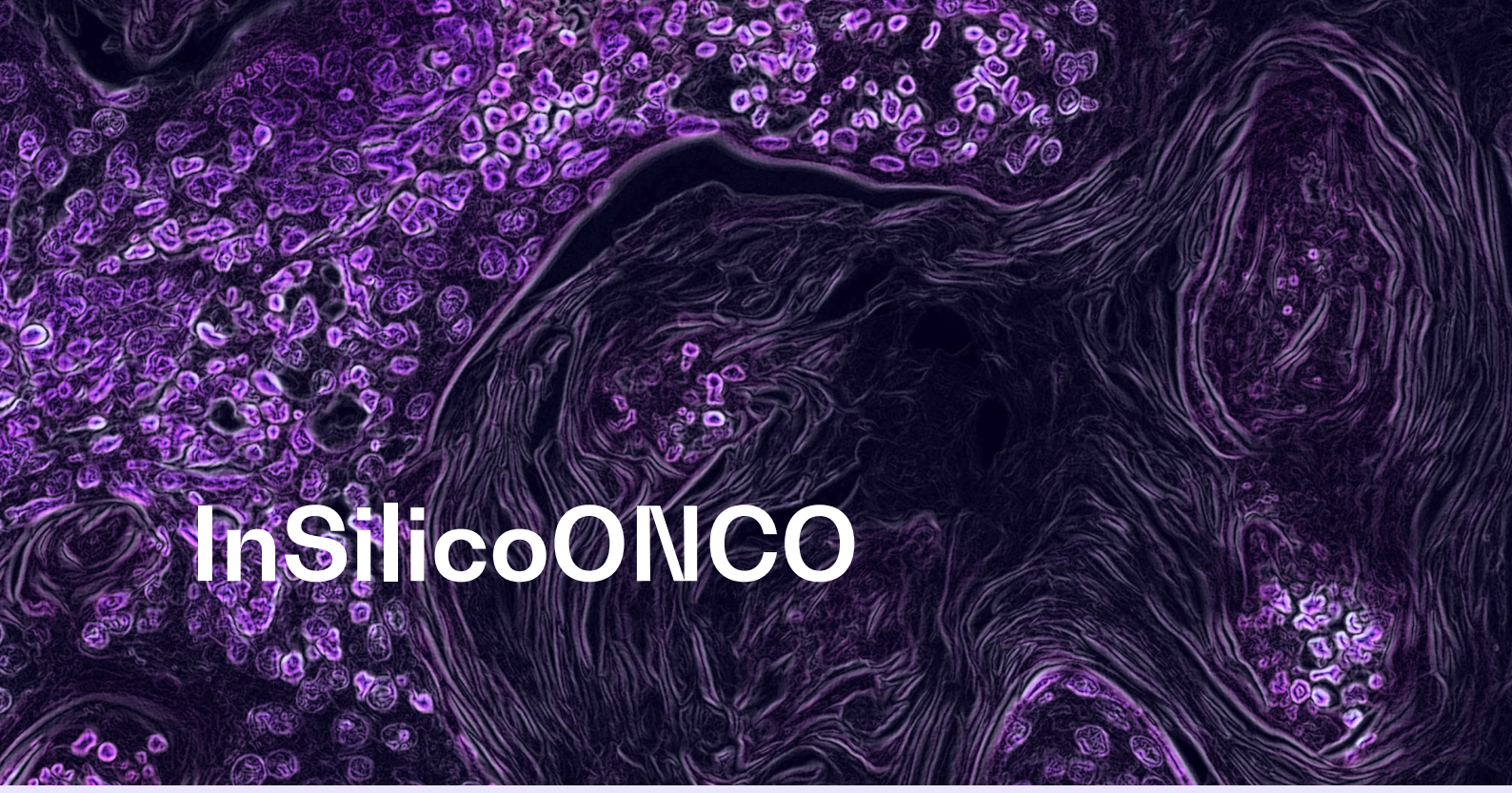


PCa GnRH Agonists Simulator

Simulation of the GnRH agonists effects on testosterone in prostate cancer patients

Gonadotropin-releasing hormone (GnRH) agonists are widely used to treat prostate cancer patients, which is one of the most frequent cancers in men (1). GnRH agonists are generally administered with slow-release formulations which result into improvement of patients' compliance and quality of life in addition to therapeutic benefits.

While setting up their oncology clinical development programs, pharma companies encounter the following challenges:

- High costs (average phase I and II clinical trials cost 4.5 and 11.2 million $, respectively (2))
- Failure risk (97% of oncology drug development programs do not reach approval, with 46% phase II trials failing to advance to phase III (3))
- Difficult comparison of new drugs with those already on the market

What is PCa GnRH Agonists Simulator

PCa GnRH Agonists Simulator is the result of a collaboration between the University of Navarra and InSilicoTrials Technologies.

PCa GnRH Agonists Simulator is based on a mechanistic pharmacokinetic/pharmacodynamic computational model which describes the process of testosterone suppression by a GnRH agonist treatment in prostate cancer patients. The computational model has been calibrated on data obtained from triptorelin and leuprorelin clinical trials and it can be easily applied to any GnRH agonists.

PCa GnRH Agonists Simulator enables simulations of clinical trials on a virtual population of prostate cancer patients being treated with a GnRH agonist. The tool can be used to explore different trial design scenarios in terms of GnRH agonists pharmacokinetic and pharmacodynamic properties, single and multiple dosing, administration route, formulation type, virtual population size as well as testosterone castration limit.

Advantages

Simulate the effect of a drug selected from a GnRH agonists library

Customize the pharmacokinetic and pharmacodynamic properties of a GnRH agonist

Optimize phase I and II clinical trial designs

Compare GnRH agonists effects with competitors on the market

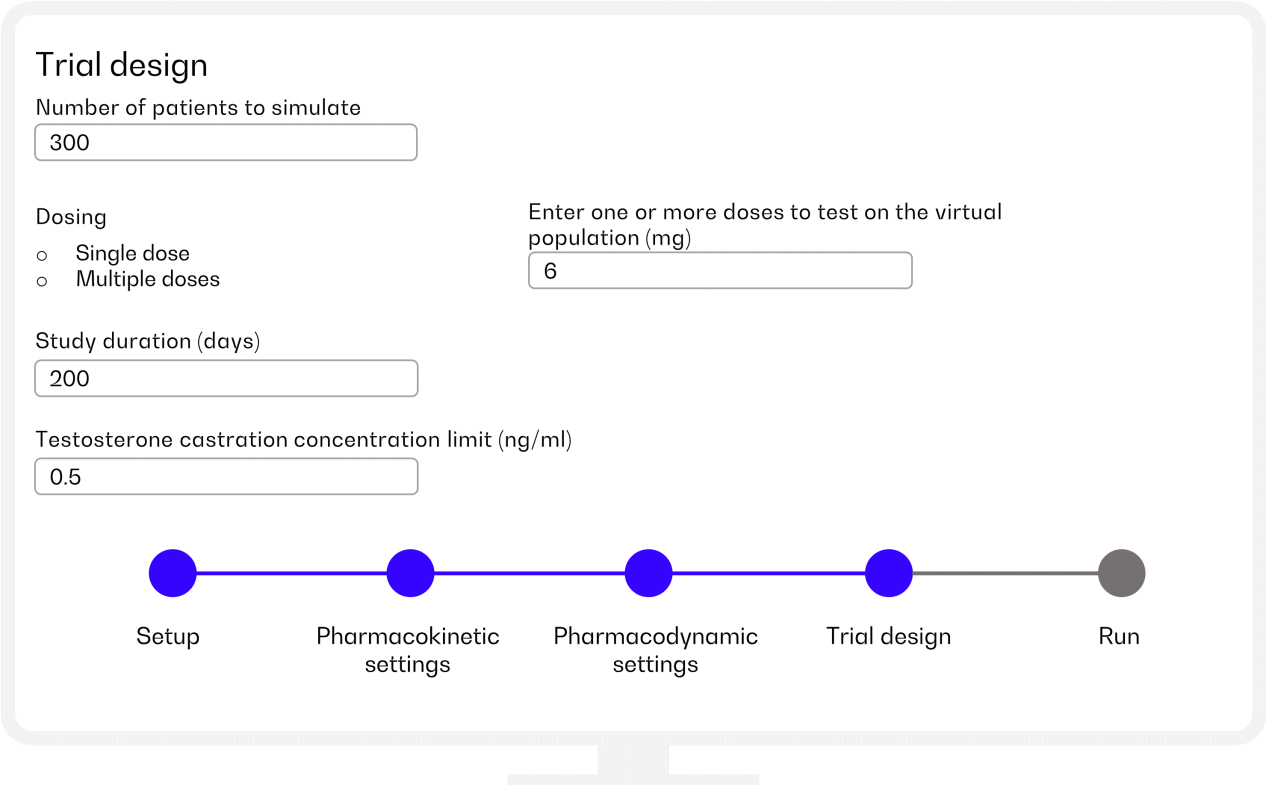
How it works

PCa GnRH Agonists Simulator enables to setup and run in silico clinical trials in a user-friendly way by using a step-by-step integrated workflow that can be applied to a known GnRH agonist selected from the library or to a custom compound:

Insert pharmacokinetic parameters (absorption and disposition) for the custom compound, or select them from a library of known GnRH agonists

Insert the GnRH agonist receptor equilibrium dissociation constant (default value is available for triptorelin and leuprorelin)

Insert the virtual population size, the dosing amount and regimen, the study duration and the testosterone concentration castration limit to define the clinical trial design



After running the simulation, results will be displayed as:

Drug and testosterone concentration levels

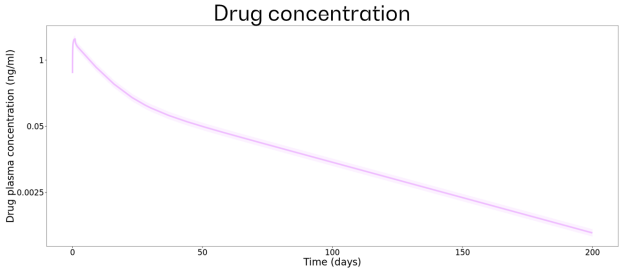
Percentage of patients who reached testosterone concentration levels below the castration limit during the study

Simulation data can be downloaded in .csv format and simulation results can be reported and exported in .pdf format

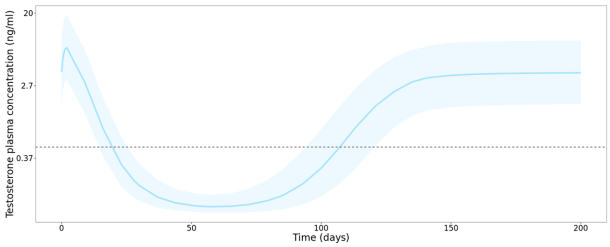
Results

Download PDF report

Drug concentration



Testosterone concentration



Percentage patients achieving castration

Day 28	Day 56	Day 84	Day 112	Day 140	Day 168	Day 196
98.8%	100%	99.8%	27.3%	0%	0%	0%

In silico is key to innovate drug development

Today, the very long and expensive development and the complex registration processes for new drugs are becoming financially unsustainable.
Regulatory agencies have been encouraging the use of in silico methods in drug research and development for years (4) because the use of these methods can greatly accelerate the time-to-market of new medicines for the benefit of the patients while significantly reducing development costs and allowing companies to exploit patents for a longer period. Solvers, IT infrastructure and computational specialists require a continuous investment from companies.

To help solve these challenges, **InSilicoTrials Technologies** has developed a game-changing-solution. Our experts:

- *Select computational models from outstanding research centers around the world*
- *Integrate them in our cloud-based platform*
- *Make them available through user-friendly online products*

This solution enables companies to leverage cutting-edge in silico methods at low costs without specific computational expertise, IT infrastructure and solvers investments requirements. On our cloud-based platform, users can select the online computational product of their choice in pay-per-use, or ask us to build the digital product they need.

Why working with InSilicoTrials

SaaS

Buy tokens and use the online products of your choice among those available on the platform

VIRTUAL PATIENTS

Design and accelerate your clinical trials with the virtual patient populations you need

ON DEMAND & CUSTOM

Ask us for the models and simulations you need, or ask us to evaluate where modeling and simulation can support you

TECHNOLOGY-ENABLED SERVICES

Ask us for support on technology integration, in silico trials planning, execution and reporting, in line with regulatory requirements

References:

1. Rawla P. Epidemiology of Prostate Cancer. World J Oncol. 2019;10(2):63–89.
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3. Wong, C.H., Siah, K.W., Lo, A.W., 2019. Estimation of clinical trial success rates and related parameters. Biostatistics 20, 273–286.
4. U.S. Department of Health and Human Services, Food and Drug Administration. Innovation or stagnation? Challenge and Opportunity on the Critical Path to New Medical Technologies. 2004.

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