

Klinički pokusi - tko je obaviješten i tko se može uključiti?

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Klinički pokusi – tko je obaviješten i tko se može uključiti?

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Zavod za kliničku farmakologiju

Klinički pokusi – tko je obaviješten i tko se može uključiti?

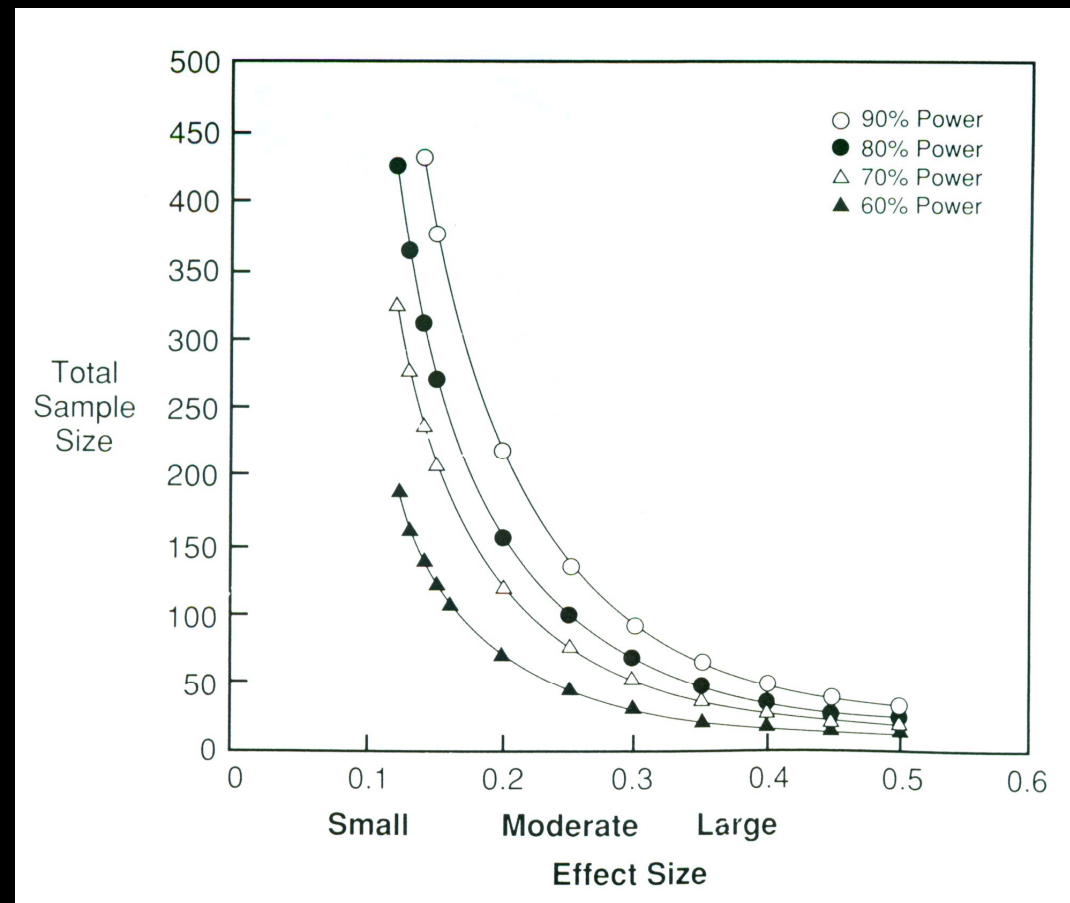
- | | |
|-----------|--|
| I. Faza | Farmakologija u čovjeku
(human pharmacology) |
| II. Faza | Istraživanje terapijskog učinka
(therapeutic explanatory) |
| III. Faza | Potvrda terapijskog učinka
(therapeutic confirmatory) |
| IV. Faza | Terapijska primjena
(therapeutic use) |

Klinički pokusi – tko je obaviješten i tko se može uključiti?

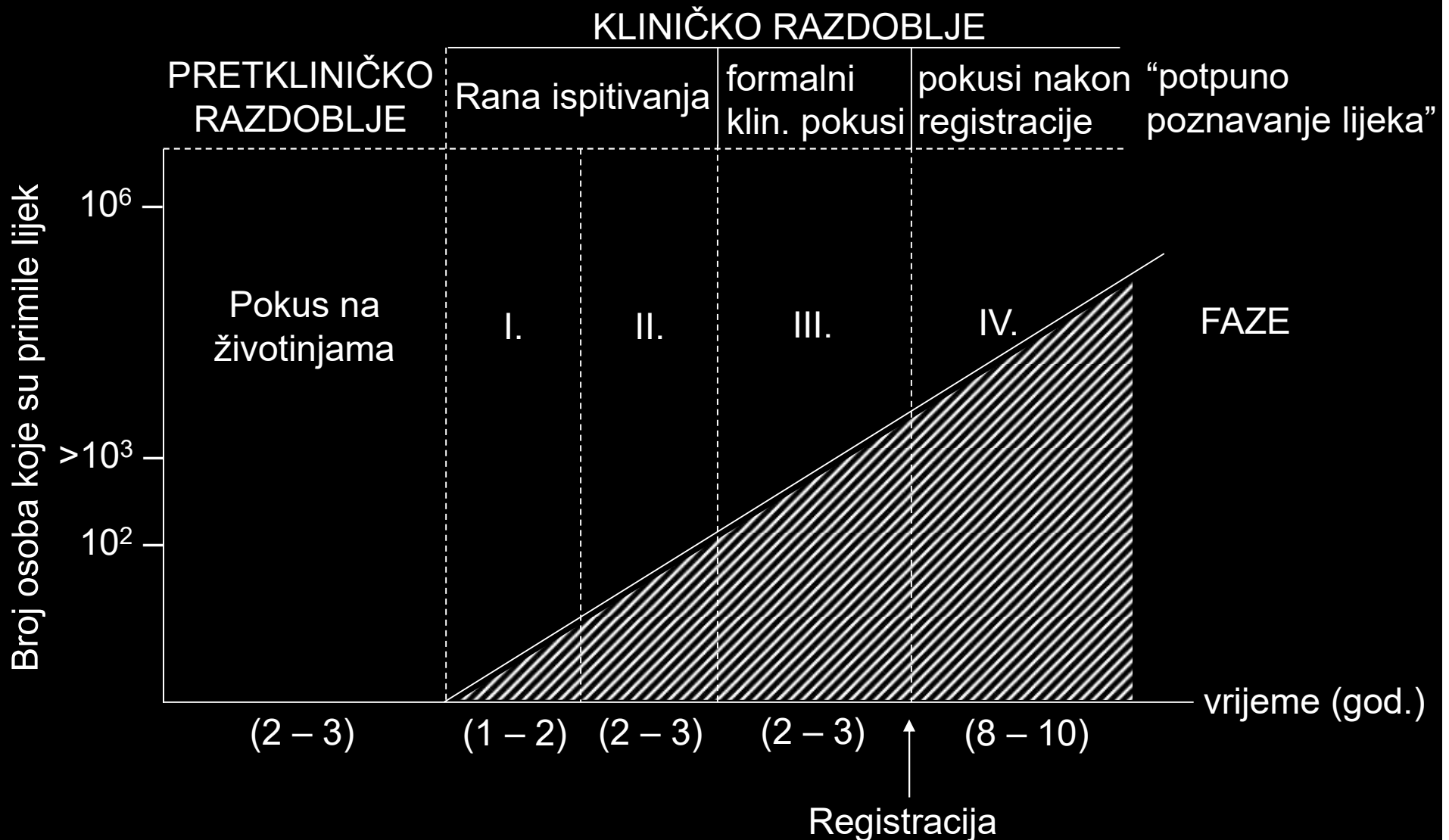
Faza	Fokus
I	<ul style="list-style-type: none">■ Sigurnost/toksičnost u zdravih dobrovoljaca ili pacijenata■ Maksimalna podnošljiva doza
II	<ul style="list-style-type: none">■ Učinkovitost i odnos korist/rizik u malih grupa pacijenata■ Najmanja učinkovita doza
III	<ul style="list-style-type: none">■ Komparativna učinkovitost u većih grupa pacijenata■ Rijede nuspojave
IV	<ul style="list-style-type: none">■ Dodatna istraživanja učinkovitosti i nuspojava:<ul style="list-style-type: none">▪ Dugotrajna istraživanja, posebne populacije pacijenata▪ Dodatne indikacije, učinkovitost u kliničkoj praksi

Klinički pokusi – tko je obaviješten i tko se može uključiti?

Power curves show sample size needed to obtain various levels of power for various levels of effect size, 5% one-tailed test. (Reprinted from Kraemer, 1986, with permission of J. B. Lippincott.)



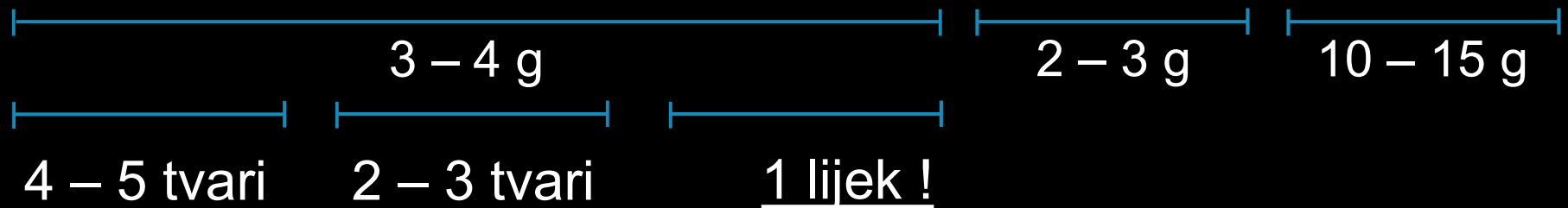
Klinički pokusi – tko je obaviješten i tko se može uključiti?



Klinički pokusi – tko je obaviješten i tko se može uključiti?

Klinički pokusi

I. faza → II. faza → III. faza → registracija (početak široke primjene) IV. faza



Klinički pokusi – tko je obaviješten i tko se može uključiti?

- Kako se provode klinička ispitivanja i tko je u njih uključen?
 - Klinička ispitivanja provode se prema unaprijed utvrđenom planu ispitivanja, koji propisuje uvjete za provođenje ispitivanja i podatke koji se prikupljaju

Klinički pokusi – tko je obaviješten i tko se može uključiti?

- Kako se provode klinička ispitivanja i tko je u njih uključen?
 - Lijekovi ili medicinski proizvodi najčešće se ispituju postupkom usporedbe s drugim, već odobrenim lijekovima (standardno liječenje) ili placeboom
 - U neintervencijski ispitivanjima se prate već odobreni lijekovi u odobrenim indikacijama kako bi se prikupili dodatni podaci o djelotvornosti i sigurnosti primjene lijeka u stvarnim uvjetima u širokoj populaciji bolesnika

Klinički pokusi – tko je obaviješten i tko se može uključiti?

- Većina se ispitanika u kliničkim ispitivanjima RANDOMIZIRA u jednu od skupina liječenja
- Ni ispitivač ni ispitanik ne mogu utjecati na to kojoj će skupini liječenja ispitanik pripasti
- RANDOMIZACIJA osigurava veću objektivnost dobivenih podataka kliničkim ispitivanjem

Klinički pokusi – tko je obaviješten i tko se može uključiti?

- **TKO MOŽE SUDJELOVATI?**
 - Svi koji su dobrovoljno pristali sudjelovati i potpisali informirani pristanak
 - Za pojedino ispitivanje treba zadovoljiti točno utvrđene kriterije koje određuje proizvođač/sponzor: dg. Bolesti, dob, spol, zdravstveno stanje
 - Mogućnost sudjelovanja u ispitivanju ispituje liječnik u potupku koji se zove probir (Screening)

Klinički pokusi – tko je obaviješten i tko se može uključiti?

- RIZICI SUDJELOVANJA U KLINIČKIM ISPITIVANJIMA?
 - Nedjelotvornost i nuspojave lijeka koji se ispituje
 - Rizici pretraga koje se provode u ispitivanju
 - Ispitanici se uvijek prije početka ispitivanja upoznaju s rizicima
 - Prije odobrenja ispitivanja, nadležna tijela procjenjuju opravdanost i prihvatljivost rizika za ispitanike

Klinički pokusi – tko je obaviješten i tko se može uključiti?

- Klinička ispitivanja u Republici Hrvatskoj odobrava Ministarstvo zdravstva i socijalne skrbi uz prethodno pozitivno mišljenje Središnjeg etičkog povjerenstva
- Središnje etičko povjerenstvo je nezavisno tijelo zdravstvenih radnika i drugih članova nemedicinske struke (pravnici, teolozi, predstavnici bolesnika) čija je odgovornost osigurati zaštitu prava ispitanika u kliničkim ispitivanjima

Klinički pokusi – tko je obaviješten i tko se može uključiti?

- Postoji NADOKNADA za slučaj da ispitanik pretrpi oštećenje u svezi s kliničkim ispitivanjem.
- Takvi su slučajevi rijetki.
- U Hrvatskoj je uvjet za odobrenje kliničkog ispitivanja sklopljena odgovarajuća polica osiguranja.

Klinički pokusi – tko je obaviješten i tko se može uključiti?

- **VAŽNO** je da obiteljski liječnik bude upoznat sa sudjelovanjem ispitanika u ispitivanju kako bi lijekovi i medicinski postupci koje propisuje bili u skladu s lijekovima i postupcima u ispitivanju.

Klinički pokusi – tko je obaviješten i tko se može uključiti?

- U kliničkim ispitivanjima ne postoje nikakvi troškovi za ispitanike
- Lijekove i postupke koji su predviđeni planom istraživanja plaća naručitelj ispitivanja (industrija, akademija, instituti, fondacije itd..)
- Za nadoknadu putnih troškova za posjete ispitivačkom mjestu, koje su predviđene planom ispitivanja, predviđena su sredstva kojima upravlja glavni istraživač.

Klinički pokusi – tko je obaviješten i tko se može uključiti?

- Koja je svrha ispitivanja?
- Tko će sudjelovati u ispitivanju?
- Koje će se pretrage provoditi?
- Je li lijek u ispitivanju već ispitan?
- Koji su rizici sudjelovanja?
- Koje su potencijalne koristi?
- Koji su drugo dostupni oblici liječenja?
- Koliko će dugo trajati ispitivanje?
- Kako će sudjelovanje u ispitivanju utjecati na svakodnevni život i obaveze?
- Hoće li terapija lijekom biti dostupna i nakon završetka ispitivanja?
- Kako će se znati da li lijek djeluje?
- Tko će biti zadužen za ispitanika tijekom ispitivanja?
- Kome se može ispitanik obratiti u slučaju dodatnih pitanja?

Klinički pokusi – tko je obaviješten i tko se može uključiti?

- Kome se obratiti s pitanjima?
 - Naručitelj/sponzor
 - Glavni istraživač ili njegovi suradnici
 - Povjerenstvo za lijekove ustanove
 - Etičko povjerenstvo ustanove
 - Središnje etičko povjerenstvo

Klinički pokusi – tko je obaviješten i tko se može uključiti?



Clinical trials for nivolumab AND pancreatic cancer

The European Union Clinical Trials Register allows you to search for protocol and results information on:

- interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA);
- clinical trials conducted outside the EU / EEA that are linked to European paediatric-medicine development.

Learn [more about the EU Clinical Trials Register](#) including the source of the information and the legal basis.

The EU Clinical Trials Register currently displays **34983** clinical trials with a EudraCT protocol, of which **5701** are clinical trials conducted with subjects less than 18 years old.

The register also displays information on **18700** older paediatric trials (in scope of Article 45 of the Paediatric Regulation (EC) No 1901/2006).

Examples: Cancer AND drug name, Pneumonia AND sponsor name.
[How to search \[pdf\]](#)

Advanced Search: [Search tools](#)

Trials with a EudraCT protocol (14)

Paediatric studies in scope of Art45 of the Paediatric Regulation (0)

14 result(s) found for: nivolumab AND pancreatic cancer. Displaying page 1 of 1.

EudraCT Number: 2016-001883-12	Sponsor Protocol Number: GI1616	Start Date * : 2016-09-14			
Sponsor Name: Herlev & Gentofte Hospital, Oncology Dept.					
Full Title: A PROSPECTIVE RANDOMIZED, OPEN-LABEL PHASE 2 STUDY OF IMMUNE CHECKPOINT INHIBITION, NIVOLUMAB WITH OR WITHOUT IPILIMUMAB IN COMBINATION WITH RADIATION THERAPY IN PRETREATED PATIENTS WITH METASTATIC...					
Medical condition: Patients with metastatic pancreatic cancer or metastatic biliary tract cancer					
Disease:	Version	SOC Term	Classification Code	Term	Level
	20.0	100000004864	10033605	Pancreatic cancer metastatic	LLT
	20.0	100000004864	10077846	Cholangiocarcinoma metastatic	LLT
Population Age: Adults, Elderly	Gender: Male, Female				
Trial protocol: DK (Ongoing)					
Trial results: (No results available)					

EudraCT Number: 2018-000339-28	Sponsor Protocol Number: CA025-006	Start Date * : 2018-10-01
Sponsor Name: Bristol-Myers Squibb International Corporation		
Full Title: A Phase 2 Study of Cabiralizumab (BMS-986227, FPA008) Administered in Combination with		

Subscribe to this Search

To subscribe to the RSS feed for this search click [here](#). This will provide an RSS feed for clinical trials matching your search that have been added or updated in the last 7 days.

Download Options:

Number of Trials to download:

Trials shown on current page

Download Content:

Summary Details


Download Format:

Plain Text

Note, where multi-state trials are shown in search results, selecting "Full Trial details" will

Klinički pokusi – tko je obaviješten i tko se može uključiti?

Joining a clinical trial

If you have found information on a specific clinical trial and are interested in joining a trial, we suggest you contact your healthcare professional for advice. The European Medicines Agency is not able to provide information related to specific trials. If you wish to contact the clinical trial sponsor you can find contact information in the trial record that interests you. However, this only applies to trials entered in the system after 10 March 2011. For trials entered before 10 March 2011, please consult the clinical trial [sponsors' contact information](#)  [134kB] document, which is also available on the [clinical trial sponsors page](#). Please note this list is not exhaustive.

If the contact information for a clinical trial sponsor is not in this PDF document, you are advised to **contact** the sponsor company or organisation directly through the contact information on its corporate website.

Please note that you should not interpret the information on the EU Clinical Trials Register website as a recommendation to use the medicine or to participate in the trial. The medicine or the clinical trial may not be suitable for you.

You should consult your healthcare professional or the trial investigator to discuss appropriate treatment options.

Version of the website

EU Clinical Trials Register version 2.2

See also:

[Glossary](#) 

[How to search](#) 

[FAQs](#) 

[Patients' and Consumers'](#)

[Organisations' contact information](#) 

[Healthcare Professionals'](#)

[Organisations contact information](#) 

[Sponsors' contact information](#) 

For technical support, please visit the [EMA Service Desk](#) portal using your user credentials for a system hosted by EMA (except Eudravigilance). If you do not have an account or have forgotten your credentials, please click [here](#).
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Klinički pokusi – tko je obaviješten i tko se može uključiti?

NIH U.S. National Library of Medicine

ClinicalTrials.gov

[Find Studies](#) [About Studies](#) [Submit Studies](#) [Resources](#) [About Site](#)

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 307,196 research studies in all 50 states and in 210 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks](#) and [potential benefits](#).

Find a study (all fields optional)

Status ⓘ

- Recruiting and not yet recruiting studies
 All studies

Condition or disease ⓘ (For example: breast cancer)

X

Other terms ⓘ (For example: NCT number, drug name, investigator name)

X

Country ⓘ

X

Search

[Advanced Search](#)

[Help](#) | [Studies by Topic](#) | [Studies on Map](#) | [Glossary](#)

Patients and Families

Search for actively recruiting studies that you may be able to participate in or learn about new interventions/treatments that are being considered.

[Learn more](#)

Researchers

Search the database to stay up to date on developments in your field, find collaborators, and identify unmet needs.

[Learn more](#)

Study Record Managers

Learn about registering studies and about submitting their results after study completion.

[Learn more](#)

Klinički pokusi – tko je obaviješten i tko se može uključiti?

816 Studies found for: **Zagreb, Croatia**

[List](#) [By Topic](#) [On Map](#) [Search Details](#)

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Filters

Showing: 1-10 of 816 studies studies per page

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	<input type="checkbox"/>	Recruiting	Community-based Mental Health Care for People With Severe and Enduring Mental Ill Health (RECOVER-E) Croatia	<ul style="list-style-type: none"> Severe Mental Disorder Schizophrenia Bipolar Disorder Severe Depression 	<ul style="list-style-type: none"> Other: Community mental health team 	<ul style="list-style-type: none"> KBC Zagreb Zagreb, Croatia
2	<input type="checkbox"/>	Completed	Influence of Intrathecal Dexamethasone Administration for Proximal Femoral Fractures	<ul style="list-style-type: none"> Femoral Fracture Cognition Disorders Cortisol; Hypersecretion 	<ul style="list-style-type: none"> Drug: 8 mg of dexamethasone Drug: 12,5 mg of 0.5 % of levobupivacaine 	<ul style="list-style-type: none"> University Hospital "Sveti Duh" Zagreb, Croatia
3	<input type="checkbox"/>	Recruiting	The Recovery of Cardiovascular Patients With Depression	<ul style="list-style-type: none"> Coronary Artery Disease Depression Cardiovascular Diseases 	<ul style="list-style-type: none"> Drug: Psychiatric treatment with sertraline Drug: Psychiatric treatment with escitalopram 	<ul style="list-style-type: none"> KBC Zagreb Zagreb, Croatia
4	<input type="checkbox"/>	Enrolling by invitation	Lidocaine and Perioperative Cytokine Levels in Blood and Cerebrospinal Fluid in Cerebral Aneurysm Patients	<ul style="list-style-type: none"> Aneurysm, Cerebral 	<ul style="list-style-type: none"> Drug: Lidocaine 	<ul style="list-style-type: none"> UHCZagreb Zagreb, Croatia
5	<input type="checkbox"/>	Recruiting	Evaluation of Multidisciplinary Recovery After Surgery Program in Orthopedics and Traumatology	<ul style="list-style-type: none"> Hip Fractures Knee Fracture Hip Arthritis Knee Arthritis 	<ul style="list-style-type: none"> Procedure: Multidisciplinary Recovery Program 	<ul style="list-style-type: none"> KBC Zagreb Zagreb, Croatia
6	<input type="checkbox"/>	Active, not recruiting	The Anti-inflammatory Effect of Anesthetics in Abdominal Surgery	<ul style="list-style-type: none"> Colon Cancer 	<ul style="list-style-type: none"> Other: Lidocaine Other: Ketamine Other: Lidocaine and Ketamine Other: Placebo (0.9% NaCl) 	<ul style="list-style-type: none"> The Anti-inflammatory Effect of Anesthetics in Abdominal Surgery Zagreb, Croatia
7	<input type="checkbox"/>	Recruiting	The Immunomodulatory Effect of Antifibrinolytic (Tranexamic Acid) in Total Knee Arthroplasty	<ul style="list-style-type: none"> Hemorrhage 	<ul style="list-style-type: none"> Drug: Tranexamic Acid 	<ul style="list-style-type: none"> Klinički Bolnički Centar Sestre Milosrdnice Zagreb, Croatia

Status

Recruitment ⓘ:

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Suspended
- Terminated
- Completed
- Withdrawn
- Unknown status†

Expanded Access ⓘ:

Eligibility Criteria

Age ⓘ: years OR

Age Group ⓘ:

- Child (birth–17)
- Adult (18–64)
- Older Adult (65+)

Sex ⓘ:

- All
- Female

Klinički pokusi – tko je obaviješten i tko se može uključiti?



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Example: liver cancer OR breast cancer NOT genetic

Search

[Search tips](#)

Search for [clinical trials in children](#)

Without Synonyms

Phases are

- All
- Phase 0
- Phase 1
- Phase 2
- Phase 3
- Phase 4

With results only

Rare diseases / orphan drugs

Welcome

- The Clinical Trials Search Portal provides access to a central database containing the trial registration data sets provided by the registries listed on the right. It also provides links to the full original records.
- To facilitate the unique identification of trials, the Search Portal bridges (groups together) multiple records about the same trial. [More information](#)
- Please note: This Search Portal is not a clinical trials registry. [How to register a trial](#)
- It is now possible to export the results of the search into XML. [More information](#)
- Crawling the ICTRP database now requires a username/password. To request access to the crawling pages please send an email to ictripinfo@who.int (This service is now enabled)
- A new field called 'Prospective registration' has been added to the ICTRP database. More details about this new field can be found [here](#)
- The WHO Database of Regulatory Information Tracking of Clinical Trials Registration & Ethics Committees (REGTRAC) is now online [here](#)

Data Providers

Data sets from [data providers](#) are updated every Friday evening according to the following schedule:
Every week:

- Australian New Zealand Clinical Trials Registry, last data file imported on 11 February 2019
- Chinese Clinical Trial Registry, last data file imported on 27 May 2019
- ClinicalTrials.gov, last data file imported on 27 May 2019
- EU Clinical Trials Register (EU-CTR), last data file imported on 14 January 2019
- ISRCTN, last data file imported on 27 May 2019
- The Netherlands National Trial Register, last data file imported on 27 May 2019

Every 4 weeks:

- Brazilian Clinical Trials Registry (ReBec), last data file imported on 15 January 2019
- Clinical Trials Registry - India, last data file imported on 21 May 2019
- Clinical Research Information Service - Republic of Korea, last data file imported on 20 May 2019
- Cuban Public Registry of Clinical Trials, last data file imported on 15 January 2019
- German Clinical Trials Register, last data file imported on 21 May 2019
- Iranian Registry of Clinical Trials, last data file imported on 21 May 2019
- Japan Primary Registries Network, last data file imported on 21 May 2019
- Pan African Clinical Trial Registry, last data file imported on 20 May 2019
- Sri Lanka Clinical Trials Registry, last data file imported on 21 May 2019
- Thai Clinical Trials Registry (TCTR), last data file imported on 22 May 2019
- Peruvian Clinical Trials Registry (REPEC), last data file imported on 25 February 2019

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<http://apps.who.int/trialsearch/>

Klinički pokusi – tko je obaviješten i tko se može uključiti?

Gensko testiranje | Genski testovi za liječenje raka | hrvatska.fmi@roche.com



[O raku](#) [Gensko testiranje](#) [FoundationOne®CDx](#) [FoundationOne®Heme](#) [FoundationOne®Liquid](#) [Rezultati](#) [ČPP](#) [Kontakt](#)



Gensko testiranje za liječenje raka



Klinički pokusi – tko je obaviješten i tko se može uključiti?

Technical Specifications



Intended Use

FoundationOne CDx™ (F1CDx) is a next generation sequencing based *in vitro* diagnostic device for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The test is intended as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in Table 1 in accordance with the approved therapeutic product labeling. Additionally, F1CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. The F1CDx assay is a single-site assay performed at Foundation Medicine, Inc.

1 |

Current Gene List²

Genes with full coding exonic regions included in FoundationOne CDx for the detection of substitutions, insertion deletions (indels), and copy-number alterations (CNAs).

ABL1	ACVR1B	AKT1	AKT2	AKT3	ALK	ALOX12B	AMER1 (FAM123B)	APC	
AR	ARAF	ARFRP1	ARD1A	ASXL1	ATM	ATR	ATRX	AURKA	
AURKB	AXIN1	AXL	BAP1	BARD1	BCL2	BCL2L1	BCL2L2	BCL5	
BCOR	BCORL1	BRAF	BRCA1	BRCA2	BRD4	BRP1	BTG1	BTG2	
BTK	C11orf93 (SMYD1)	CALR	CARD11	CASP8	CBFB	CBL	CCND1	CCND2	
CCND3	CCNE1	CD22	CD24 (pD-L1)	CD70	CD79A	CD79B	CDC73	CDH1	
CDK12	CDK4	CDK6	CDK8	CDKN1A	CDKN1B	CDKN2A	CDKN2B	CDKN2C	
CEBPA	CHEK1	CHEK2	CIC	CREBBP	CRKL	CSF1R	CSF3R	CTCF	
CTNNA1	CTNNB1	CUL3	CUL4A	CXCR4	CYP17A1	DAXX	DDR1	DDR2	
DIS3	DNMT3A	DOT1L	EED	EGFR	EP300	EPHA3	EPHB1	EPHB4	
ERBB2	ERBB3	ERBB4	ERCC4	ERG	ERRF1	ESR1	EZH2	FAM64C	
FANCA	FANCC	FANCG	FANCL	FAS	FBXW7	FGF10	FGF12	FGF14	
FGF19	FGF23	FGF3	FGF4	FGF6	FGFR1	FGFR2	FGFR3	FGFR4 FH	
	FLCN	FLT1	FLT3	FOXL2	FUBP1	GABRA6	GATA3	GATA4	
GATA6	GID4 (c17orf26)	GNA11	GNA13	GNAQ	GNAS	GRM3	GSK3B	H3F3A	
HDAC1	HGF	HNF1A	HRAS	HSD3B1	ID3	IDH1	IDH2	IGF1R	
IKBKE	IKZF1	INPP4B	IRF2	IRF4	IRS2	JAK1	JAK2	JAK3	
JUN	KDM5A	KDM5C	KDM6A	KDR	KEAP1	KEL	KIT	KLH6	
KMT2A (MLL)	KMT2D (MLL2)	KRAS	LTK	LYN	MAF	MAP2K1 (MEK1)	MAP2K2 (MEK2)	MAP2K4	
MAP3K1	MAP3K13	MAPK1	MCL1	MDM2	MDM4	MED12	MEF2B	MEN1	
MERTK	MET	MITF	MKNK1	MLH1	MPL	MRE11A	MSH2	MSH3	
MSH6	MST1R	MTAP	MTOR	MUTYH	MYC	MYCL (MYCL1)	MYCN	MYD88	
NBN	NF1	NF2	NFE2L2	NFKBIA	NKX2-1	NOTCH1	NOTCH2	NOTCH3	
NPM1	NRAS	NTSC2	NTRK1	NTRK2	NTRK3	P2RY8	PALB2	PARK2	
PARP1	PARP2	PARP3	PAX5	PBRM1	PDCD1 (pD-1)	PDCD1LG2 (pD-L2)	PDGFRA	PDGFRB	POK1
PIK3C2B	PIK3C2G	PIK3CA	PIK3CB	PIK3R1	PIM1	PMS2			
POLD1	POLE	PPARG	PPP2R1A	PPP2R2A	PRDM1	PRKAR1A	PRKCI	PTCH1	
PTEN	PTPN11	PTPRO	QKI	RAC1	RAD21	RAD51	RAD51B	RAD51C	
RAD51D	RAD52	RAD54L	RAF1	RARA	RB1	RBM10	REL	RET	
RICTOR	RNF43	ROS1	RPTOR	SDHA	SDHB	SDHC	SDHD	SETD2	
SF3B1	SGK1	SMAD2	SMAD4	SMARCA4	SMARCB1	SMO	SNCAIP	SODS1	
SOX2	SOX9	SPEN	SPOP	SRC	STAG2	STAT3	STK11	SUFU	
SYK	TBK1	TEK	TET2	TGFB2	TIPARP	TNFAIP3	TNFRSF14	TP53	
TSC1	TSC2	TYRO3	UZAF1	VEGFA	VHL	WHSC1 (MDS1)	WHSC1L1	WT1	
XPO1	XRCC2	ZNF217	ZNF703						

Klinički pokusi – tko je obaviješten i tko se može uključiti?

HVALA NA PAŽNJI!