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
regorafenib
Pharmaprojects. (Jul 18, 2018).

Overview:

Marketing:
Approvals

Cancer, liver
Bayer


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).
Licensing:
Agreements

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


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

(. . .)

Drug Development Phases

<table>
<thead>
<tr>
<th>Region</th>
<th>Phase</th>
<th>Year of Launch</th>
<th>Licensing Availability</th>
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<tbody>
<tr>
<td>Argentina</td>
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<td>Australia</td>
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<tr>
<td>Austria</td>
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<td>Brazil</td>
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<tr>
<td>Canada</td>
<td>Registered</td>
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<td>Unknown</td>
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<td>Chile</td>
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<td>China</td>
<td>Registered</td>
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<td>Colombia</td>
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<tr>
<td>Denmark</td>
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<td>Finland</td>
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<td>France</td>
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<tr>
<td>Germany</td>
<td>Withdrawn</td>
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<td>Greece</td>
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<td>Hong Kong</td>
<td>Phase III Clinical Trial</td>
<td></td>
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</table>

(. . .)
SUBST

**Substance:** 4-{4-(((4-chloro-3-(trifluoromethyl)phenyl)carbamoyl)amino)-3-fluorophenoxy)-N-methylpyridine-2-carboxamide

**CAS:** 755837-03-7

RN

**Molecular formula:** C21H15ClF4N4O3

**Molecular weight:** 462.82

**New chemical entity:** Yes

**Generic name:** 4-(4-(((4-chloro-3-(trifluoromethyl)phenyl)carbamoyl)amino)-3-fluorophenoxy)-N-methylpyridine-2-carboxamide

SYN

**Synonym:** 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-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
  - Family: Receptor, Enzyme > Kinase
- Name: platelet-derived growth factor receptor, alpha polypeptide
  - Family: Receptor, Enzyme > Kinase
- Name: ret proto-oncogene
  - 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: lymphome: unspecified (Phase I Clinical Trial)
- Cancer: myeloma (Phase I Clinical Trial)

( ... )

TST

**Therapy status:** Anticancer: other

**Status:** Launched

ST

**Drug status:** Launched

DOR

**Originator:** Bayer, Status: Launched

LCO

**Licensee:** Onyx Pharmaceuticals, Status: Launched

TI

**Title:** regorafenib
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<td>2007-01-19: New Product</td>
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<td>2008-09-30: Change in Global Status Phase II Clinical Trial</td>
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<td>2009-05-30: New Disease Cancer, colorectal</td>
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<td>2015-06-04: Orphan Drug Status Granted The US; Hepatocellular carcinoma</td>
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<tr>
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<td>2016-07-13: Orphan Drug Status Granted Australia; Hepatocellular carcinoma</td>
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<tr>
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<td></td>
<td>2017-02-16: New Disease Cancer, sarcoma, soft tissue</td>
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<td>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</td>
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<td>2017-06-26: Additional Registrations Japan; Unresectable hepatocellular carcinoma, second-line treatment after progression on chemotherapy</td>
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<td>2017-07-17: Additional Registrations South Korea; Cancer, liver, unresectable</td>
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<td>2017-08-07: Additional Registrations China; metastatic colorectal cancer, metastatic gastrointestinal stromal tumours</td>
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<td>2016-04-15: Withdrawn Products Germany</td>
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<td>2018-07-17: Completion of Phase III trial ( REGARD) for colorectal cancer reported</td>
</tr>
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<td>2018-07-17: Completion of Phase III trial ( REGARD) for colorectal cancer reported</td>
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<td>PD, YR</td>
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<td>DREV</td>
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<p>| Database | Pharmaprospects (1981 - current) |</p>
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<td>A unique document identification number assigned by the information provider.</td>
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<td>&quot;colorectal cancer&quot;</td>
<td>Use adjacency and/or Boolean operators to narrow or broaden your search, and double quotes to search for a precise phrase.</td>
</tr>
<tr>
<td>All fields (no full text)</td>
<td>ALL</td>
<td>all(&quot;colorectal cancer&quot;)</td>
<td></td>
</tr>
<tr>
<td>CAS® Registry Number</td>
<td>RN</td>
<td>rn(755037-03-7)</td>
<td>The Registry Number is also searchable using the Substance field code (SUBST)</td>
</tr>
<tr>
<td>Company¹</td>
<td>CO</td>
<td>co(bayer)</td>
<td>Company, including Originator and Licensee. In addition to the company’s name, the highest status of the drug is included here.</td>
</tr>
<tr>
<td>Date revised</td>
<td>DREV</td>
<td>drev(2018)</td>
<td>The date on which the report was revised, and usually a statement describing the revision. The date is searchable but the text is not</td>
</tr>
<tr>
<td>Development history</td>
<td>HI</td>
<td>hi(2016)</td>
<td>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.</td>
</tr>
<tr>
<td>Document text</td>
<td>TX</td>
<td>See Text</td>
<td>See Text</td>
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<tr>
<td>Document title</td>
<td>TI</td>
<td>See Title</td>
<td>See Title</td>
</tr>
<tr>
<td>Document type</td>
<td>DTYPE</td>
<td>dtype(report)</td>
<td>All documents in Pharmaprojects are reports.</td>
</tr>
<tr>
<td>Drug name</td>
<td>DN</td>
<td>dn(regorafenib)</td>
<td>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</td>
</tr>
<tr>
<td>Drug synonym</td>
<td>SYN</td>
<td>syn(stivarga)</td>
<td>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).</td>
</tr>
<tr>
<td>First available</td>
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<td>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.</td>
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¹ A Lookup/Browse feature is available for this field in the Advanced Search dropdown or in Browse Fields.
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<thead>
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<th>Field Code</th>
<th>Example</th>
<th>Description and Notes</th>
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<tr>
<td>From database&lt;sup&gt;2&lt;/sup&gt;</td>
<td>FDB</td>
<td>&quot;metastatic colorectal carcinomas&quot; AND fdb(pharmaprojects) &quot;common environmental compounds&quot; AND fdb(1007827)</td>
<td>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.</td>
</tr>
<tr>
<td>Generic name</td>
<td>GN</td>
<td>gn(posaconazole)</td>
<td>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.</td>
</tr>
<tr>
<td>Highest phase</td>
<td>HP</td>
<td>hp(launched) hp(&quot;phase ii&quot;)</td>
<td>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.</td>
</tr>
<tr>
<td>Indications&lt;sup&gt;1&lt;/sup&gt;</td>
<td>IND</td>
<td>ind(melanoma)</td>
<td>The indication is usually displayed with the phase the drug has reached. The indication, but not the phase, is searchable in this field.</td>
</tr>
<tr>
<td>Language</td>
<td>LA</td>
<td>la(english)</td>
<td>All documents are in English</td>
</tr>
<tr>
<td>Licensee</td>
<td>LCO</td>
<td>lco(onyx pharmaceuticals)</td>
<td>This is the licensee. The originator can be searched with field code DOR, and both can be searched with the company field, CO</td>
</tr>
<tr>
<td>Licensing availability</td>
<td>AVLC</td>
<td>avlc(yes) phs(china LNK available)</td>
<td>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'</td>
</tr>
<tr>
<td>Mechanism of action&lt;sup&gt;1&lt;/sup&gt;</td>
<td>MEC</td>
<td>mec(&quot;angiogenesis inhibitor&quot;) mec(kinase n/2 inhibitor)</td>
<td>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</td>
</tr>
<tr>
<td>Molecular formula</td>
<td>MF</td>
<td>mf(C21H15ClF4N4O3)</td>
<td>Search the molecular formula as a single string of letters and numbers</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>MW</td>
<td>mw(482.81)</td>
<td>The drug's molecular weight</td>
</tr>
<tr>
<td>New chemical entity</td>
<td>NCE</td>
<td>nce(true) nce(false)</td>
<td>There are two options: yes and no, searched as nce(true) and nce(false) respectively</td>
</tr>
</tbody>
</table>

<sup>2</sup> 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.

Page 7
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Code</th>
<th>Example</th>
<th>Description and Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Origin of substance</td>
<td>OS</td>
<td>os(&quot;chemical synthetic peptide&quot;)</td>
<td>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.</td>
</tr>
<tr>
<td>Originator</td>
<td>DOR</td>
<td>dor(bayer) co(bayer)</td>
<td>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.</td>
</tr>
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<td>Patent information</td>
<td>PAT</td>
<td>pat(601981) pat(au) pat(2003238544)</td>
<td>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.</td>
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<tr>
<td>Patent publication country</td>
<td>PC</td>
<td>pc(au)</td>
<td>Also searchable using field code PAT</td>
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<td>Patent publication number</td>
<td>PN</td>
<td>pn(601981) pn(2003238544)</td>
<td>Also searchable using field code PAT</td>
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<tr>
<td>Patent priority country</td>
<td>PC</td>
<td>pc(au)</td>
<td>Also searchable using field code PAT</td>
</tr>
<tr>
<td>Patent priority date</td>
<td>PRD</td>
<td>prd(19991226)</td>
<td>Also searchable using field code PAT</td>
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<tr>
<td>Pharmacokinetic data</td>
<td>PK</td>
<td>pk(human AND mouse) pk(&quot;auc - 52mghr/l&quot;)</td>
<td>Includes model, parameter, value, dose</td>
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<tr>
<td>Phase</td>
<td>PHS</td>
<td>phs(registered LNK austria)</td>
<td>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.</td>
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<td>All documents are reports.</td>
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<td>RG</td>
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<td>Route of administration</td>
<td>RO</td>
<td>ro(oral) ro(capsule hard)</td>
<td>The drug’s route of administration, and often its formulation, is displayed here.</td>
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<td>SU</td>
<td>su(“human papilloma virus”) su(topical)</td>
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<td>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</td>
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<td>Synonym</td>
<td>SY</td>
<td>syn(stivarga) syn(DAST) syn(DAST inhibitor) syn(BAY 73 4506)</td>
<td>The drug’s synonyms or alternative forms of the name are included here. Synonyms are also searchable with the Substance field code - SUBST</td>
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<td>TG</td>
<td>tg(3.1.1.7) tg(enzyme PRE/1 kinase) tg(ret proto oncogene)</td>
<td>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.</td>
</tr>
<tr>
<td>Text</td>
<td>TX</td>
<td>tx(flouropyrimidine N/5 chemotherapy) tx(“fast-track designation” AND mcrc) phs(brazil LNK “registered”)</td>
<td>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.</td>
</tr>
<tr>
<td>Therapy status</td>
<td>TST</td>
<td>tst(anticancer AND launched)</td>
<td>Status of the drug for the specified therapy</td>
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<tr>
<td>Title</td>
<td>TI</td>
<td>ti(regorafenib) ti(zka-190)</td>
<td>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.</td>
</tr>
<tr>
<td>Updates</td>
<td>UD</td>
<td>ud(2018) ud(201807) ud(20180721)</td>
<td>This is the date on which the report was updated on ProQuest Dialog. Search year, year and month, or year month and date.</td>
</tr>
</tbody>
</table>

**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 Pharmaprocesses include:

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

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<th>Notes</th>
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<td>Accession Number</td>
<td>Pharmaprojects’ unique document identifier</td>
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<tr>
<td>Article Type</td>
<td></td>
</tr>
<tr>
<td>CAS Registry Number</td>
<td></td>
</tr>
<tr>
<td>Company Information</td>
<td>Supports One-to-Many; the following four fields will also be output if you select <em>Multiple rows per item by: Company Information</em></td>
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<td>• Company Information – Name</td>
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<tr>
<td>• Company Information – Type</td>
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<tr>
<td>• Company Information – Role</td>
<td>Contains phase of development</td>
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<tr>
<td>• Company Information – Parent</td>
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<tr>
<td>Database</td>
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<tr>
<td>Date Delivered</td>
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<td>• Phase of Development – Country/Region</td>
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<td>The name of the drug</td>
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<td>Updates</td>
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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.

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<tr>
<td>Detailed view</td>
<td>Brief view plus a three-line KWIC window</td>
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<td>KWIC (Keyword in Context)</td>
<td>Detailed view plus all occurrences of your search terms, highlighted in fields where the terms appear.</td>
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<td>✓</td>
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<tr>
<td>Preview</td>
<td>Brief view</td>
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<td></td>
</tr>
<tr>
<td>Brief citation</td>
<td>Brief view plus Molecular formula, Patent information, Date revised, First available and Update dates.</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Full text</td>
<td>The complete record with full text.</td>
<td>✓³</td>
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<tr>
<td>Custom</td>
<td>Choose the fields you want</td>
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</table>

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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