



clinical trials | medical education | health care

Company Presentation

**STRAIGHT TO
SCIENTIFIC FACTS!**



Clinical research is a really complex game...

It requires not only credible data and suggestive evidence, but also a hybrid of practical clinical expertise, knowledge of clinical needs and innovation potential....



.... That's why you must meet us!

WHO ARE WE?

We Are Scientists. We Are Researchers. We Are Healthcare Specialists. Together, We Are An Innovative Research Organization Based In Romania, Dedicated To Research And Development In Healthcare

Study design
Site Selection
Regulatory Affairs
Monitoring
Project Management
Medical Writing
eCRF Design

Vaginitele nespecifice: când e momentul să acționăm?

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Abstract

The imbalance of the vaginal flora, the decreased estrogen levels or certain endogenous infections cause symptomatic, nonspecific vaginitis. Nonspecific vaginitis includes atrophic vaginitis, inflammatory squamous vaginitis, irritative vaginitis, and erosive planar vulvar lichen. During menopause, atrophic vaginitis has a high prevalence due to low estrogen levels, and increased vaginal pH, leading to a decrease in lactobacilli species and the multiplication of bacterial species that cause infections. Squamous inflammatory vaginitis is characterized by irritation, inflammation, the presence of purulent leukorrhea and a high degree of discomfort. It is estimated that 75% of adolescents and women experience at least one episode of vulvovaginitis during their lifetime, with the most common cases beginning in adolescence. The presence of purulent, yellow to green leukorrhea, and signs of irritation in the vulva and vulva are reasons for the urgent presentation to the gynecologist. The specialist will diagnose nonspecific vulvovaginitis by excluding candidiasis or trichomoniasis infections. In this type of vaginitis, due to the decrease in the number of lactobacilli, other types of bacteria will multiply, such as group B Streptococcus or Escherichia coli. Nonspecific vaginitis in pregnancy leads to severe complications, miscarriage or chorioamnionitis. The purpose of treatment in nonspecific vaginitis is to reduce inflammation, restore the vaginal ecosystem and, in the case of atrophic vaginitis, hormone replacement. To prevent recurrences, it is recommended to combine adjuvant treatments that support anti-infective treatment regimens and contribute to the rapid restoration of vaginal pH and to the preservation of lactobacilli species.

Rezumat

Dezechilibrul florei vaginale, scăderea nivelului de estrogen și anumite infecții endogene reprezintă factori etiologici pentru apariția vaginitelor simptomatice, nespecifice. Vaginile nespecifice includ vaginita atrofică, vaginita inflamatorie descuamativă, vaginita infantilă sau lichenul plan vulvar eroziv. La femeile aflate în menopauză, vaginita atrofică are o prevalență ridicată ca urmare a nivelului de estrogen redus și a pH-ului vaginal ridicat, ceea ce duce la scăderea numărului de lactobacili și la înmulțirea speciilor bacteriene care produc infecții. Vaginile inflamatorii descuamative sunt caracterizate prin iritație, inflamație, prezența leucoreei purulente și un grad mare de disconfort. Este estimat că 75% dintre adolescente și femei experimentează cel puțin un episod de vulvovaginită în timpul vieții, cele mai frecvente cazuri debutând în cursul adolescenței. Prezența leucorei purulente, de culoare galbenă până la verde, și semnele de iritație la nivelul vulvei sunt motive de prezentare de urgență la medicul specialist ginecolog. Medicul specialist va pune diagnosticul de vulvovaginită nespecifică prin excluderea infecțiilor candidazice sau trichomonazice. În acest tip de vaginită, ca urmare a scăderii numărului de lactobacili, se vor înmulți alte tipuri de bacterii, cum ar fi de exemplu streptococul de grup B sau Escherichia coli. Vaginita nespecifică în sarcină duce la complicații severe, avort spontan sau chorioamnionită. Scopul tratamentului în vaginitile nespecifice îl reprezintă reducerea inflamației, refacerea ecosistemului vaginal și, în cazul vaginitei atrofice, substituția hormonală. Pentru a preveni recidivele, este recomandat să se asociază tratamente adjuvante care susțin schemele de tratament antiinfecțios și care contribuie la restaurarea rapidă a valorii pH-ului vaginal și la conservarea speciilor de lactobacili.

Protocol ID: CRN00011807 Study Support ID: _____
Study Name: Clinical Investigation To Evaluate Contraceptive In Symptomatic Vaginitis Study Subject Birth Year: _____
Site: _____
Event Name: SCREENING VISIT
Event Date: _____

VAGINAL SMEAR (COLLECTION OF VAGINAL DISCHARGE) - VL1

Section Title: VAGINAL SMEAR (COLLECTION OF VAGINAL DISCHARGE)

Please choose the results:

Lactobacilli ☐ Yes ☐ No

Leukocytes ☐ Yes ☐ No

Trichomonads ☐ Yes ☐ No

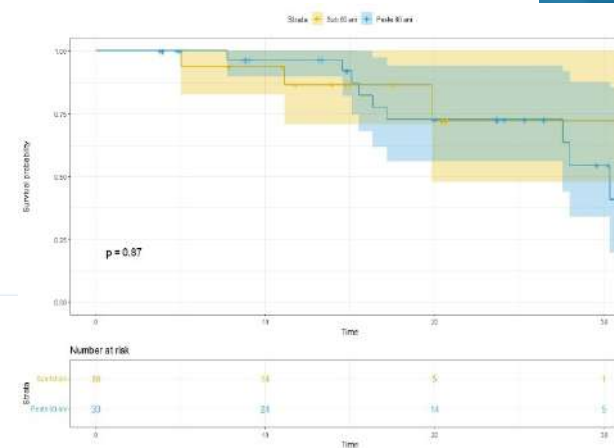
Squamous epithelial cells ☐ Yes ☐ No

Candida vaginitis ☐ Yes ☐ No

Trichomonas vaginitis ☐ Yes ☐ No

Candida ☐ Yes ☐ No

Wet cells and RBCs ☐ Yes ☐ No



Data Management
Biostatistics
Dissemination of study results

CERTIFICATIONS AND AWARDS



**Most Innovative
Data-Focused CRO**

**Healthcare &
Pharmaceutical
Awards 2022,
hosted by Global
Health & Pharma.**

A National, Multicentric, Double-Blind, Randomized, Crossover Study to Evaluate Menstrual Cramp Pain in Patients with Primary Dysmenorrhea Treated with a Fixed Dose Combination of Ibuprofen 400 mg and Hyoscine Butylbromide 20 mg Versus Ibuprofen 400 mg

NCT05135104

Non-interventional, Single-institution Study of Real-world Evidence In Estrogen Receptor Positive, HER2 Negative Metastatic Breast Cancer Patients Treated With Palbociclib During A 2.5 Years Follow-up Period

NCT04735705

A Prospective, Open-label, Pilot, Multicentric Clinical Investigation to Evaluate The Performance and Safety Of Cerviron® Ovules In the Local Treatment of Non-specific or Endogenous, Symptomatic Vaginitis

NCT04735718

A Prospective, Open-Label, Pilot, Multicentric Clinical Investigation to Evaluate the Performance and Safety of Cerviron® Ovules in Cervix Lesions Postoperative Care

NCT04469686

THREE-ARM, RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND PHASE 3 STUDY TO EVALUATE THE SAFETY AND EFFICACY OF ONCE-DAILY AND TWICE-DAILY DOSING OF A NOVEL HYDROCORTISONE ACETATE 90 MG SUPPOSITORY FORMULATION ADMINISTERED WITH THE SEPHURE® APPLICATOR IN SUBJECTS WITH ULCERATIVE COLITIS OF THE RECTUM

Phase I-IV

Our company is a scientifically-driven, **full-service CRO** providing Phase I-IV clinical development services.

Medicinal Products + Medical Devices

We aim to provide support to drug and medical device manufacturers for **product research and development**.



Therapeutic Expertise

Our company has various therapeutic expertise including **Oncology, Cardiology, Neurology, Psychiatry, Gynecology, Metabolic Diseases** and **Infectious Diseases**.



Shifting the focus from solving clinical problems to achieving valuable patient outcomes

Experienced CRAs and
Project Managers



Flexibility.
Clinical Operations
require an eye for detail

OUR ADVANTAGES



GLOBAL IN MINDSET

Serving the global markets with local expertise and knowledge. Strong Collaboration with partners in Moldova, Ukraine, Georgia, Serbia, Hungary and Austria.



FAST START-UP

We bring our experience to achieve fast start-up and fast enrolment. We gained strong relationships with more than 100 investigational sites and over 300 investigators throughout Europe.



QUALITY-FOCUSED

We are focusing in the design, development and maintenance of quality clinical trial documents throughout the study.

HEALTH AUTHORITIES SUBMISSION



Regulatory Manager
experienced in
preparing regulatory
submissions



Regulatory compliant
Study Design

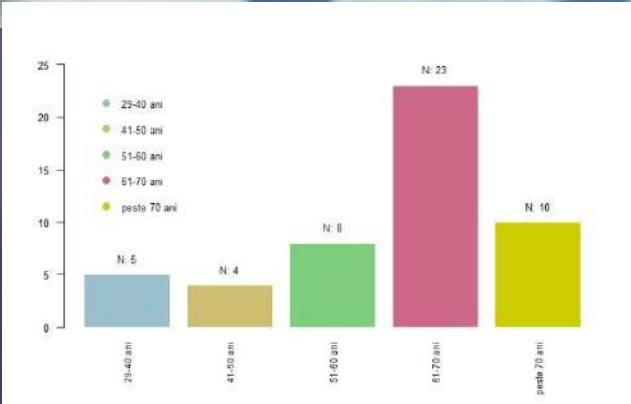
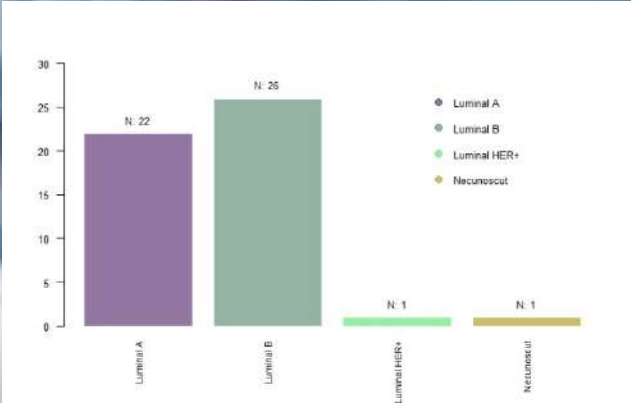
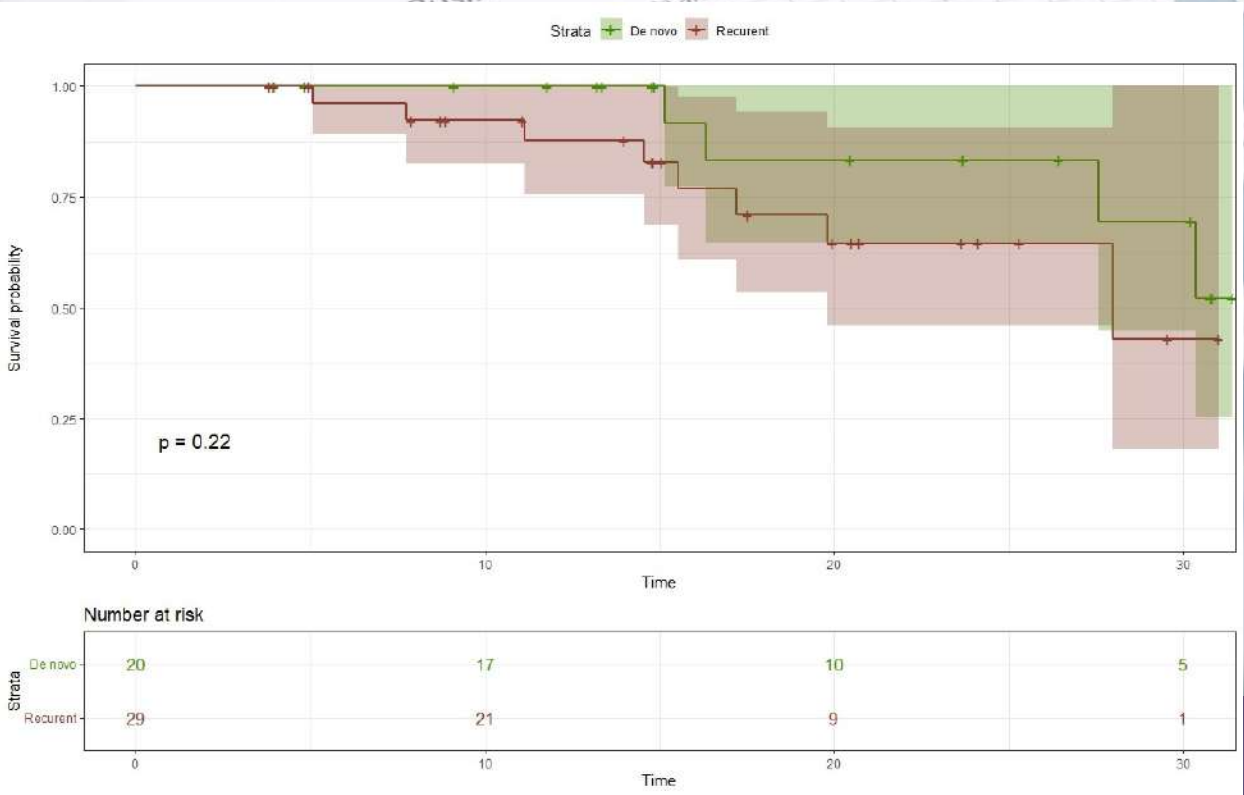


Knowledge of European
Guidelines and
Regulations

Networking with other
regulators from
European countries



Networking with other
CROs



Istoric	Grad tumoral					TOTAL
	G1	G2	G3	G4	Gx	
De Novo	3 15.00 %	14 70.00 %	1 5.00 %	0 0.00 %	2 10.00 %	20 100.00 %
Recurrent	3 10.71 %	19 67.86 %	3 10.71 %	0 0.00 %	3 10.71 %	28 100.00 %

SITES AND INVESTIGATORS



Research clinics are equipped with latest generation clinical and medical equipment

+300 Experienced Investigators

We select investigators that are GCP-trained and have conducted studies with proven high recruitment rates



Our company has **outstanding and proven relationships with sites and investigators** located in CEE Region. These relationships ensure that we can work together to create a sound study protocol and subsequently ensure that accurate study results are collected and reported back to you, on time and within budget.

AMBITION

Driven by scientific evidence and the premises of obtaining high-value research data, we support you with the evaluation of several strategies for your clinical development plan.

HIGH QUALITY

We aim to obtain the highest quality data, with adherence to good documentation and good clinical practices to obtain credible data and persuasive evidence.



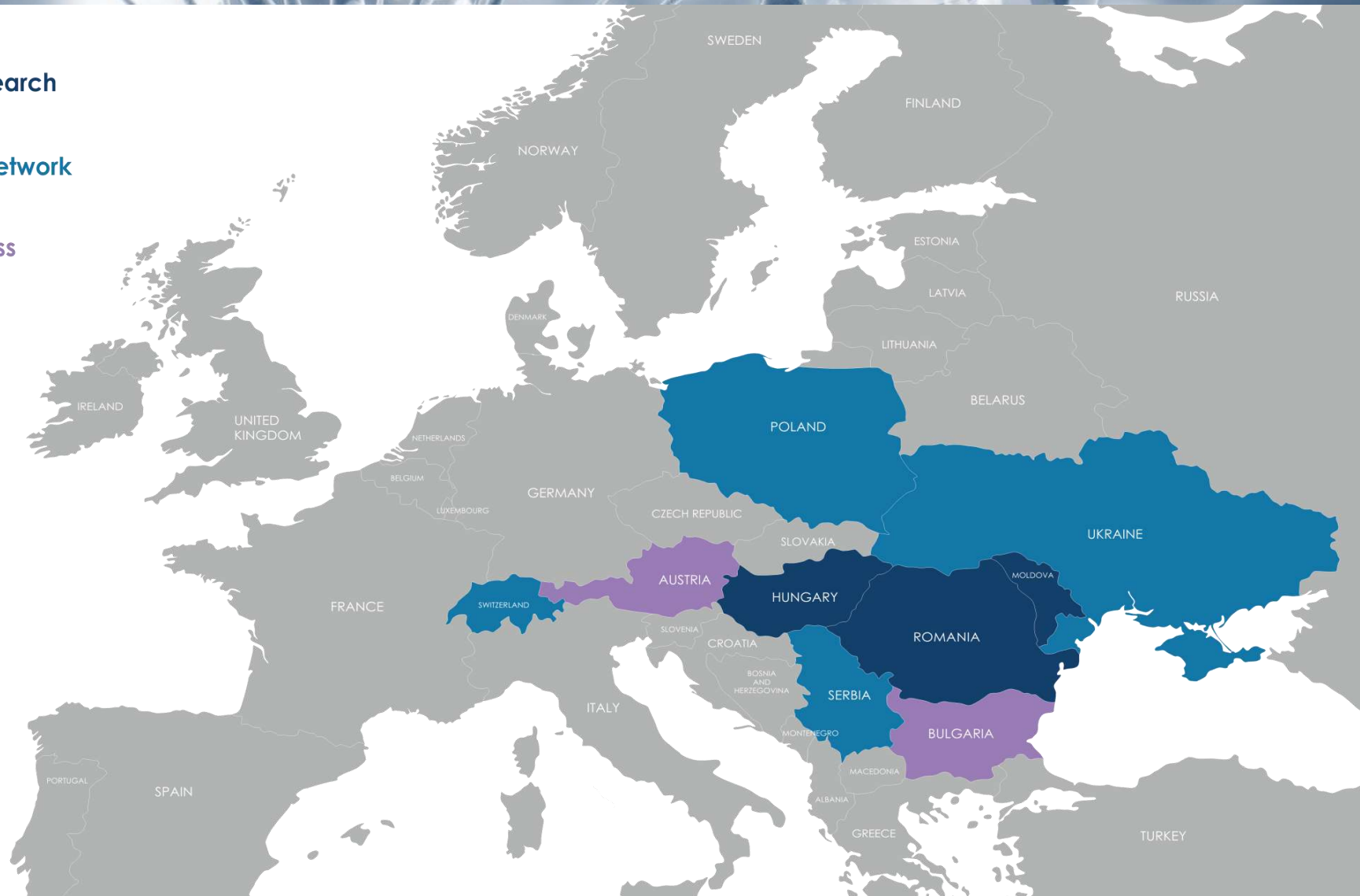
SUCCESS

We look forward to assisting you and to make your clinical project a very successful one!

MDX RESEARCH, A GLOBAL CRO



-  MDX Research
-  Partner Network
-  In progress



Thank You!

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