



Empowering the generic drug ecosystem with market intelligence

Leveraging market intelligence solutions for a well founded product portfolio.

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Profile

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Reena V. Gupta is a Solution Consultant at Clarivate for Life Sciences Intelligence Solutions.

She has a doctorate in Organic Chemistry and around 14 years of unique comprehensive experience in pharmaceutical industry holding multiple senior roles. She has a broad and rich knowledge of R&D, quality, regulatory, manufacturing, portfolio optimization and business aspects of the pharma industry.

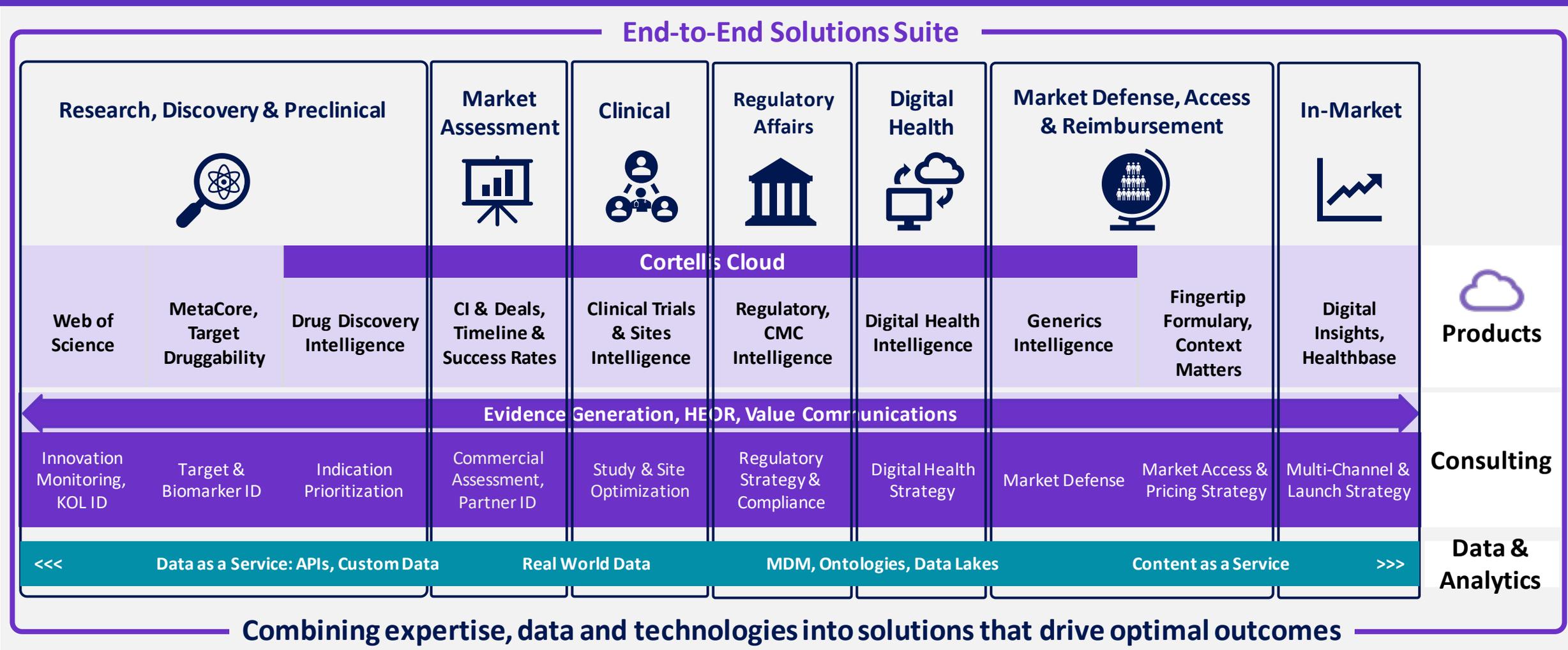
Her objective is to get data and information driven quality intelligence accessible across the industry, enabling rapid access of life saving affordable medicines across the globe.

Agenda

1. Clarivate and Cortellis Suite
2. Use cases
3. Live Demo
4. Q and A
5. Webinar Poll

Our premier suite of intelligence solutions

Data-driven insights spanning the entire innovation & product lifecycle



Cortellis suite of Intelligence solutions

What can we offer to accelerate your business decisions

Cortellis Generic Intelligence (CGI)	<ul style="list-style-type: none">• Single source for Generics and API intelligence
Cortellis Competitive Intelligence (CCI)	<ul style="list-style-type: none">• Drug pipeline information database
Cortellis Supply Chain Network (CSCN)- New	<ul style="list-style-type: none">• Efficient API sourcing and contracting execution database
Cortellis Regulatory Intelligence (CRI)	<ul style="list-style-type: none">• Single reliable source to navigate the global regulatory landscape
Cortellis CMC Intelligence	<ul style="list-style-type: none">• Database with granular global CMC requirements.
Cortellis Clinical Trial and Site Intelligence (CTI and CSI)	<ul style="list-style-type: none">• Breadth and granularity of global clinical trials data in one place• Insight on global trial sites
Cortellis Deals Intelligence (CDI)	<ul style="list-style-type: none">• Biopharma deals database
Cortellis Drug Discovery Intelligence (CDDI)	<ul style="list-style-type: none">• Comprehensive biology, chemistry & pharmacology data in one place for drug development
Cortellis Digital Health Intelligence (CDHI)- New	<ul style="list-style-type: none">• First-of-its kind solution covering the global digital health ecosystem
Derwent Innovation	<ul style="list-style-type: none">• Patent research & analytics platform

Generics Market

It's about staying ahead..

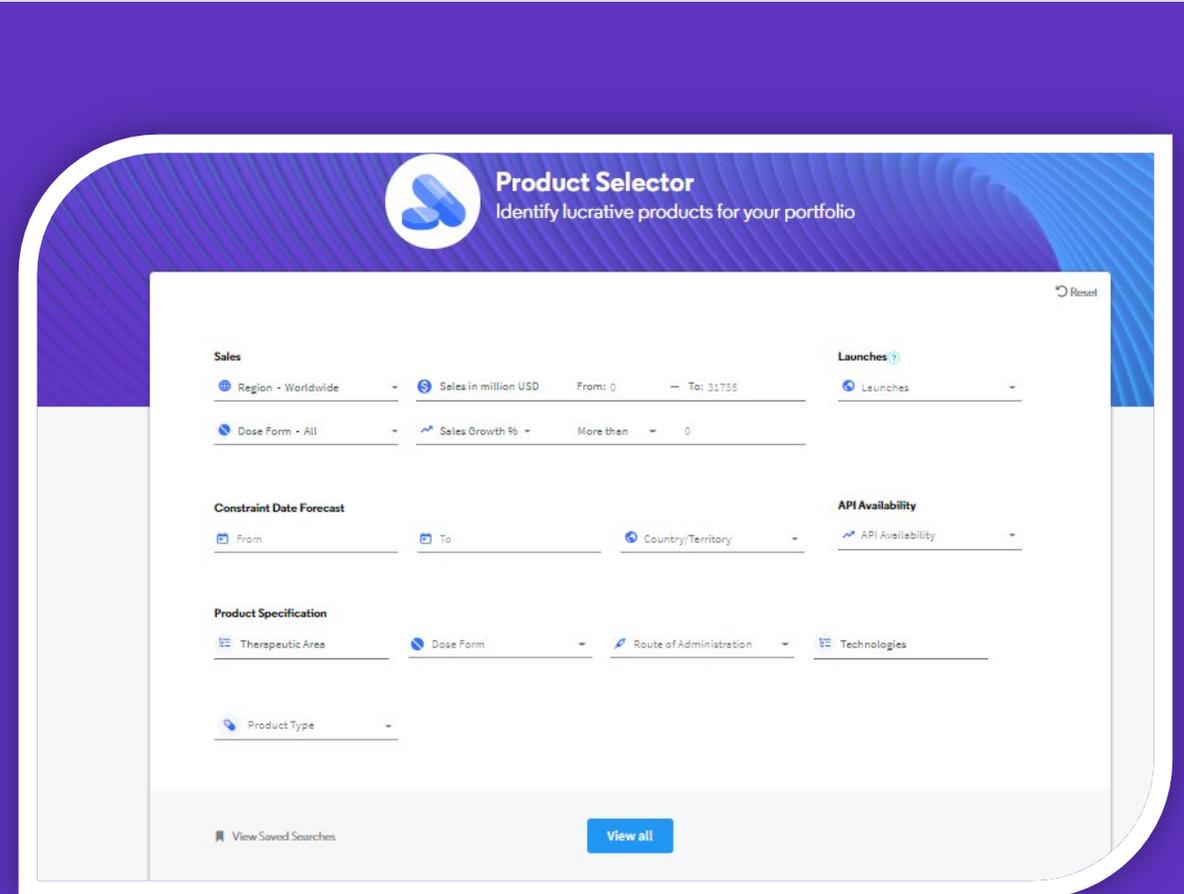
- ✓ Gaining insight on when drugs go off patent/exclusivity.
- ✓ Identifying ,analyzing, predicting, and penetrating markets
- ✓ Monitoring your competition.
- ✓ Identifying partners and new market opportunities
- ✓ Maintaining compliance- Quality, Regulatory, CMC, etc.
- ✓ Finding global suppliers for your manufacturing process requirements and finished goods.

Use Cases

Demonstrating the use of solutions for sifting your portfolio candidates

- ✓ Create a short list of portfolio candidates in just a few clicks, based on your specific strategic criteria and capabilities
- ✓ Compare and evaluate multiple candidates in a single view with customizable options to focus on your most critical needs
- ✓ Continue to track each market and product to identify additional opportunities or changes that could impact your decision making – On the go ‘Alerts’

Note: These use cases are for illustrative purpose only.



Few potential questions during portfolio candidate selection process:

- ✓ What is the **Constraint date forecast (CDF)**-Loss of exclusivity for a particular molecule?
- ✓ Which products will lose exclusivity in the next 3/5/7 years?
- ✓ How and which drugs should we monitor as potential portfolio candidates?
- ✓ Is there a SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis available for a potential candidate?
- ✓ How can I access the demand/ intelligence data for an API?
- ✓ How do I stay updated on the developments on the go?

Constraint date forecast(CDF)

Proprietary algorithm to estimate when a product loses patent or exclusivity protection.

- ✓ Patents and Patent extensions
- ✓ SPCs
- ✓ Data and Market exclusivities
- ✓ Other types of protections like PED (pediatric) exclusivity.....for a specific product in specific country/territory.

****Useful to consolidate patent expiry/exclusivity information for targeted products and should not be taken as a definitive date**

Use Case 1:

Evaluate potential oral tablet dosage form candidates (small molecules) which have WW sales > 100Mn USD and can be launched between 2025 to 2030

- **in which the API candidates has 20% growth potential**

Live Demo with CGI and CCI

Potential questions during portfolio candidate selection process:

- ✓ How to identify FTF molecules/NCE-1 opportunities
- ✓ Does the desired portfolio candidate have enough API suppliers?

Use Case 2:

Evaluate Oral solid and injectable products (small molecule) that would have FTF filing opportunities in USA from 2024 to 2032, with a projected growth of 10%.

Live Demo with CGI and CCI

Potential questions during portfolio candidate selection process:

- ✓ Evaluating products markets for specific regions/countries
- ✓ Finding specific constraining patents for a product's entry in a specific market

Use Case 3:

Identify small molecule products (tablets, injectables) which are launched in North America and Europe but is not still launched in Middle east and Africa and LATAM; has WW sales > 75 Mn USD, growth of 5%, and has opportunities for API manufacturers.

Live Demo with CGI

Cortellis Generics Intelligence

Leverage comprehensive intelligence so you never miss an opportunity



Quickly grow your business while reducing the workload needed to find, collate, and analyze all crucial market performance, patent, and manufacturing data



Defend market share, evaluate your chances of success, and assess competitiveness with up-to-date market data including sales, launches, pack prices, market share, and more



Enable all teams – sourcing, portfolio, business development, and IP – to make more informed and confident business decisions, stay ahead of your competition, and grow your business



Accurately make decisions regarding market, product and partner selection with a complete understanding of manufacturing, patent and market performance in one integrated solution



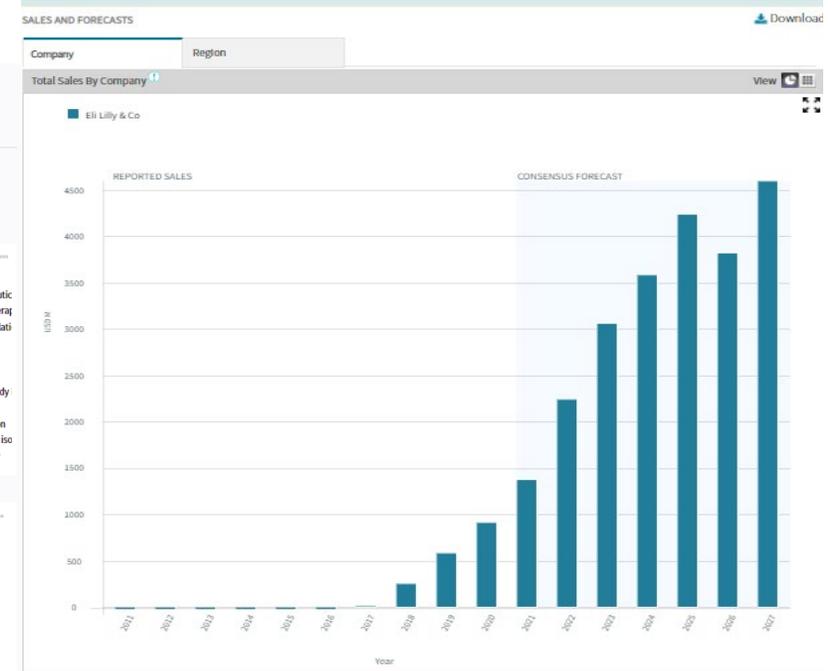
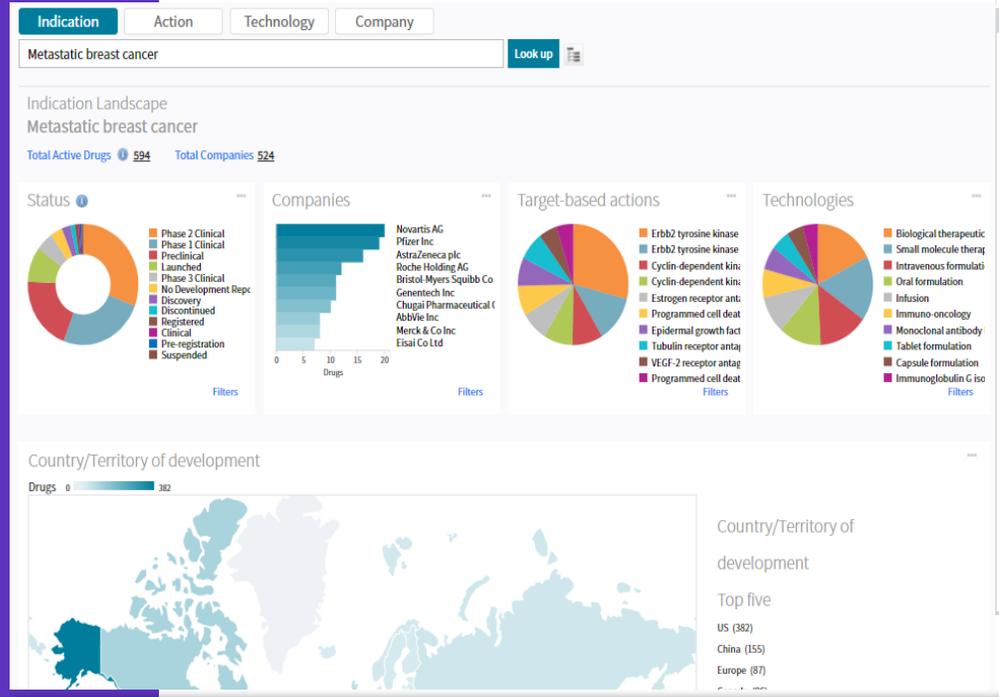
Reduce the fear of missing out on potential opportunities with access to a timely and trusted source of data to identify and evaluate product, partner, or market opportunities that may arise

Competitive Intelligence

The trusted and industry-leading drug pipeline database

- Efficiently track the competitive landscape
- Understand competitors' product positioning
- Differentiate your asset
- Assess expected product performance
- Determine potential market share
- Examine safety findings

Confidently make critical product, portfolio and competitor-based decisions.



Highlight Search Terms & Synonyms < Previous Next >

SWOT ANALYSIS

Anticancer cell cycle checkpoint protein kinase inhibitors

Strengths

- Approved in HR-positive HER2-negative advanced breast cancer as monotherapy in the third-line setting, in combination with fulvestrant in the second-line following progression on endocrine therapy and in combination with an aromatase inhibitor as initial endocrine-based therapy; the only CDK4/6 inhibitor approved as monotherapy [1966430]
- Improved PFS (16.4 versus 9.3 months) and OS (46.7 versus 37.3 months) when combined with fulvestrant versus fulvestrant alone in the phase III MONARCH-2 study in patients with chemotherapy-naïve HR-positive HER2-negative advanced breast cancer progressing on endocrine therapy; the clinical benefit rate was 75.0 and 64.3%, respectively, and overall survival was 46.7 vs 37.3 months [1960651], [2178328], [2199375], [2198470], [2199375]
- Impressive single-agent activity in heavily pretreated HR-positive HER-negative metastatic breast cancer (objective response rate (ORR) 19.7%, median progression-free survival (PFS) 6 months, median overall survival (OS) 17.7 months), according to the phase II MONARCH-1 trial [1766201]
- Significantly improved PFS when combined with aromatase inhibitors (anastrozole or letrozole), according to final data from the phase III MONARCH-3 study in postmenopausal HR-positive, HER2-negative advanced breast cancer not previously treated in the metastatic setting (28.3 versus 14.8 months, with a significant PFS HR of 0.54). The 13.5 month benefit was the longest reported with CDK4/6 agents at that time [2025841]

Weaknesses

- Not approved in pre/perimenopausal women undergoing initial therapy in the metastatic setting, unlike Kisqali [1966430], [1908326]
- MONARCH-3 data in patients previously untreated in the metastatic setting indicated patients with a long treatment-free interval since their prior treatment (neoadjuvant or adjuvant chemotherapy, or neoadjuvant or adjuvant aromatase inhibitor therapy) did not benefit from treatment; HR was 0.83, according to interim data [1920317], [1960740]
- Label warns of diarrhea; antidiarrheal therapy should be initiated at first sign of loose stool. In MONARCH-3, 80% patients had diarrhea, with almost 10% reporting Grade 3 diarrhea; the drug has the worst diarrhea rate among its currently approved competitors in the class [1966430]
- Warning also for neutropenia (occurring in 37 to 46% of patients, versus ~10% with Kisqali or Ibrance), hepatotoxicity and venous thromboembolism, which all require regular monitoring; notably venous thromboembolism, which has not been seen with other drugs in the class [1966430], [1631196], [1908326]
- The FDA issued a warning in September 2019 that Verzenio may cause rare but severe inflammation of the lungs; the drug has been updated to include a warning for interstitial lung disease/pneumonitis [2193897], [1966430]
- Risk of embryo-fetal toxicity [1966430]

Opportunities

- Leverage survival benefit in MONARCH-2; while market leader Ibrance has shown a numerical survival benefit, this was not significant in either PALOMA-1 (when added to letrozole in the first line) or PALOMA-3 (when added to fulvestrant in the second line) [2198470], [1932009], [2085376]
- The drug's ability to be dosed continuously could be an advantage over competitors Ibrance and Kisqali, as could its flexibility in being paired with either anastrozole or letrozole (comparative studies of Ibrance and Kisqali only included letrozole) [1974825]

Threats

- Ibrance and Kisqali, competitors in the CDK4/6 inhibitor space; market leader Ibrance is capitalizing on its first-to-market advantage following approval in both the first- (February 2015) and second-line (February 2016) metastatic settings; it is not clear yet whether differentiating data will be enough to outshine these two rivals in either of these two settings [1974825], [1908326]
- While Pfizer has already established Ibrance as standard of care across multiple segments of metastatic breast cancer, the company is also conducting a wide range of other trials (PENELOPE-B, PATINA)

Potential questions during portfolio candidate selection process:

- ✓ What are regulatory requirements to market a generic drug in a specific country X?

Use Case 4:

Understanding regulatory requirements of specific markets-Cortellis Regulatory intelligence

Live Demo with CRI

Use case 4 :What are regulatory requirements for a drug to get to market in country X?

E.g. 1. South Korea 2. China

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1 of 12 Automatic Zoom

Continuously monitored and updated

How to Market Generics and Biosimilars (South Korea)

Reason for update	Date	Reason for update description
Content Update	2021-08-04	This review added information in Q2.1 on data exclusivity for clarification and updated reference Law No. 18307: The Pharmaceutical Affairs Act (PAA), 20-Jul-2021 (IDRAC 333939).
Content Update	2021-06-11	This update added reference: Guideline: Guide-0223-03: Q&A on Common Technical Document for Generic Drugs, 17-May-2021 (IDRAC 330222) in Q5.1.
Content Update	2021-04-13	This edit updated reference: MFDS Notification No. 2020-91: Standards for Pharmaceutical Equivalence Test, 22-Sep-2020 (IDRAC 318219).
Formatting Change	2020-11-11	This update updated the link of MOHW Ordinance No. 757: Enforcement Regulations (FR) of Pharmaceutical Affairs Act (PAA) (20 Oct 2020) (IDRAC 318219).

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1 of 25 Automatic Zoom

Continuously monitored and updated



Regulatory Summary

How to Market Generics and Biosimilars (China)

Reason for update	Date	Reason for update description
Content Update	2021-08-20	NMPA Announcement No. 2021/51: Announcement on List of Reference Products for Generics (43th Batch), 23-Jul-2021 (IDRAC 334415) and NMPA Announcement No. 2021/61: Announcement on List of Reference Products for Generics (44th Batch), 16-Aug-2021 (IDRAC 334462), updated the reference in section Q3.1.

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1 of 10 Automatic Zoom

File 1

- Internal English version
- Original file
 - 国家药监局关于发布化学药品注册分类及申报资料要求的通告(2020年第44号)
 - 化学药品注册分类及申报资料要求
 - 一、化学药品注册分类
 - 二、相关注册管理要求
 - 三、申报资料要求

Notice of NMPA on the Release of *Registration Classification and Application Dossiers Requirements of Chemical Drugs*

([2020] No. 44)

Released on 30 June, 2020

In order to facilitate the implementation of the *Measures for the Administration of Drug Registration*, the National Medical Products Administration (NMPA) has organised people to prepare the *Registration Classification and Application Dossiers Requirements of Chemical Drugs*, which are hereby released. Relevant matters are explained as follows:

Regulatory Intelligence

Single reliable source to navigate the global regulatory landscape

- Ensure compliance to the latest regulations
- Quickly compare cross-country requirements
- Learn from precedence
- Understand local practice
- Increase approval rates
- Never miss an update while on the go.

Clinical Trial Application and Ethics Committee Expected Authority Review Times

9695 Drugs and Biologics Clinical Research

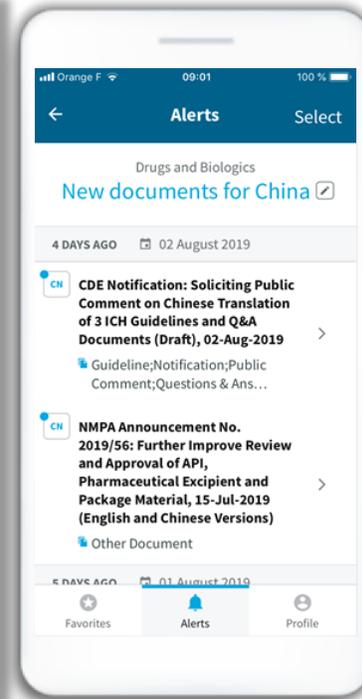
Abstract
This subject provides expected time in days for the regulatory authority review of a clinical trial application (CTA) or investigational new drug application (IND) for research involving human subjects for medicinal drug products. Expected review times are indicated for ethics committee and regulatory authority. Complementary explicative notes are provided to illustrate local practice and type of approval (when available). The number in brackets [...] refers to the numeric value identified in the previous columns.
The total expected review time is calculated by taking into account whether ethics committee review is done sequentially to the regulatory authority review (i.e. ethics committee plus regulatory authority review timeframe) or in parallel (i.e. the longest review information about the type of review or when neither the regulatory authority nor the ethics committee review.)

Last Updated Date
10-Dec-2020

Global Comparison

Apply Filters

Country/Region	Calendar Days / Working Days	Type of Review	Expected Review Time for Ethics Committee Review and Approval (Maximum Number of Days)	Expected Review Time for Regulatory Approval of CTA (Maximum Number of Days)	Total Time (EC + RA Approval and Notification) (Cortellis RI Calculation of Maximum Number of Days)	Ethics Committee Approval Time Notes / Type of Approval	Regulatory Authority Approval Time Notes / Type of Approval
Brazil	Calendar Days	Sequential and Parallel	90	90	N/A	EC review is done first on a local level by the Ethics Committee of the Clinical ...	ANVISA issues a special communication (CE) which is the authorization ...
China	Working Days	Sequential (RA/EC)	60	65	125	No official timeline. Each site operates on different timeline - EC review time ...	RA review time steps: Step 1: Communication meeting with CDE. This is ...
Japan	Calendar Days	Sequential (RA/EC)	30	30	60	IRB review time varies depending on the institution, in most cases ...	The RA review is required prior to IRB review. It is a notification process, there ...
USA							



New Drug Application for: VERZENIO

- APPROVAL LETTER
 - CONTENT OF LABELING
 - CARTON AND IMMEDIATE CONTAINER LABELS
 - ADVISORY COMMITTEE
 - REQUIRED PEDIATRIC ASSESSMENTS
 - POSTMARKETING REQUIREMENTS UNDER 505(o)
 - POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B
 - PROMOTIONAL MATERIALS
 - REPORTING REQUIREMENTS
 - MEDWATCH-TO-MANUFACTURER PROGRAM
 - POST APPROVAL FEEDBACK MEETING
- LABELING
 - HIGHLIGHTS OF PRESCRIBING INFORMATION
 - FULL PRESCRIBING INFORMATION: CONTENTS*
 - FULL PRESCRIBING INFORMATION
 - 1 INDICATIONS AND USAGE
 - 2 DOSAGE AND ADMINISTRATION
 - 2.1 Recommended Dose and Schedule
 - 2.2 Dose Modification

CENTER FOR DRUG EVALUATION AND RESEARCH

New Drug Application for:

VERZENIO (abemaciclib) Tablet
Company: Eli Lilly and Company
Application No.: NDA 208716
Approval Date: 09/28/2017

CONTENTS

Approval Package Documents	Included
Approval Letter	X
Labeling	X
Multi-Discipline Review	X
Officer/Employee List	X
Product Quality Review(s)	X

Increase your likelihood of approval and rapidly expand to new markets.

Introducing Cortellis Supply Chain Network

A digital partnering solution to accelerate global sourcing and supply of pharmaceutical ingredients, products or services.



Source

- Identify experienced API suppliers
- Assess suppliers based on regulatory filings, inspection history and more
- Securely negotiate deals within the platform



Supply

- Find new customers
- Ensure global visibility
- Receive and manage inquiries



Monitor

- Track new opportunities
- Monitor competitors
- Stay up to date on the latest supply trends



Explore

- Find the right partner and make contact quickly
- Speed up negotiations with online chat and secure communications
- Request a quote and a batch sample

Thank you!