# **Clarivate Analytics**

Scientific information to support Healthcare in Romania

Romanian Hospitals Network Romanian Ministry of Health



# Who is Clarivate Analytics?

Clarivate Analytics is the global leader in trusted insights and analytics that accelerate the pace of innovation.

Trusted by the world's top universities, corporations, hospitals and brands, Clarivate Analytics is on a bold entrepreneurial path to help customers accelerate how quickly they turn new ideas into solutions and help them sustain and grow their business as they face continual challenges — shrinking budgets, rapidly growing data coming from diverse new sources, and innovation remaining central to competitiveness.

It's more critical than ever to provide these innovators with insights they can trust. Clarivate has a long tradition in all aspects of the innovation lifecycle.















# **Clarivate Analytics helps Hospitals to**

Direct patient to recruiting clinical trials in Romania, attract company sponsors, follow standards of care and get the latest approved medicines at the best price

Clinical Trials Intelligence	Standards of care	Medicines Supply
☐ Which drugs are currently being studied for various diseases of interest?	☐ Identify the best treatment per type of patient	Get an overview of all the medicines available with price by manufacturer
Which trial design elements (incl. selection of biomarkers, endpoints, patient segments) were relevant in predicting the success of those drugs?  Which trials are currently recruiting patients in locations accessible to Romanian hospitals patients?  See which patient sub-groups were included in trials that had more success achieving endpoints  How long should we expect a particular trial phase to last?  How are other institutions designing their clinical trials (treatment arms, inclusion/exclusion criteria, biomarkers)?  How does Romania compare to other countries when it comes to the number, phase, enrollment of clinical trials?  Which hospitals in Romania are most active in clinical trials, with additional insights into the effectiveness of those sites / organisations.	<ul> <li>□ Be up to date about disease knowledge</li> <li>□ Which of those drugs have already been proven safe and effective for other conditions in some markets?</li> <li>□ What are the disease incidence and prevalence rates in Europe? How are those expected to change over the coming years?</li> <li>□ Are there particular subgroups of disease populations that are more relevant than others?</li> <li>□ What are the best practices when it comes to treating various diseases?</li> <li>□ Which drugs are currently approved for various conditions in different countries?</li> </ul> CORTELLIS DISEASE BRIEFING	□ Forecast stocks to avoid shortage □ Who is currently marketing drugs of interest and where? □ How are the prices for drugs of interest differing across marketers and countries? □ When do the patents and exclusivities expire in Romania? □ Who is manufacturing the active substance for the drugs of interest? □ How experienced are the marketers selling their products in Romania?
CORTELLIS CLINICAL TRIALS	INCIDENCE AND PREVALENCE DATABASE	NEWPORT

Standards of care (slides 9-11)

Medicines Supply (slides 12-14)

# **Romanian Ministry of Health**

Centralized health system. With more than 40000 medical doctors, and 400 hospitals spread within the country, Romania offers multiple opportunities to perform clinical studies in many desired indications.

One of the most attractive aspects of the clinical research in Romania is the high number of eligible patients, the high enrollment rates and fast recruitment (GCT, 2017)

The legislation and regulations of the country are in line with the EU Directives and Guidelines and the principles of conducting the clinical trials are driven by the Declaration of Helsinki. Romanian Competent Authority and Ethics Committee are two official bodies involved in running the clinical trials.



# **Cortellis Clinical Trials Intelligence**

Intelligence gained from Global clinical trials gathered from all the major Global trial registries is combined with manually curated scientific knowledge from full text journal articles, conferences and company communications to provide you the best intelligence to inform your clinical development and improve patient access to innovative therapeutics:

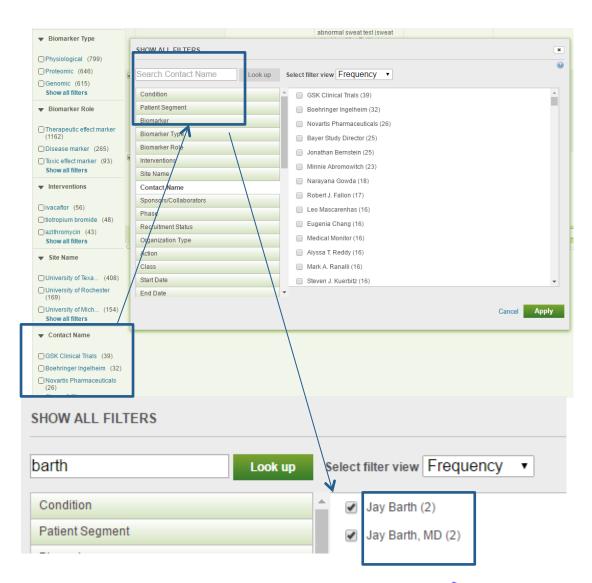
- Gain insights into patient sub-populations defined within successful and less successful clinical trials
- Learn from the trial design and outcomes of clinical trials from the best Global clinical centres
- Understand likely patient experiences and outcomes regarding efficacy and toxicity
- Understand growth and likely economic benefit of comparator countries Globally
- Gain comparable data and insights into the volumes and effectiveness of clinical trials that involve Romanian sponsors / collaborators / sites.



#### **CLINICAL TRIALS PERFORMANCE**

1- Gather content from multiple sources, including registries, conferences, press releases and journals, compiled into a single record. This saves hospitals and Principal Investigators time when looking for information from various registries about a particular trial and additional information that isn't available from registries alone.

2- Gain insights into the volume of trials sites and activity across Romania.





# **CLINICAL TRIALS PERFORMANCE**

As many as 30% of Phase 3 trials fail due to lack of patient recruitment. As such, a good site selection and performance is crucial for hospitals to benchmark themselves

Endpoint Types	Efficacy; Pharmacokinetics; Safety	
Enrollment Count	35	
Evaluable Subject Count		
Start Date	30-Apr-2013	
End Date	30-Apr-2017 (Estimated)	
Primary Endpoint Completion Date	30-Apr-2017 (Anticipated)	
		_
Enrollment End Date	31-Dec-2016 (Actual)	
	31-Dec-2016 (Actual) 44.06 Months	
Enrollment End Date		
Enrollment End Date Enrollment Period	44.06 Months	
Enrollment End Date  Enrollment Period  Enrollment Rate	44.06 Months 0.79 Patients/Month	



#### **CLINICAL TRIALS PERFORMANCE**

Under the latest research and clinical insights into patient subgroups and biomarkers applied within the clinic

Look up

✓ HER2 (11)

Creatinine (3)

■ Tumor mass (3)

Bilirubin (2)

Androgen receptor (2)

CA-125 antigen (2) CA19-9 antigen (2)

Carcinoembryonic antigen (2)

SHOW ALL FILTERS

Search Biomarker

Condition

Biomarker

Site Name

Contact Name

Patient Segment

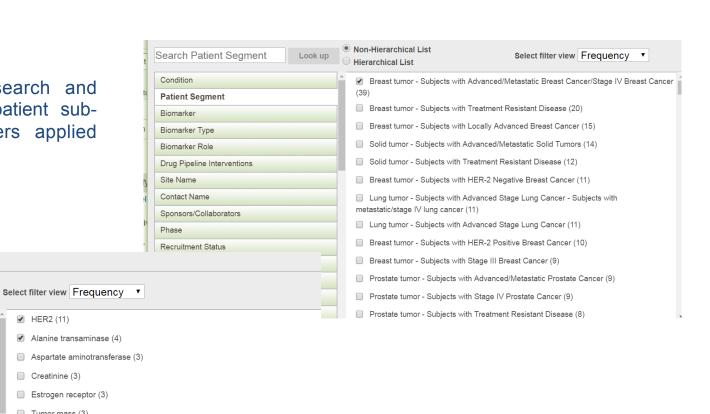
Biomarker Type

Biomarker Role

Drug Pipeline Interventions

Sponsors/Collaborators

Recruitment Status





#### STANDARDS OF CARE

**Disease Briefings** in Cortellis offer a full overview of the condition including diagnosis, prevention, different types of treatment as well as drugs available in the market and under development

as drugs available in the market and under development Risk Factors Genetics **Epidemiology** Morbidity and Mortality Arterial Hypertension Cost Highlight Search Terms & Synonyms Disease Briefing Next > DIAGNOSIS Latest Headlines **DISEASE BRIEFINGS** Screening Expand all Multimedia **PREVENTION** FACTS ABOUT ARTERIAL HYPERTENSION Glossary **TREATMENT** Suggested Reading Pathophysiology Lifestyle Modification Related Information Pharmacotherapy When the heart beats it produces a pressure wave in the arteries. The peak of this wave is called systolic pre heartbeats is called diastolic pressure. Both systolic and diastolic measures are important in determining hyp Sources units of millimeters of mercury (mmHg). Hypertension is defined by both WHO and the American Heart Assoc Diuretics pressure of 140 or higher and diastolic pressure of 90 or higher, with various grades or stages of hypertension Joint National Committee (JNC 8) specifies a higher cutoff point for systolic blood pressure (150 mmHg) in pa Beta-adrenoceptor Antagonists Evidence-based guideline for the management of high blood pressure in adults: Report from the panel memb Committee (JNC 8)). Imidazoline I1 Receptor Agonists The Renin-Angiotensin System Arterial Hypertension: Blood Pressure Classifications and Cut Off Points ACE Inhibitors ACE2 Modulators Enlarge Renin Inhibitors Abnormally high blood pressure causes the heart to work harder than normal and leaves the heart and arteric Angiotensin Receptor Blockers is not treated and the heart is forced to work harder and harder for a prolonged period of time, it becomes en arterioles become scarred, hardened and less elastic, a process called arteriosclerosis. The hardened and no Aldosterone Antagonists adequate amount of blood to the body's organs and tissues, meaning that they cannot function properly. Bloo the narrowed arteries, depriving a part of the body of its blood supply altogether.

FACTS ABOUT ARTERIAL HYPERTENSION

Pathophysiology

#### STANDARDS OF CARE

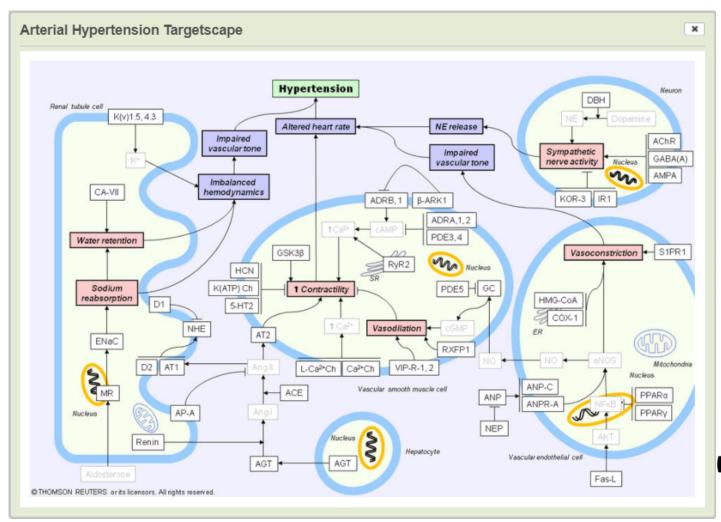
**Disease Briefings** in Cortellis helps you identify all the drugs available for hypertension (for example) according to specific mechanism of action like Calcium channel blocker shown here.

Calcium channel blockers						
Verapamil hydrochloride (Isoptin)	Abbott	1963				
Diltiazem hydrochloride (Cardizem)	Mitsubishi Tanabe Pharma	1974 (Japan)				
Nifedipine (Adalat)	Bayer	1975				
Nicardipine hydrochloride (Cardene)	Astellas Pharma/Mitsui Chemicals/Bayer	1981 (Japan)				
Nitrendipine (Bayotensin)	Bayer	1985 (Germany)				
Felodipine (Plendil)	AstraZeneca	1988 (Denmark, Sweden)				
Nilvadipine (Nivadil)	Astellas Pharma	1989 (Japan)				
Isradipine (Lomir)	Novartis	1989 (U.K.)				
Amlodipine besylate (Istin)	Pfizer	1990 (U.K.)				



#### STANDARDS OF CARE

**The targetscape** for hypertension shown here displays an overall cellular and molecular landscape or comprehensive network of connections among the current therapeutic targets for the treatment of the condition and their biological actions.





**Newport** provides launches data including marketers, brand names, dose forms and description of the product by country and date. Pack prices are also included to make it easier for Hospitals to indentify products and providers with more convenient prices.

Save Search

Search Criteria: Product Name begins with amlodipine and Launch Country In Bulgaria or Romania or Slovenia and Pack Launch Date is after 1/1/2012

Worldwide Pack Price Search Results

Search returned 187 records.

Worldwide Fack Frice Search Results										
Pages: 1 2 3 4 5 6 7 Excel ▼ Expc									Export	
Dose Form	Strength	Active Ingredient	Trade Name	△ Marketer	Corporate Group	Launch Counrty	Pack Description	Latest Retail Pack Price	Latest Hospital Pack Price	Pack Launch Date
Tablet	10MG	amlodipine besylate; atorvastatin calcium	LUXTANOR	ACTAVIS	Allergan Pic	Bulgaria	F.C.TABS 10 10MG 30	LEV 9.81	LEV 9.54	31 Jul 2014
Tablet	10MG	amlodipine besylate; atorvastatin calcium	LUXTANOR	ACTAVIS	Allergan Pic	Bulgaria	F.C.TABS 5 10MG 30	LEV 8.68	LEV 8.44	31 Jul 2014
Capsule	10MG	ramipril; amlodipine besylate	VIVACE DUO	ACTAVIS	Allergan Pic	Bulgaria	CAPS 10 10MG 30	LEV 11.13	LEV 11.57	29 Feb 2016
Capsule	10MG	ramipril; amlodipine besylate	VIVACE DUO	ACTAVIS	Allergan Pic	Bulgaria	CAPS 5 10MG 30	LEV 9.10	LEV 8.83	31 Jan 2016
Tablet	5MG	amlodipine besylate; valsartan	VALTENSAM	ACTAVIS	Allergan Pic	Bulgaria	F.C.TABS 160 5MG 30	LEV 6.49		31 Mar 2017
Capsule	5MG	ramipril; amlodipine besylate	VIVACE DUO	ACTAVIS	Allergan Pic	Bulgaria	CAPS 5 5MG 30	LEV 6.86	LEV 6.70	31 Jan 2016
Tablet	10MG	amlodipine besylate; atorvastatin calcium	TORVALIPIN PLUS	ACTAVIS TEVA	Teva Pharmaceutical Industries Ltd	Romania	FC TABS 10MG 10MG 30	RON 12.77		31 Jul 2014
Tablet	5MG	amlodipine besylate; atorvastatin calcium	TORVALIPIN PLUS	ACTAVIS TEVA	Teva Pharmaceutical Industries Ltd	Romania	FC TABS 5MG 10MG 30	RON 10.96		31 Jul 2014
Tablet	10MG	amlodipine besylate	AMLODIPINA AUROBIN	AUROBINDO	Aurobindo Pharma Ltd	Romania	TABS 10MG 30	RON 3.29	RON5.10	31 Oct 2013
Tablet	5MG	amlodipine besylate	AMLODIPINA AUROBIN	AUROBINDO	Aurobindo Pharma Ltd	Romania	TABS 5MG 30	RON 1.94	RON 3.62	31 Oct 2013
Tablet	20MG	hydrochlorothiazide; amlodipine besylate; olmesartan medoxomil	TESPADAN HCT	BERLIN- CH/MENARINI	Menarini - Industrie Farma Riunite Srl	Bulgaria	F.C.T.5/12.5 20MG 28	LEV 40.30		30 Jun 2014
Tablet	20MG	amlodipine besylate: olmesartan medoxomil	INOVUM	BERLIN- CH/MENARINI	Menarini - Industrie Farma Riunite Srl	Romania	F.TABS 20MG 5MG 56	RON 168.80		31 Oct 2012

**Newport** will help you identify new hypertensive products recently launched in Eastern Europe as tablets. Marketers profile and portfolio are also available so you can contact them and get all the medicines needed for your hospital at the best price.

Search Criteria: Dose Form Tablet or Tablet, Delayed Release or Tablet, Extended Release or Tablet, Orally Disintegrating or Tablet, Orally Disintegrating, Delayed Release or Tablet, Sublingual or Tablet, Sublingual, Delayed Release and Therapeutic Category (EphMRA) C2 - Antihypertensives and Launch Country In Eastern Furone and Pack Launch Date is after 1/1/2015

Country In Eastern Europe and Pack Launch Date is after 1/1/2015

Search returned 965 records.

Worldwide Pack Price Search Results										
Pages: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33										
Dose Form	Strength	Active Ingredient	Trade Name	Marketer	Corporate Group	Launch Counrty	Pack Description	Latest Retail Pack Price	Latest Hospital Pack Price	Pack Launch Date
Tablet	50MG	sildenafil citrate	SILFECT	TK ILAC	TK ILAC	Turkey	FILMTAB 50MG 4	TL 74.81	TL 0.01	30 Apr 2017
Tablet, Extended Release	100MG	metoprolol succinate	METOZOK	SANDOZ	Novartis AG	Estonia	TABS PR 100MG 100	EUR 9.98		31 Mar 2017
Tablet	100MG	losartan potassium	LOSARTAN CANON	CANONPHARMA PRODUC	Zakritoe Aktsionernoe Obshestvo CanonPharma Production	Russia	FILM C.TABS 100MG 14	RUB 331.50		31 Mar 2017
Tablet	100MG	sildenafil citrate	VIVAYRA	BELUPO	Belupo	Russia	TABS CHEW 100MG	RUB 97.14		31 Mar 2017
Tablet	100MG	sildenafil citrate	VIVAYRA	BELUPO	Belupo	Russia	TABS CHEW 100MG 2	RUB 145.70		31 Mar 2017
Tablet	10MG	olmesartan medoxomil	OLSART	TCHAIKAPHARMA BG	Commercial League Healthcare Group	Bulgaria	FILM C.TABS 10MG 30	LEV 7.03	LEV 6.83	31 Mar 2017
Tablet	10MG	bisoprolol fumarate	BIBLOC FF8>>	FORFARM >>	Forfarm Sp Ltd	Poland	FILM C.TABS 10MG 30	ZLO 5.05	ZLO 0.95	31 Mar 2017
Tablet	10MG	<u>amlodipine</u>	AMLODIPINE	MEDISORB	Medisorb ZAO	Russia	TABS 10MG 50	RUB 86.12		31 Mar 2017



**Target searches in Newport** will help you identify products available in other countries that haven't been launched in Romania, so you can identify new treatments for your patients. These flexible searches can be run by launched date, therapeutic category and country of interest, as shown next.

Search Criteria: Launched Products In Germany and Not in Romania and Pack Launch Date is after 1/1/2015 and Therapeutic Category (EphMRA) L1G - Monoclonal antibody antineoplastics or L1H - Protein kinase inhibitor antineoplastics

Displaying 13 of 13 records

					1
		Show:	all products	▼ Country: Romania	▼
					Excel ▼ Export
Local Brand Name	Local Marketers	Product Details			Market CI
		EphMRA TC	▼		
None	No Data Available	Antineoplastics			View
None	No Data Available	Antineoplastics			View
None	No Data Available	Antineoplastics			View
None	No Data Available	Antineoplastics			View
None	No Data Available	Antineoplastics			View
None	No Data Available	Antineoplastics			View
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None	No Data Available	Antineoplastics			View
None	No Data Available	Antineoplastics			View
None	No Data Available	Antineoplastics			View
	None None None None None None None None	None No Data Available	Local Brand Name  Local Marketers  EphMRA TC  None  No Data Available  Antineoplastics  None  No Data Available  Antineoplastics	None  No Data Available  None  No Data Available  Antineoplastics  None  No Data Available  Antineoplastics	Local Brand Name  Local Marketers  EphMRA TC  None  No Data Available  Antineoplastics  None  No Data Available  Antineoplastics



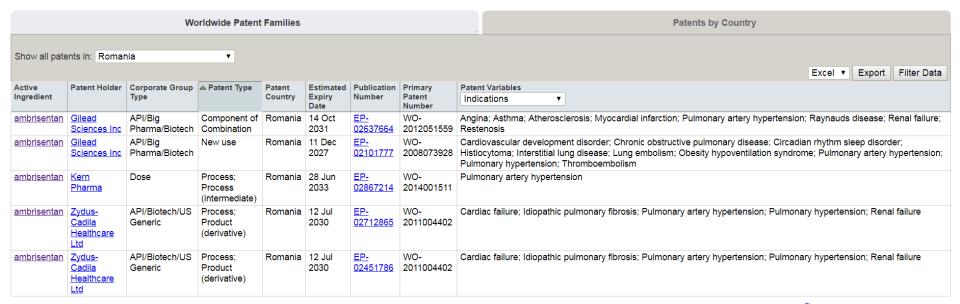
**Newport Constraint Date** is calculated to make it easy to anticipate the date when generics will be launched in your market.

Patents in Newport will help you identify patent holders and expiry dates in your country.

Product Profile Approvals Launches US Market Stats R & D Patents US Patent Challenges API Pathways Deals Market CI Regulations Product Changes

Mewport Constraint Date

Newport Constraint Date in Romania is 21 Apr 2018. It is based on the expiry date of Data + Marketing Exclusivity.





#### Important links and email addresses:

Cortellis (including clinical trials, regulatory, disease briefings) platforma access: <a href="https://www.cortellis.com/intelligence/login.do">https://www.cortellis.com/intelligence/login.do</a>

https://www.e-nformation.ro/resurse/clarivate

Date for online demonstration: Tuesday, 28 November @ 11:30 am Bucharest

Please click here to register: <a href="https://clarivatesupport.webex.com/clarivatesupport/k2/j.php?">https://clarivatesupport.webex.com/clarivatesupport/k2/j.php?</a>
<a href="https://clarivatesupport.webex.com/clarivatesupport/k2/j.php?">https://clarivatesupport.webex.com/clarivatesupport/k2/j.php?</a>
<a href="https://clarivatesupport.webex.com/clarivatesupport/k2/j.php?">https://clarivatesupport.webex.com/clarivatesupport/k2/j.php?</a>

Clarivate support: ts.support.emea@clarivate.com



