Pharmaprojects*

*Subscriber access only

Pharmaprojects is the complete drug intelligence service covering global drug research and development across all disease areas since 1980. It sets the standard for comprehensive intelligence about drugs in the development pipeline from the lab to the market. The database contains profiles of over 80,000 drugs including 15,000 drugs in active development. Pharmaprojects also gives you access to over 30 years of R&D developments on 53,000 additional drugs, an unrivalled set of historical data.

Detailed, robust drug profiles include

- Chemical data (origin, chemical name, chemical structure)
- Originators and licensees
- Countries where drug is launched/approved
- Preclinical information
- Licensing availability
- Clinical information
- Orphan drug status
- All diseases the drug has been studied in and highest status it has reached
- Event history – tracking major events such as change in status, orphan drug status granted, first launch
- Mechanism of action and target

Sources include 50+ country/multinational trial registries, other trials listings, 4,400+ company webpages, all major medical meetings, news feeds, investor presentations, SEC filings, annual reports, health authority webpages, medical schools and clinical trial center postings, medical journals, USAN and INN lists, online resources, plus not so obvious sources such as research center websites, community hospital websites, grant awards lists, university protocol/IRB approval lists, CRO project listings, and primary research.

Use Pharmaprojects to answer such questions (amongst many others) as:

- Which drugs and indications have been studied with a certain target, such as PD-L1?
- Which late phase drugs indicated for melanoma are available in Brazil and Argentina?
- How has the landscape for prophylactic vaccines changed over the last 15 years?

Date Coverage 1981 to present

Update Frequency Daily

Geographic Coverage International

Document Types Reports of clinical and R&D drug development covering all therapy areas including rare and orphan drugs

Publisher

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Date Revised: 26 July 2018

ProQuest Dialog **Pharmaprojects**

Basic Search | Advanced | Command Line

Full text « Back to results

Add to selected items Save to My Research Em

TI regorafenib

PUB, PD, YR **Pharmaprojects**. (Jul 18, 2018).

Highlighting: Off | Single | Multi

TX **Full Text** Translate

Overview:

Regorafenib (BAY-73-4506; DAST) is an oral kinase inhibitor, developed by Bayer for the treatment of cancer (HealthCare Invest Day, Bayer, 17 Jun 2007; Company presentation, Bayer, 1 Sep 2009; FDA Web Page, 27 Sep 2012, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails). It targets VEGFR, KIT, RET, FGFR and PDGFR (44th ASCO (Chicago), 2008, Abs 2558).

Marketing:

Approvals

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Cancer, liver

Bayer

China; as Stivarga for the second-line treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib (Press release, Bayer, 13 Dec 2017, http://www.investor.bayer.de/en/nc/news/investor-news/investor-news/bayer-receives-approval-in-china-for-stivargaR-regorafenib-for-the-second-line-systemic-treatment/).

EU; approved as Stivarga for the treatment of adult patients with HCC who have been previously treated with Nexavar (sorafenib) (Press release, Bayer, 7 Nov 2016, http://www.news.bayer.com/baynews/baynews.nsf/id/7473C476F3B39963C1258061003458E4/$File/2016-0256E.pdf; Press release, Bayer, 23 Jun 2017, http://www.investor.bayer.de/en/nc/news/investor-news/investor-news/bayer-receives-positive-chmp-opinion-for-regorafenib-for-the-second-line-systemic-treatment-of-liver/; Press release, Bayer, 7 Aug 2017, http://www.investor.bayer.de/en/nc/news/investor-news/investor-news/bayer-receives-eu-approval-for-stivargaR-regorafenib-for-the-second-line-systemic-treatment-of-li/).

Germany; it was withdrawn from the German market in 2016 due to a reimbursement issue (Press release, Bayer, 15 Apr 2016, http://www.presse.bayer.de/baynews/baynews.nsf/id/Konsequenz-aus-G-BA-Beschluss-Bayer-stellt-Vertrieb-fuer-Regorafenib-in-Deutschland-ein).

Japan; as Stivarga tablets for the second-line treatment of patients with unresectable hepatocellular carcinoma (HCC) who have progressed after treatment with Nexavar (sorafenib) (Press release, Bayer, 26 Jun 2017, http://www.news.bayer.com/baynews/baynews.nsf/id/Bayer-Receives-Approval-for-Stivarga-in-Japan-for-Second-Line-Treatment-of-Hepatocellular-Carcinoma?OpenDocument&sessionID=1498729831; Company presentation, Bayer, 27 Jul 2017, Slide 26, http://www.quarterly-report-2017-q2.bayer.com/servicepages/downloads/files/bayer_ir2_17_entire.pdf).

South Korea; as Stivarga for the second-line treatment of patients with unresectable hepatocellular carcinoma (Press release, Bayer, 17 Jul 2017, http://www.koreabiomed.com/news/articleView.html?idxno=894).

USA; as Stivarga (regorafenib) tablets for the second-line treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with Nexavar (sorafenib) (Press release, Bayer, 28 Apr 2017, http://www.investor.bayer.de/securedl/15345).

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Licensing:

Agreements

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Onyx Pharmaceuticals (now Amgen)

Worldwide; Onyx and Bayer entered into a new agreement. As per the agreement, regorafenib will be a Bayer compound, and Bayer will have the final decision making authority for global development and commercialization. Onyx will receive a royalty on any future global net sales of regorafenib in oncology. In addition, Bayer will contract the Onyx sales force to promote regorafenib, along with Bayer sales representatives in the US (Press release, Bayer, 12 Oct 2011, http://www.investor.bayer.com/en/news/investor-news/investor-news/showNewsItem/1327/1318420680/c6dc6319e4/).

Key Clinical Information - Phase III:

Cancer, colorectal

It is in a randomized, double-blind, placebo-controlled Phase III trial (ARGO) in1100 patients with stage IIIa and IIIb colon cancer, to evaluate the disease free survival of regorafenib as adjuvant therapy following completion of standard chemotherapy. Secondary endpoints include overall survival and safety. Patients will receive either 120mg of regorafenib or placebo for 2yr (Press release, Bayer, 1 Jun 2016, http://www.news.bayer.com/baynews/baynews.nsf/id/7AAEC889B2A93047C1257FC4004E82EA/$File/2016-0100E.pdf?open&mod=01.06.2016_12:39:23; JP Morgan 35th Ann Healthcare Conf (San Francisco), 2017, Slide 18, http://www.investor.bayer.de/securedl/14706).

A randomized, double-blind, placebo-controlled, parallel-assignment Phase III trial (COAST; 15983) in Australia, Belgium, Brazil, Canada, China, France, Germany, Israel, Italy, Japan, Portugal, Spain, the UK and the US in 25 subjects with stage IV colorectal cancer (CRC) after curative resection of liver metastases and completion of all

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PHS

Drug Development Phases

Region	Phase	Year of Launch	Licensing Availability
Argentina	Phase III Clinical Trial		Unknown
Australia	Phase III Clinical Trial		Unknown
Austria	Launched		Unknown
Belgium	Launched		Unknown
Brazil	Phase III Clinical Trial		Unknown
Canada	Registered		Unknown
Chile	Not Applicable		Unknown
China	Registered		Unknown
Colombia	Not Applicable		Unknown
Denmark	Launched		Unknown
Finland	Launched		Unknown
France	Launched		Unknown
Germany	Withdrawn		Unknown
Greece	Launched		Unknown
Hong Kong	Phase III Clinical Trial		Unknown

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Indexing (details) Cite

SUBST	**Substance**	Substance:	4-(4-(((4-chloro-3-(trifluoromethyl)phenyl)carbamoyl}amino)-3-fluorophenoxy)-N-methylpyridine-2-carboxamide
RN		CAS:	755037-03-7
MF	**Molecular formula**	C21H15ClF4N4O3	
MW	**Molecular weight**	482.82	
NCE	**New chemical entity**	Yes	
GN	**Generic name**	4-(4-(((4-chloro-3-(trifluoromethyl)phenyl)carbamoyl}amino)-3-fluorophenoxy)-N-methylpyridine-2-carboxamide	
SYN	**Synonym**	BAY 73-4506 BAY-73-4506 DAST DAST-Inhibitor Stivarga	
OS	**Origin of substance**	Chemical, synthetic	
MEC	**Mechanism of action**	Angiogenesis inhibitor C-kit inhibitor FGF receptor tyrosine kinase inhibitor Platelet-derived growth factor receptor kinase inhibitor Raf kinase inhibitor RET tyrosine kinase inhibitor Vascular endothelial growth factor (VEGF)receptor antagonist VEGFR-2 tyrosine kinase inhibitor VEGFR-3 tyrosine kinase inhibitor	
RO	**Route of administration**	Oral, Oral: swallowed, Tablet	
TG	**Target information**	Name: v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homologue Locus: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=gene&cmd=Retrieve&dopt=Graphics&list_uids=3815 Family: Receptor, Enzyme > Kinase Name: platelet-derived growth factor receptor, alpha polypeptide Locus: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=gene&cmd=Retrieve&dopt=Graphics&list_uids=5156 Family: Receptor, Enzyme > Kinase Name: ret proto-oncogene Locus: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=gene&cmd=Retrieve&dopt=Graphics&list_uids=5979 Family: Enzyme > Kinase, 2.7.10.1	
IND	**Indication**	Cancer: breast (Phase I Clinical Trial) Cancer: colorectal (Launched) Cancer: liver (Registered) Cancer: lung: non-small cell (Phase I Clinical Trial) Cancer: lymphoma: unspecified (Phase I Clinical Trial) Cancer: myeloma (Phase I Clinical Trial)	

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TST	**Therapy status**	Therapy: Anticancer: other Status: Launched
ST	**Drug status**	Launched
DOR	**Originator**	Bayer, Status: Launched.
LCO	**Licensee**	Onyx Pharmaceuticals, Status: Launched
TI	**Title**	regorafenib

HP	**Highest phase**	Launched
HI	**Development history**	2007-01-19: New Product 2008-09-30: Change in Global Status Phase II Clinical Trial 2009-05-30: New Disease Cancer, colorectal (. . .) 2015-06-04: Orphan Drug Status Granted The US; Hepatocellular carcinoma 2016-07-13: Orphan Drug Status Granted Australia; Hepatocellular carcinoma 2017-02-16: New Disease Cancer, sarcoma, soft tissue 2017-04-28: Additional Registrations The US; for the second-line treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with Nexavar 2017-06-26: Additional Registrations Japan; Unresectable hepatocellular carcinoma, second-line treatment after progression on chemotherapy 2017-07-17: Additional Registrations South Korea; Cancer, liver, unresectable 2017-08-07: Additional Registrations China; metastatic colorectal cancer, metastatic gastrointestinal stromal tumours 2016-04-15: Withdrawn Products Germany 2018-07-17 Completion of Phase III trial (REGARD) for colorectal cancer reported
LA	**Language**	English
DTYPE	**Document type**	Report
PUB	**Publication title**	Pharmaprojects
RTYPE	**Publication type**	Report
PD, YR	**Publication date**	Jul 18, 2018
DREV	**Date revised**	2018-07-17: Completion of Phase III trial (REGARD) for colorectal cancer reported
	Source attribution	Pharmaprojects, © Publisher specific
AN	**Accession number**	36855
	Document URL	https://dialog.proquest.com/professional/docview/577445804?accountid=174335
FAV	**First available**	2010-07-13
UD	**Updates**	2017-05-16 2017-05-17 2017-05-18 2017-06-30 2017-07-04 2017-07-18 2017-08-02 2017-08-09 2017-08-15 2017-09-28 2017-10-24 2017-11-22 2017-12-15 2018-01-10 2018-02-14 2018-04-10 2018-05-04 2018-05-16 2018-07-12 2018-07-18
	Database	Pharmaprojects (1981 - current)

SEARCH FIELDS

Field Name	Field Code	Example	Description and Notes
Accession number	AN	an(36855)	A unique document identification number assigned by the information provider.
All fields (plus full text)	-	"colorectal cancer"	Use adjacency and/or Boolean operators to narrow or broaden your search, and double quotes to search for a precise phrase.
All fields (no full text)	ALL	all("colorectal cancer")	
CAS® Registry Number	RN	rn(755037-03-7)	The Registry Number is also searchable using the Substance field code (SUBST)
Company[1]	CO	co(bayer) co(launched)	Company, including Originator and Licensee. In addition to the company's name, the highest status of the drug is included here.
Date revised	DREV	drev(2018)	The date on which the report was revised, and usually a statement describing the revision. The date is searchable but the text is not
Development history	HI	hi(2016) hi(withdrawn Germany)	The drug's development milestones, consisting of a date and a short statement. The full date is displayed but only the year is searchable. The text is searchable.
Document text	TX	See Text	See Text
Document title	TI	See Title	See Title
Document type	DTYPE	dtype(report)	All documents in Pharmaprojects are reports.
Drug name	DN	dn(regorafenib) dn(keytruda)	Retrieves generic name and synonyms, including the drug name as it appears in the title. Drug name can also be searched with the substance field code - SUBST
Drug status	ST	st(launched)	There are three possibilities: launched, ceased, active.
Drug synonym	SYN	syn(stivarga)	Synonyms include tradenames, lab codes and other designations of the drug, but not usually the generic name, which appears in its own field. Synonyms are also searchable in the Substance field (SUBST).
First available	FAV	fav(20100713)	The date on which the document was loaded for the first time on ProQuest Dialog. It will not change regardless of how many times the record is subsequently reloaded, as long as the Accession Number does not change.

[1] A Lookup/Browse feature is available for this field in the Advanced Search dropdown or in Browse Fields.

Field Name	Field Code	Example	Description and Notes
From database[2]	FDB	"metastatic colorectal carcinomas" AND fdb(pharmaprojects) "common environmental compounds" AND fdb(1007827)	Useful in multi-file searches to isolate records from a single file. FDB cannot be searched on its own; specify at least one search term then AND it with FDB. Pharmaprojects can be specified by name or the ID 1007827.
Generic name	GN	gn(posaconazole)	The Generic name field does not include synonyms and other drug designations - these are in the Synonym field. The generic name is also searchable with the Substance field, SUBST.
Highest phase	HP	hp(launched) hp("phase ii")	This is the highest level of development the drug has reached anywhere in the world, also known as global status. Options can be browsed and selected via a list on the Advanced Search page.
Indications[1]	IND	ind(melanoma)	The indication is usually displayed with the phase the drug has reached. The indication, but not the phase, is searchable in this field.
Language	LA	la(english)	All documents are in English
Licensee	LCO	lco(onyx pharmaceuticals)	This is the licensee. The originator can be searched with field code DOR, and both can be searched with the company field, CO
Licensing availability	AVLC	avlc(yes) phs(china LNK available)	If the drug is available for licensing in a country, a line item to this effect will appear in the Drug Development Phases table in the text of the report. To find any drug available for licensing anywhere, simply search AVLC(YES). To find availability in a country, use the LNK operator between the country and the word 'available'
Mechanism of action[1]	MEC	mec("angiogenesis inhibitor") mec(kinase n/2 inhibitor)	The drug's mechanisms of actions. There may be more than one, so use double quotes or proximity operators to search for a precise phrase
Molecular formula	MF	mf(C21H15ClF4N4O3)	Search the molecular formula as a single string of letters and numbers
Molecular weight	MW	mw(482.81)	The drug's molecular weight
New chemical entity	NCE	nce(true) nce(false)	There are two options: yes and no, searched as nce(true) and nce(false) respectively

[2] Click the "Field codes" hyperlink at the top right of the Advanced Search page. Click "Search syntax and field codes", then click on "FDB command" to get a list of database names and codes that can be searched with FDB.

Field Name	Field Code	Example	Description and Notes
Origin of substance	OS	os("chemical synthetic peptide")	The main options are chemical, biological and natural product. All options can be browsed and selected via the Origin of Substance list on the Advanced Search page. The origin of substance is not available for every drug
Originator	DOR	dor(bayer) co(bayer)	This is the originator of the drug. The licensee can be searched with field code LCO, and both can be searched with the company field, CO
Patent information	PAT	pat(601981) pat(au) pat(2003238544)	Patent information is included in some reports, with patent publication number, publication country, priority country and priority date. All patent information is searchable with field code PAT, and individual elements are searchable with their own fields listed below.
Patent publication country	PC	pc(au)	Also searchable using field code PAT
Patent publication number	PN	pn(601981) pn(2003238544)	Also searchable using field code PAT
Patent priority country	PC	pc(au)	Also searchable using field code PAT
Patent priority date	PRD	prd(19991226)	Also searchable using field code PAT
Pharmacokinetic data	PK	pk(human AND mouse) pk("auc - 52mghr/l")	Includes model, parameter, value, dose
Phase	PHS	phs(registered LNK austria) phs("phase iii" LNK china) phs("phase I" LNK germany LNK available)	The Drug Development Phases table in the text of the report lists each country, the phase the drug has reached there, and whether the drug is available for licensing in that country. To search for a drug's phase in a country use the LNK operator to combine terms. See also Highest Phase – HP.
Publication date	PD	pd(20180721)	The publication date is derived from the date the information provider supplied the report
Publication title	PUB	pub(pharmaprojects)	All documents have the publication title Pharmaprojects
Publication type	RTYPE	rtype(report)	All documents are reports.
Publication year	YR	yr(2018)	The publication year is derived from the date the information provider supplied the report
Region	RG	rg(brazil) phs(brazil LNK launched)	Country names displayed in the Drug Development Phases table are searchable individually using field code RG, or in combination with phase using field code PHS. See also Phase – PHS.

Field Name	Field Code	Example	Description and Notes
Route of administration	RO	ro(oral) ro(capsule hard)	The drug's route of administration, and often its formulation, is displayed here.
Subjects	SU	su("human papilloma virus") su(topical)	The Subject field code – SU – can be used to search Origin of substance, Mechanism of action, Route of administration, Target, and Indication.
Substance	SUBST	subst(regorafenib) subst(129722-12-9) subst(stivarga) subst(4 4 4 chloro 3 trifluoromethyl)	The Substance field code can be used to search the CAS registry number as well as all forms of the drug name – chemical, generic and synonyms. Remove parentheses from chemical names for searching
Synonym	SYN	syn(stivarga) syn(DAST) syn(DAST inhibitor) syn(BAY 73 4506)	The drug's synonyms or alternative forms of the name are included here. Synonyms are also searchable with the Substance field code - SUBST
Target data	TG	tg(3.1.1.7) tg(enzyme PRE/1 kinase) tg(ret proto oncogene)	Includes Target name, Entrez Gene ID, Target family, and Enzyme Commission (EC) numbers, when available. Gene IDs are linked when possible to the National Center for Biotechnology Information, U.S. National Library of Medicine.
Text	TX	tx(fluoropyrimidine N/5 chemotherapy) tx("fast-track designation" AND mcrc) phs(brazil LNK "registered")	Use adjacency and/or Boolean operators to narrow or broaden your search, and double quotes to search for a precise phrase. Note that the last item in the Text is the Drug Development Phases table. To search the countries, phases and licensing availability in this table use the Phases field code – PHS.
Therapy status	TST	tst(anticancer AND launched)	Status of the drug for the specified therapy
Title	TI	ti(regorafenib) ti(zka-190)	The title is the name of the drug discussed in the report. The name is usually the generic name, but it may also be a lab code or other designation. The company's name and the formulation of the drug are sometimes included in the title.
Updates	UD	ud(2018) ud(201807) ud(20180721)	This is the date on which the report was updated on ProQuest Dialog. Search year, year and month, or year month and date.

SEARCH TOOLS

Field codes are used to search document fields, as shown in the sample document. Field codes may be used in searches entered on the **Basic Search**, **Advanced Search**, and **Command Line** search pages. **Limit options**, **Look up** lists, and "Narrow results by" filters tools are available for searching. Some data can be searched using more than one tool.

Limit Options

Limit options are quick and easy ways of searching certain common concepts**.** Check boxes are available for:

Available for licensing, Development ceased, In development, Launched, New chemical entity

Short lists of choices are available for:

Phase, Highest phase, Drug status, Route of administration, Origin of substance

Date limiters are available in which you can select single dates or date ranges for the **Publication, Last updated,** and **Revised date.**

Look up Lists

You can browse the contents of certain fields by using Look up lists. These are particularly useful to validate spellings or the presence of specific data. Terms found in the course of browsing may be selected and automatically added to the Advanced Search form. Look up lists are available in the fields drop-down and in the search options for:

Indications, Mechanism of action

and in the fields drop-down only for:

Company

Common Command Line Searches

On the Command Line search page you can add common concepts to your search.

Find reports on drugs in a particular status with these search terms:

ST(ACTIVE)
ST(LAUNCHED)
ST(CEASED)

Find reports with images using **IMGANY(YES)**

"Narrow Results By" Filters

When results of a search are presented, the results display is accompanied by a list of "Narrow results by" options shown on the right-hand panel. Click on any of these options and you will see a ranked list showing the most frequently occurring terms in your results. Click on the term to apply it to "narrow" your search results. "Narrow results by" limiters in Pharmaprojects include:

Highest phase, Company, Publication date, Mechanism of action, Indication

NOTES

Excel Custom Export Fields

If you choose to export your data in Excel (XLS) you have the option to use a custom format to output only the fields you need. ProQuest Dialog shows ALL fields for ALL databases in the custom pick list – not just the ones that are appropriate to this database. The following table lists only those fields that may appear in the *Pharmaprojects* database.

Field Name	Notes
Accession Number	Pharmaprojects' unique document identifier
Article Type	
CAS Registry Number	
Company Information	Supports One-to-Many; the following four fields will also be output if you select *Multiple rows per item by: Company Information*
• Company Information – Name	
• Company Information – Type	
• Company Information – Role	Contains phase of development
• Company Information – Parent	
Database	
Date Delivered	Contains date revised
Document Type	
Document URL	
Drug Status	
Drug Synonym	
First Available	
Generic Name	
Indication	
Language	
Language of Summary	
Mechanism of Action	
Molecular Formula	
Origin of Substance	
Patent Publication Country	
Patent Publication Date	
Patent Publication Number	
Pharmacokinetics	
Phase of Development	Supports One-to-Many; the following three fields will also be output if you select *Multiple rows per item by: Phase of Development*
• Phase of Development (Highest)	
• Phase of Development – Country/Region	
• Phase of Development – Phase	
Publication Date	
Publication Title	
Publication Type	
Publication Year	
Route of Administration	
Source Attribution	
Source Type	
Store ID	ProQuest Dialog's internal unique document identifier
Substance	
Title	The name of the drug
Updates	

Pre-defined document formats are available for viewing and download. Search results can be downloaded with the Download all results, Email, Print and Export/Save options, and when creating an alert. To design your own download format, choose the "Custom" format option and check the fields to be displayed.

Document Format	Fields	Online	Export/Download
Brief view	Title, Publication title, and Publication date	✓	
Detailed view	**Brief view** plus a three-line KWIC window	✓	
KWIC (Keyword in Context)	**Detailed view** plus all occurrences of your search terms, highlighted in fields where the terms appear.	✓	✓
Preview	**Brief view**	✓	
Brief citation	**Brief view** plus Molecular formula, Patent information, Date revised, First available and Update dates.	✓	✓
Full text	The complete record with full text.	✓[3]	✓
Custom	Choose the fields you want		✓[4]

[3] In Online-view mode, PQD gives access to two Document Formats only: *Brief citation*, and the 'most complete' format available. Depending on the database, or the amount of data available for a record, the most complete format may be any one of *Citation*, *Citation/Abstract*, *Full text*, or *Full text – PDF*.

[4] Custom export/download format is available in the following mediums only: HTML, PDF, RefWorks, RTF, Text only, XLS.

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