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Trialtrove

临床试验数据

最大程度提升临床试验成功机率

利用业内领先的临床试验信息，进一步优化及管理临床项目方案与预算

- 做出更好更快的临床试验投资、战略布局或实际执行的最终决策
- 通过筛选患者群体、特定疾病领域、临床相关标签及关键词检索等，快速评估特定临床试验完整格局
- 通过使用详细的临床试验时间数据，有效地计划、评估及管理自身临床试验及项目成本
- 通过比对分析与自身临床方案相似的成功及失败案例，进一步降低潜在风险
- 查阅所有拥有新颖设计的临床项目方案，如：创新性临床试验（篮式或伞式临床研究）或免疫肿瘤类药物联合治疗方案
- 掌握临床试验的最新研发动态，如：主要医学会议中的各期临床数据披露
- 联系Trialtrove分析师团队并获取专业解答或进行特定调研
- 利用经过业内专家亲自验证及编制的可靠数据

业界最值信赖、即时及全面的临床试验数据平台

308,000+
完整临床试验报告
（通过详细编制并分为各种检索标签以便搜索）

43,000+
引用来源
（持续增长中）

250+
适应症

750+
患者及疾病分类

78,000+
受试者募集时间表

129,000+
临床试验用时时间表

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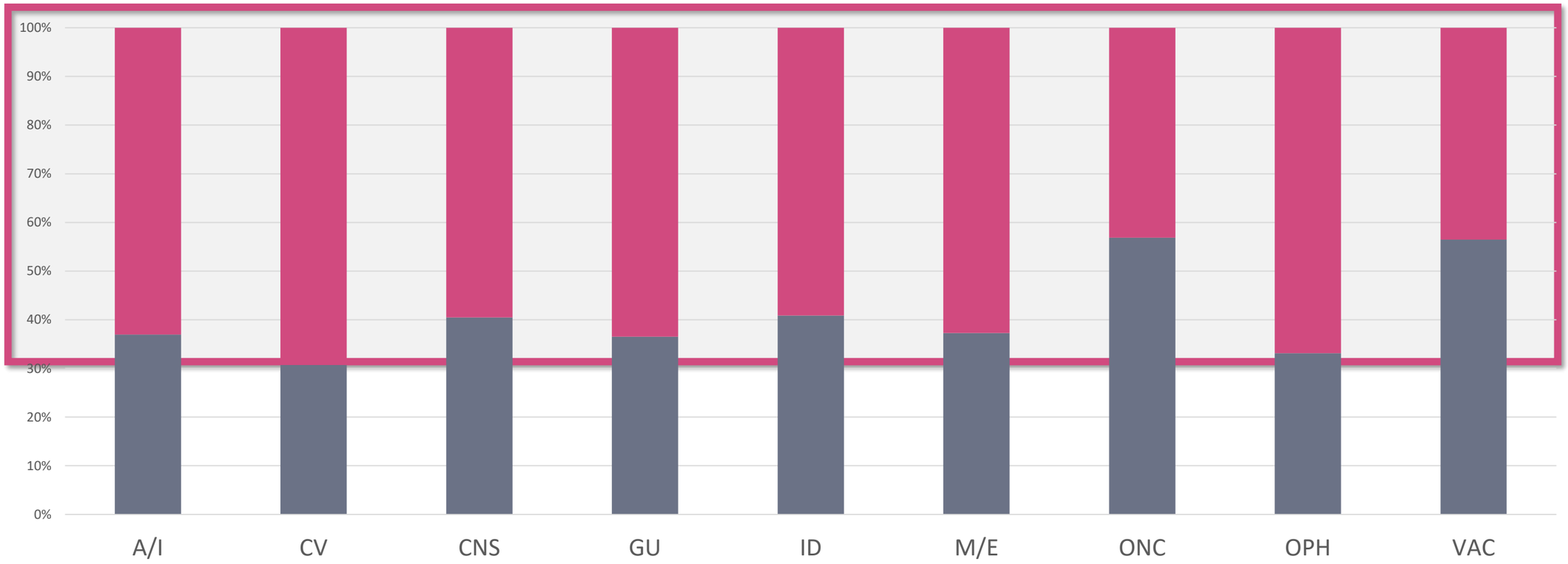
Trialtrove vs. ClinicalTrials.gov – 您少用了多少信息资源?

不含在Clinicaltrials.gov数据库却能在Trialtrove中查询的信息资源数量



数据取自2018年11月29日

ClinicalTrials.gov信息涵盖范围

Trial Title
A Randomized, Double-Blind, Placebo-Controlled, Phase III Study of Nonsteroidal Aromatase Inhibitors plus LY2835219 or Placebo in Postmenopausal Women with Hormone Receptor-Positive, HER2-Negative Locoregionally Recurrent or Metastatic Breast Cancer with No Prior Systemic Therapy

Trial Phase
III

Sponsorship
Eli Lilly

Disease Type
Breast Cancer

Start Date
Nov 2014

Target Accrual
450

Trial Locations
Global

Drugs Tested
abemaciclib
anastrozole or letrozole

Protocol IDs
NCT02246621, 15417, EudraCT Number: 2014-001502-18, I3Y-MC-JPBM

Treatment Plan
Participants will be randomized to abemaciclib or pla

Patient Population
Postmenopausal women with HR+, HER2-negative
Ages Eligible for Study: 18 Years and older, Gende

Inclusion Criteria:
Have a diagnosis of hormone receptor-positive (HR
receptor 2-negative (HER2-) breast cancer
Have locoregionally recurrent disease not amenabl
curative intent or metastatic disease
Have postmenopausal status
Have either measurable disease or nonmeasurable bone-only disease
Have a performance status ≤1 on the Eastern Cooperative Oncology Group (ECOG) scale
Have adequate organ function
Have discontinued previous localized radiotherapy for palliative purposes or for lytic lesions at risk of fracture prior to randomization and recovered from the acute effects of therapy
Are able to swallow capsules

ngeal carcinomatosis;Have
a history of central nervous system

Are currently receiving or have previously received endocrine therapy for locoregionally recurrent or metastatic breast cancer; ……;Have received treatment with a drug that has not received regulatory approval for any indication within 14 or 21 days of randomization for a nonmyelosuppressive or myelosuppressive agent, respectively; Have had major surgery within 14 days prior to randomization

Primary Endpoint/Outcome measures/objectives: Progression Free Survival (PFS) [Time Frame: Baseline up to Measured Progressive Disease or Death from Any Cause (Approx 34 Mos)

Trial Results

https://clinicaltrials.gov/ct2/show/NCT02246621

所有业内人士的信息来源起点 –
引用官方机构或研究报告

初始数据引自：www.clinicaltrials.gov

Trialtrove报告完整覆盖

Trial Title
A Randomized, Double-Blind, Placebo-Controlled, Phase III Study of Nonsteroidal Aromatase Inhibitors plus LY2835219 or Placebo in Postmenopausal Women with Hormone Receptor-Positive, HER2-Negative Locoregionally Recurrent or Metastatic Breast Cancer with No Prior Systemic Therapy

Trial Phase
III

Trial Status
Completed

Sponsorship	Disease Type	Patient Segment	Start Date	Treatment Duration	End Date	Target Accrual	Actual Accrual	Identified Sites
Eli Lilly	Breast Cancer	Estrogen receptor positive, Progesterone receptor positive, HER2 negative, First line, Stage III, Stage IV	Nov 2014	2.5 to 6.5 months	4/24/2017	450	493	84

Trial Locations
Global

Drugs Tested
abemaciclib
anastrozole or letrozole

Protocol IDs
NCT02246621, 15417, EudraCT Number: 2014-001502-18, I3Y-MC-JPBM
IRAS ID: 164539, 15-LILA-2, JapicCTI-142749, MONARCH 3, NL51156.028.14, REec-2015-1307,
TrialTroveID-210961

Trial Outcome
Completed, Positive outcome/primary endpoint(s) met

Outcome Details
Eli Lilly…announced that MONARCH 3…met its primary endpoint of demonstrating statistically significant improvement in progression-free survival (PFS)...

Trial Tag/Attribute
Registration, PGX – Patient Preselection/Stratification

Treatment Plan
Participants will be randomized to abemaciclib or placebo in a 2:1 ratio.

Patients will be randomized 2:1, and stratified by nature of disease (visceral vs bone-only metastases vs other) and prior (neo)adjuvant endocrine therapy (aromatase inhibitor vs other vs none). Abemaciclib 150 mg or placebo will be given continuously PO every 12 hours until progression, along with anastrozole 1 mg or letrozole 2.5 mg once daily at the investigator's discretion, and assessments will occur every 28 days.

Patient Population
Postmenopausal women with HR+, HER2-negative breast cancer
Ages Eligible for Study: 18 Years and older, Genders Eligible for Study: Female

Inclusion Criteria:
Have a diagnosis of hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer
Have locoregionally recurrent disease not amenable to resection or radiation therapy with curative intent or metastatic disease
Have postmenopausal status
Have either measurable disease or nonmeasurable bone-only disease
Have a performance status ≤1 on the Eastern Cooperative Oncology Group (ECOG) scale
Have adequate organ function
Have discontinued previous localized radiotherapy for palliative purposes or for lytic lesions at risk of fracture prior to randomization and recovered from the acute effects of therapy
Are able to swallow capsules

Exclusion Criteria:
Have visceral crisis, lymphangitic spread, or leptomeningeal carcinomatosis;Have inflammatory breast cancer; Have clinical evidence or a history of central nervous system (CNS) metastasis
Are currently receiving or have previously received endocrine therapy for locoregionally recurrent or metastatic breast cancer; ……;Have received treatment with a drug that has not received regulatory approval for any indication within 14 or 21 days of randomization for a nonmyelosuppressive or myelosuppressive agent, respectively; Have had major surgery within 14 days prior to randomization
Have received recent (within 28 days prior to randomization) yellow fever vaccination. Have serious preexisting medical conditions that, in the judgment of the investigator, would preclude participation in this study (for example, history of major surgical resection involving the stomach or small bowel, or preexisting Crohn's disease or ulcerative colitis). Have a personal history within the last 12 months of any of the following conditions: syncope of cardiovascular etiology, ventricular tachycardia, ventricular fibrillation, or sudden cardiac arrest.

Primary Endpoint/Outcome measures/objectives: Progression Free Survival (PFS) [Time Frame: Baseline up to Measured Progressive Disease or Death from Any Cause (Approx 34 Mos)

Trial Results

Lilly Announces Phase 3 MONARCH 3 Breast Cancer Study of Abemaciclib Demonstrated Superior Progression-Free Survival At Interim Analysis
The Phase 3 study compared abemaciclib in combination with an aromatase inhibitor versus an aromatase inhibitor alone in patients with HR+, HER2- advanced breast cancer
…Following this MONARCH 3 interim analysis, Lilly intends to begin global submissions of these results in the third quarter of 2017…

Supporting URLs: https://clinicaltrials.gov/ct2/show/NCT02246621
http://ejghtrials.org/trials/breast/I3YMCJPBM.htm,
http://grls.rosminzdrav.ru/CIPermissionMini.aspx?CIStatementGUID=26ACF951-D...
http://ironwoodcrc.com/clinical-studies/currently-enrolling/
http://jpmorgan.metameetings.com/confbook/healthcare17/webcast_oi.php?p=226...
http://kap.titck.gov.tr/home/arastirmalar?aramatext=&rbgrup=0&pageno=17
http://lilly.mediaroom.com/index.php?s=9042&item=137472
http://meeting.ascopubs.org/cgi/content/abstract/33/15_suppl/TPS624

http://www.cancervic.org.au/trials/breast/trial.asp?ContentID=nct02246621
http://www.ceavc.org/index.php?r=site/elenco&a=36
http://www.clinicaltrials.jp/user/showCteDetailE.jsp?japicId=JapicCTI-14274...
http://www.epgonline.org/clinical-trials/a-study-of-nonsteroidal-aromatase-...
http://www.gru.edu/cancer/trials/breast/
https://www.clinicaltrialsregister.eu/ctr-search/search?query=2014-001502-1...
https://www.sec.gov/Archives/edgar/data/59478/000005947816000353/lly-331201...
https://www.toetsingonline.nl/to/ccmo_search.nsf/fABRpop?readform&unids=C12...
https://www.ukctg.nihr.ac.uk/trials/trial-details/trial-details?trialId=190...

完整覆盖
公共领域信息

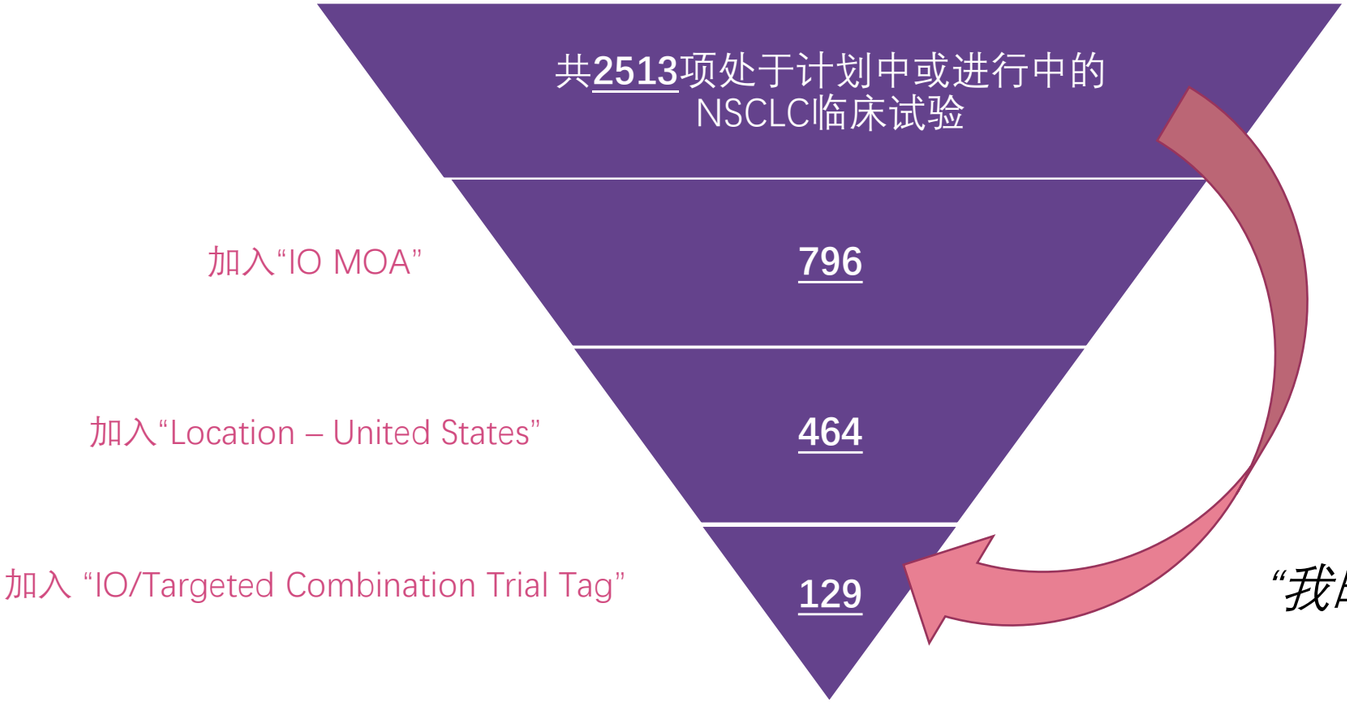
Last Modified 06/19/2017 **Last Full Review** 05/02/2017

调研工作仅需数秒即可完成

通过Trialtrove数据库快速检索系统节省宝贵时间

实际案例：

“查阅所有在美国市场目前处于计划中或正在进行中，并同时应用免疫肿瘤类药物或疗法联合其他药物的非小细胞肺癌（NSCLC）临床试验列表”



点击查阅检索条件

*“若在普通情况下逐一查阅超2500项符合适应症及状态的临床试验，可能将花费超过**40小时**…”*

[@1 min/trial]

*“若在普通情况下逐一查阅近800项临床试验来看是否有应用免疫肿瘤类药物，可能将花费超过**13小时**…”*

[@1 min/trial]

*“若在普通情况下逐一查阅近130项临床试验的治疗方案及相关目标终点信息，可能将花费超过**2小时**…”*

[@ 1 min/trial]

“我昨天还以为这种调研项目由于费时费力而不可行，但现在我却能直接轻易完成…”

客户反馈

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与业内领先的分析师团队进行直接联系

拥有超过250名高资历（硕士及博士学位）并充分了解您独特需求的资深专家团队...

专家解答 – 为订阅者独家提供可行的个性化咨询服务，其中包括订制的数据收集及调研支持

高效答复 – 通过透明及可查证的信息来源，提供完整解答以便作出正确决策

跨产品调研支持 – 引用我司其他医药产品，提供完整资讯辅助

Citeline如何帮助临床试验管理及评估可行性?

Trialtrove

优化临床用时及成本管理
提高投资回报率及研发成功率

- 评估竞争对手临床试验方案，优化自身临床项目
- 分析临床终点及结果
- 掌握所有临床试验及其研究地点，评估当前临床试验密度以作可行性分析
- 通过Trialpredict快速查阅受试者募集及临床用时数据，进一步优化自身临床项目方案及创建最佳临床时间表

Sitetrove

识别最佳临床研究人选及地点
降低成本及潜在风险

- 发掘拥有相关资历并符合自身临床方案的最佳临床研究人选
- 识别最具资历临床研究人员的所在地
- 制定符合自身临床试验的最佳研究人才及机构列表
- 降低选择Non-Enrolling Sites的风险

Pharmaprojects

通过深入比对调研药物、研发趋势及里程碑，**优化**自身临床战略布局

- 掌握竞争对手研发项目的关键里程碑及研发时间表
- 通过分析特定药物类别的相似研发方案，验证自身的研发战略
- 了解比对药物的各国或地区上市状态，为选择目标上市地提供更多资讯

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Trialpredict【内置于Trialtrove】

临床试验时间数据

避免临床试验用时风险

临床试验用时管理的低估或错判将影响整个研发计划

全面的临床试验用时数据
将使您避免任何潜在问题

Trialpredict
Pharma intelligence | informa

通过使用全面时间数据，更有效地预先调研、计划及管理您的临床项目及预算

业内领先的临床试验用时数据将使您避免任何潜在问题及风险

- 快速准确预估受试者募集情况
- 统一查阅受试者募集及临床试验实际用时信息
- 快速查阅最佳或最差患者募集案例，并评估其成功及失败因素
- 通过比对调研相似临床项目方案的患者募集及研究用时，以便作出更准确的用时评估

✓ 可通过7个领域进行检索：

- ✓ 开始日期（Start Date）
- ✓ **受试者募集用时（Enrollment Duration）**
- ✓ **受试者募集结束日期（Enrollment Close Date）**
- ✓ **临床试验用时（Treatment Duration）**
- ✓ 临床试验结束日期（Primary Completion Date）
- ✓ 主要临床终点披露日期（Primary Endpoints Reported Date）
- ✓ **每月平均募集人数（Pts/Site/Mon）**

**蓝色领域仅供Trialpredict订阅者使用*

✓ 查阅实际及预测用时数据

✓ 通过临床试验结束日期或主要临床终点披露日期进行检索

Trialpredict
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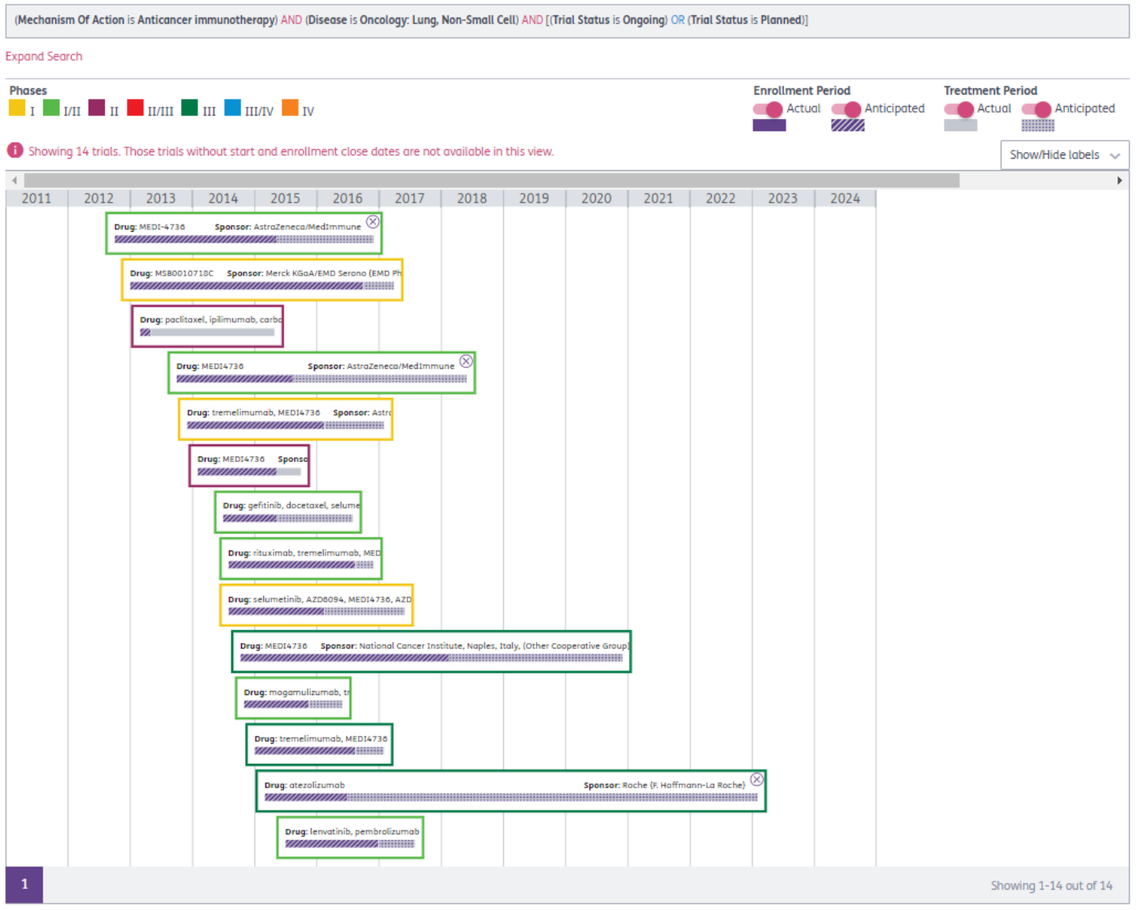
通过图表方式快速查阅及评估临床试验格局

通过使用独有的时间表（Timeline）图标功能，识别有利临床竞争空间，评估研发战略，并分析潜在可用受试者人数



- **立即查阅目标临床项目信息**，包括临床阶段、实际或预计受试者募集、临床用时数据等
- 通过加入其他检索条件（如：药物或作用机制、临床阶段、入选或去除条件、患者群体、临床标签、申办方以及其他Trialtrove检索范围），**进一步筛选检索范围**
- **自主选择显示或隐藏信息**（如：药物、适应症、患者群体、临床阶段、临床试验编号、临床状态及申办方标签等）

Trialpredict如何能帮到您?

临床试验管理

- 通过预估临床试验用时，对临床项目设计作进一步优化及预算管理
- 比对调研以往、当前及竞争对手的临床项目
- 预估受试者募集成功率
- 评估潜在可用受试者人数

竞争市场调研

- 评估竞争对手临床项目信息及预测其进入下一临床阶段或上市所需时间
- 分析特定竞争空间中的临床战略布局

避免研发失败的巨大代价

考虑研发成本：

[1]新药研发总成本约5-25亿美元…

同时伴有98%失败率

Citeline系列将在研发各领域提供专业帮助

范围涵盖研发趋势、临床研究人员及地点选择，以及临床项目计划等…

临床试验阶段尤其重要
【约总成本的80%】

Citeline综合智库可助您作出更经济及高效的明智决策

- ✓ 作出可行或不可行的正确决策（同时降低失败机率）
- ✓ 设计无须额外临床试验的临床项目
- ✓ 减低受试者募集及临床试验用时

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Citeline – 降低研发用时及成本，同时优化临床方案

- ✓ 全面了解全球研发药物及临床试验格局及竞争趋势
- ✓ 根据评估竞争对手的药物信息及临床试验方案，进一步优化研发计划及临床方案
- ✓ 通过分析临床试验项目的目标终点及临床结果，避免日后作出不必要的临床方案修订
- ✓ 通过查阅以往、当前及未来的临床试验、研发人员及地点的相关活动及研发密度等信息并提前作出可行性分析，以便选择合适的国家进行临床试验
- ✓ 数千条衡量基准均可一秒检索相关信息，以便优化临床计划及时间方案
- ✓ 识别最具资历及研发记录、并符合您研究方案的临床研究人员、地点及机构
- ✓ 降低选择Non-Enrolling Sites的风险
- ✓ 评估相似临床方案的临床试验时间信息，以便作出更准确的预算管理及用时预测
- ✓ 准确追踪及评估竞争对手的研发药物与临床试验进展

业内最全面及准确的全球R&D综合数据库

250+
业内专家
全面追踪、分析、扩大研发数据

43,000+
信息来源
持续增加中

308,000+
临床试验完整报告
（一至四期）

76,000+
全球研发药物完整报告
（记录超过35年的研发历程）

437,000+
临床研究人员
（通过以往经验进行等级排行）

165,000+
临床研究地点
（通过类型及临床经验区分）

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Citeline分析师团队

拥有超250名常驻全球主要市场的各疾病领域专家团队
了解您的独特需求

精通各研发领域

跨产品的分析师团队通力合作，统一收集、评估及分析从临床前至上市的一切研发信息

多年经验值得信赖

累积数千年的从业及专业经验，分析师团队可提供值得信赖的专业见解

业内顶级分析

以全面、透明及独立的视角作出专业分析

数据均由业内专家验证，并配有无限制分析支持

无可比拟的数据“质”与“量”

涵盖临床试验、研究人员及地点，以及药物研发管线

原始数据均由业内专家亲自确认、分析及增强

配有无限制分析师咨询服务

引用

超43,000条网上资源

- 基于事件的更新
- 反复验证关键信息来源
- 排除重叠数据

分析

分析师专业见解是关键所在

增强

通过业界及各疾病领域专家分析与运用所有相关额外补充数据，最大程度优化信息范围及质量

编辑

信息均可在线上统一平台查询，各种信息（如：药物、临床试验、受试者募集及临床用时、研究人员及地点等）均以相互连接的方式编辑及排列

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内容范围涵盖整个公共领域

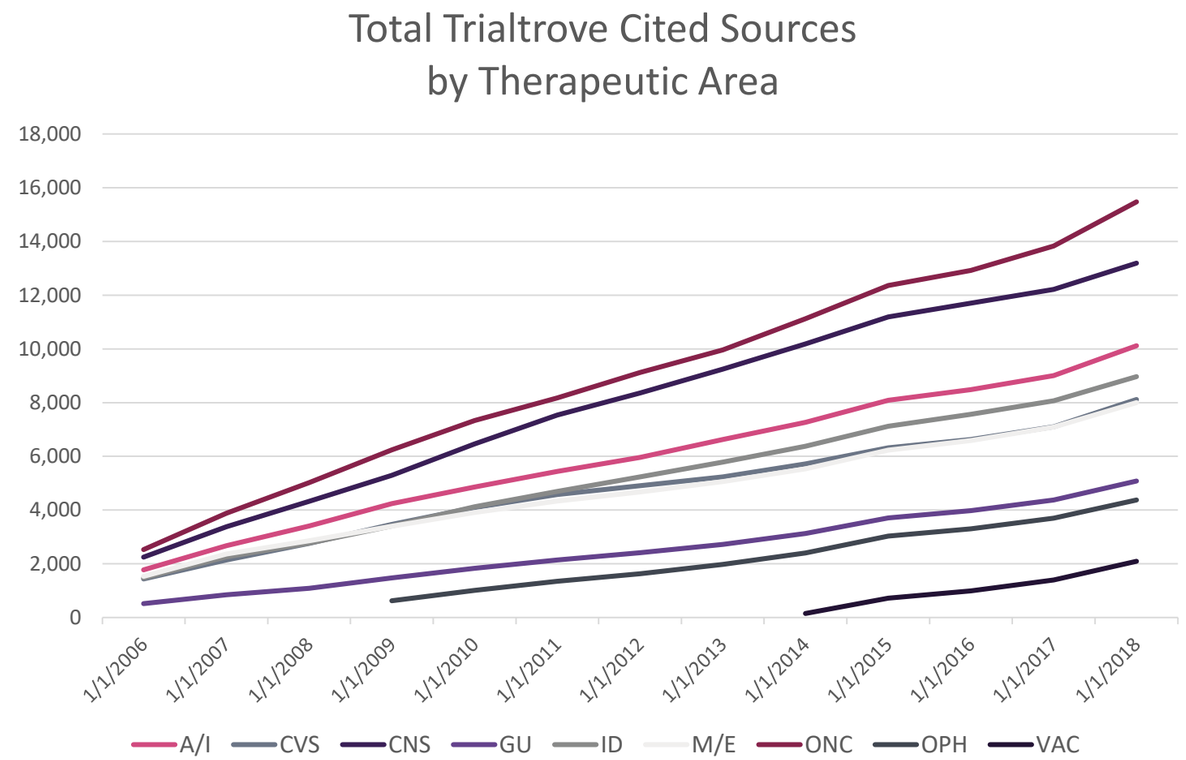
主要信息来源 – 目前引用超过43,000个信息来源并持续增长

- 超过70个来自各国或地区的临床试验注册机构（如：ClinicalTrials.gov, EUCTR, JAPIC, ChiCTR等）
- 超过90个其他临床试验资讯来源（如：申办方注册信息、合作机构、主要医疗中心）
- 超过5000个企业信息（全面涵盖管线、新闻报道、投资者，以及其他网页）
- 所有主要医疗会议（超过250个会议）
- 新闻资源、投资者演讲、美国证监会文件，以及公司年度报告等
- 各国医疗及卫生机构的官方网页
- 医学杂志及论坛
- USAN与INN lists, eMolecules, ChemSpider, & ChemIDplus
- 其他线上资源，如：Gene（前身为EntrezGene）、PubMed，以及Espacenet等

引用额外信息来源以确保全面市场情报覆盖

那些看似无多关联的信息资源也能提供具有价值的见解:

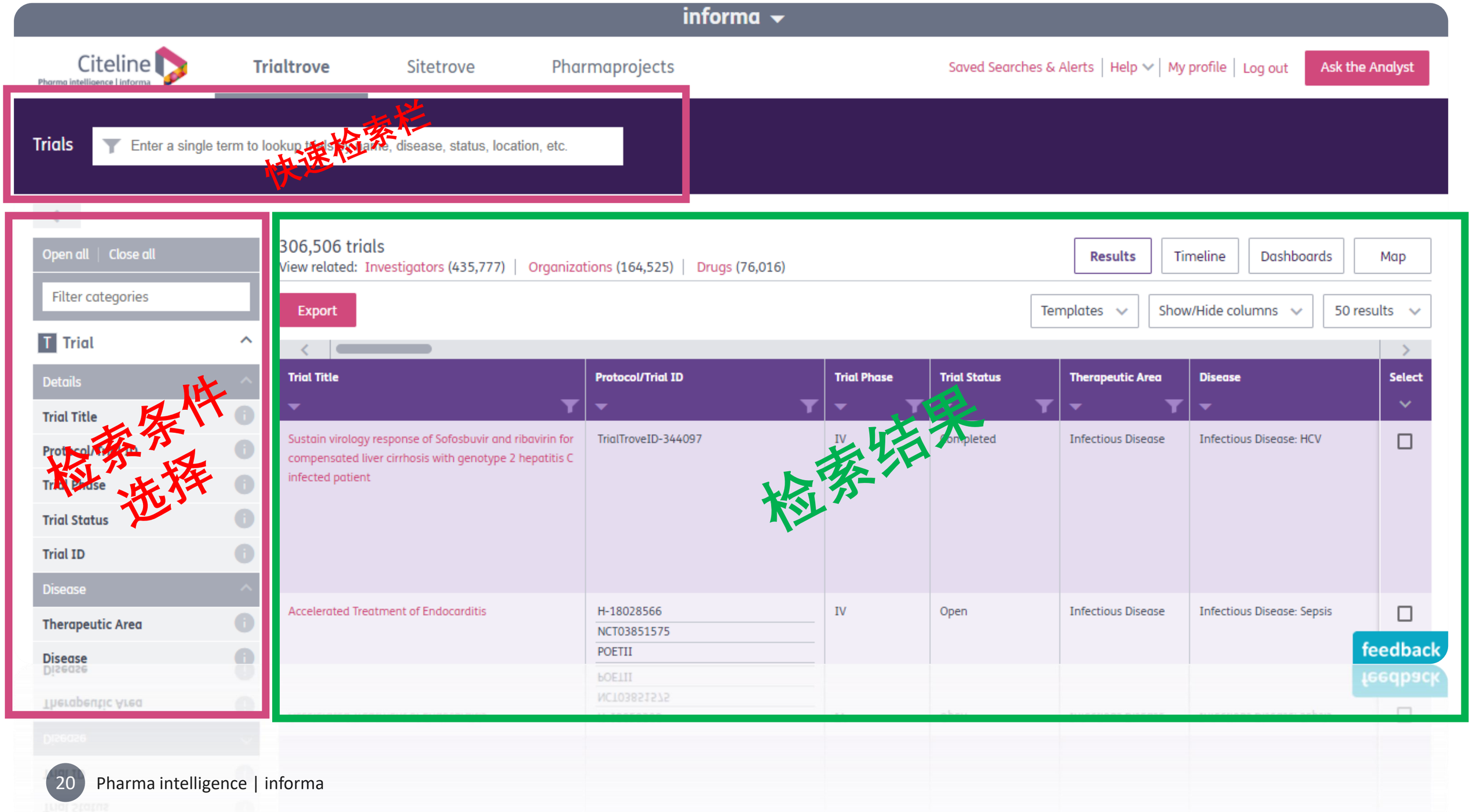
- 研究中心网站
- 社区医院网站
- 大学研究规章/IRB审核批准目录
- 患者权益相关网站
- 调访研究报告（Primary Research）



- 内容持续更新
- 所有资料均提供完整出处信息，以确保查证的透明性

Citeline
Pharma intelligence | informa

Citeline线上平台界面 （各模块拥相同设计）



视觉逻辑搜索（Visual Boolean Search）

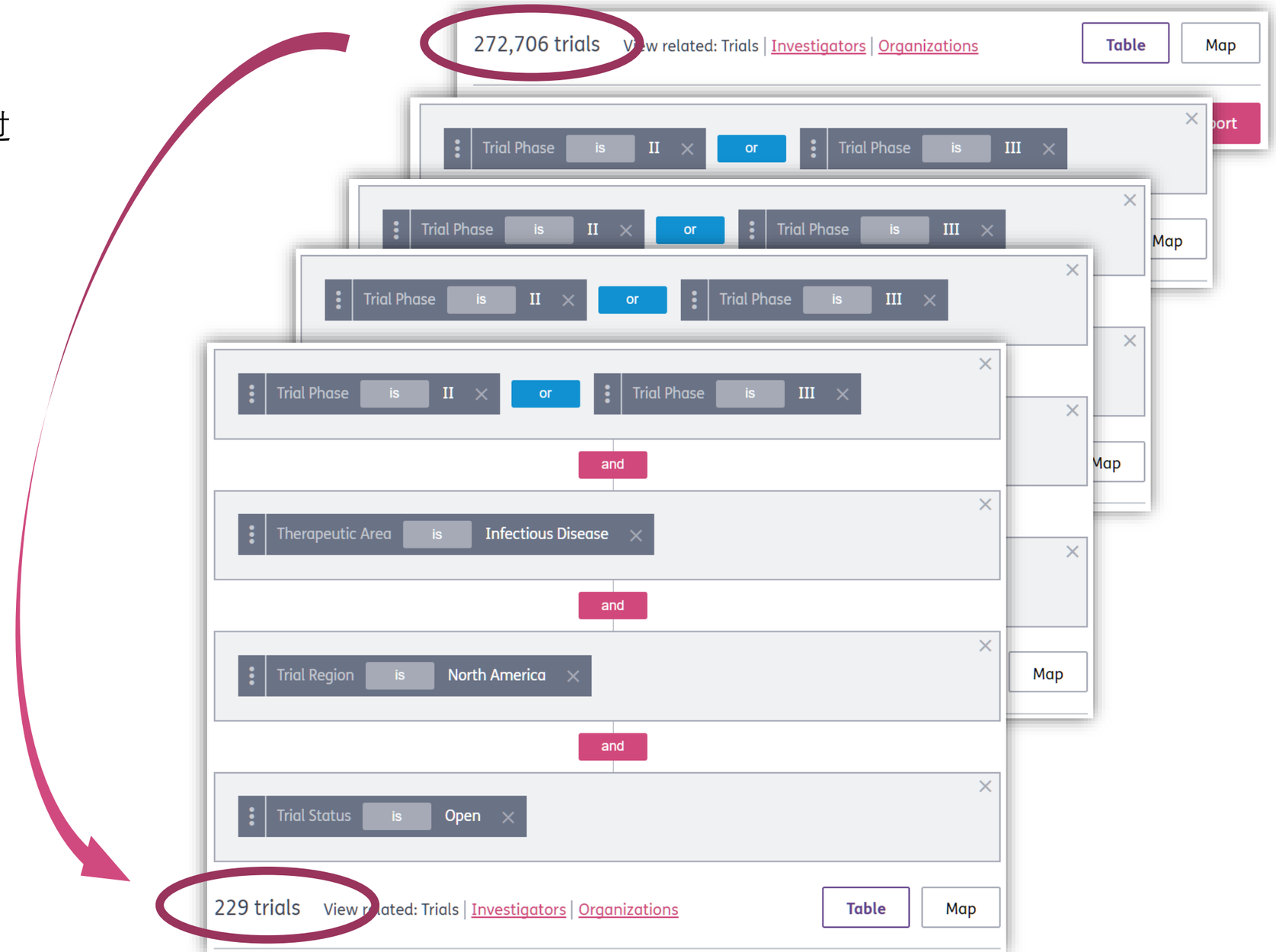
进行动态交互式搜索

- 凭直觉建立复杂的搜索
- 调整搜索并同步查看筛选经过

✓ 快速获取所需的信息

✓ 提高搜索结果的准确性，即便是不常用的用户也可轻易做到

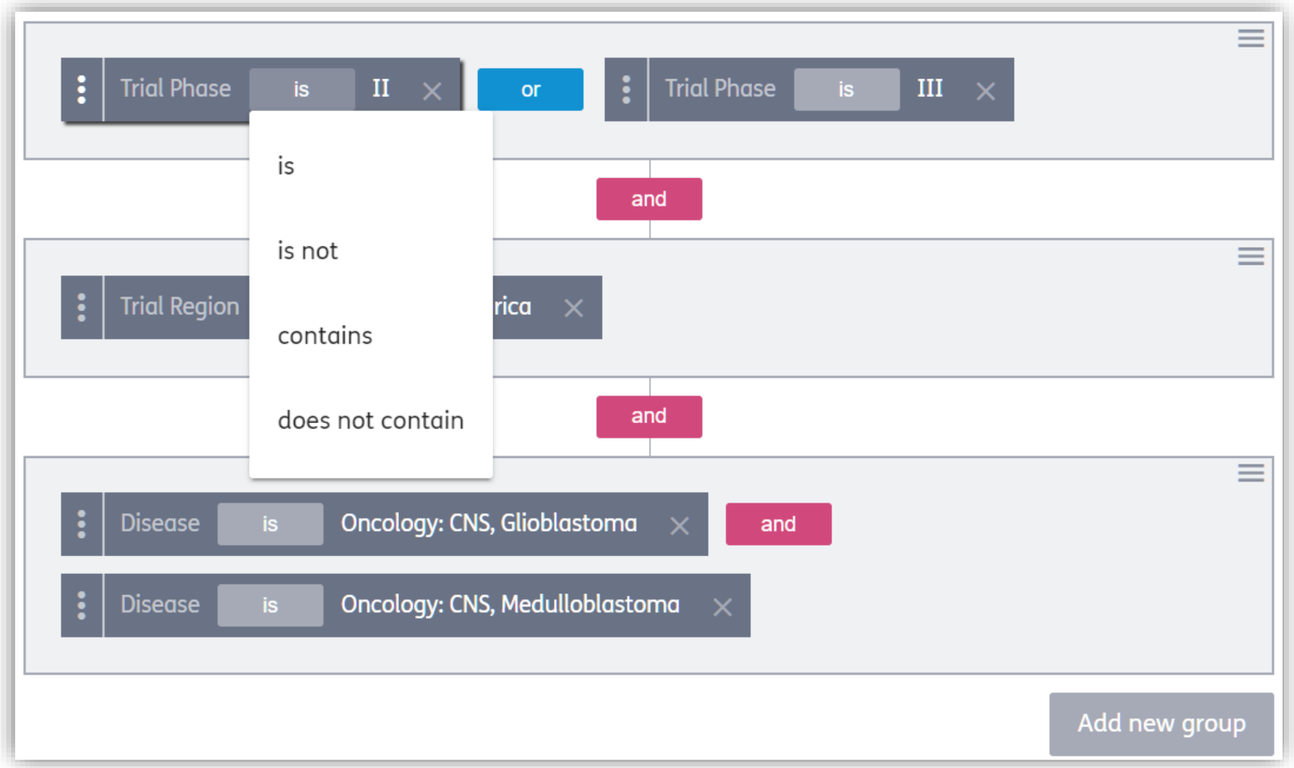
✓ 随意尝试各种搜索和开发新的见解



视觉逻辑搜索（Visual Boolean Search）

方便修改，注重逻辑思维

- 指定每个连接词语该如何使用（is, is not, contains, does not contain）
- 组合词语用于处理复杂逻辑思维
- 使用参数连接词（and/or）建立复杂搜索

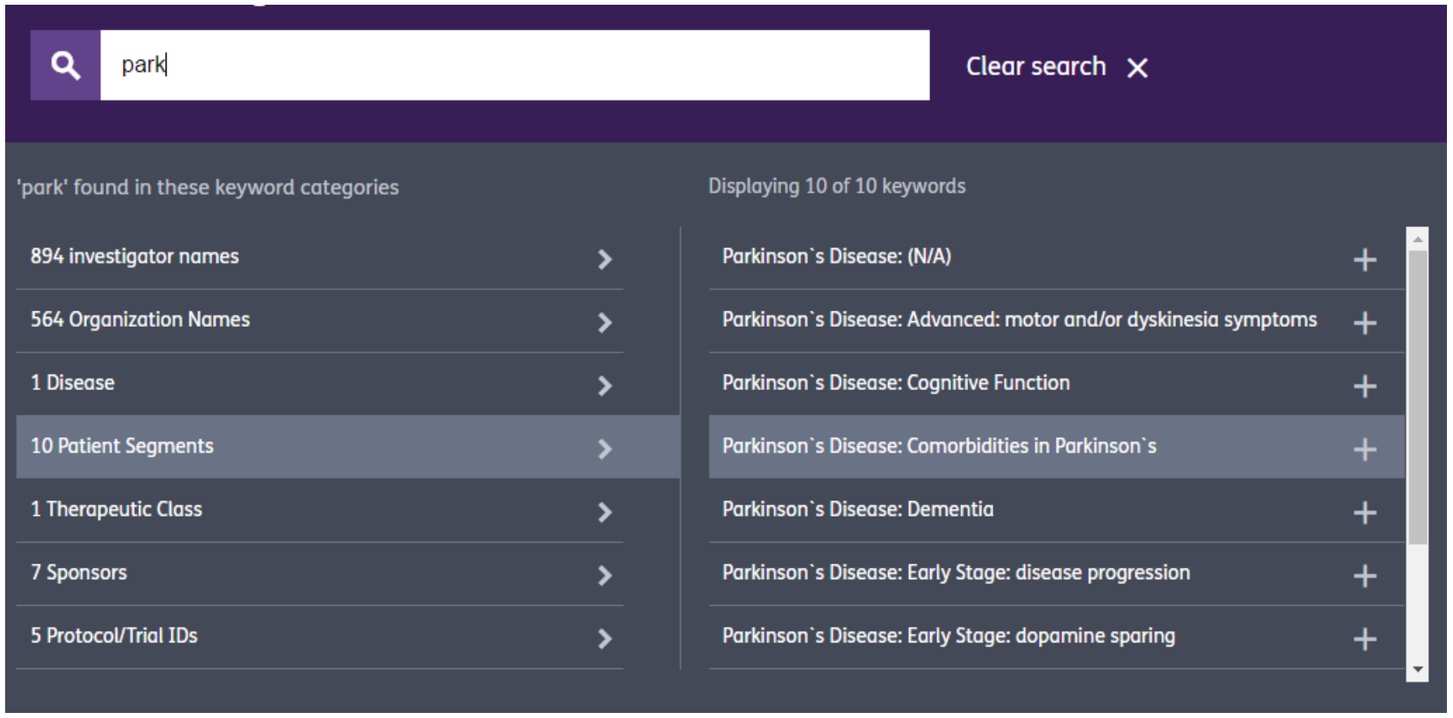


- ✓ 无须再记住复杂的搜索配搭及结构
- ✓ 实时同步查看与验证检索结果
- ✓ 快速与准确地确认搜索条件，即便是储存或共享的检索

快捷搜索栏

快速查询相关数据

- 输入关键词
- 根据以上词语快速查询可用的搜索结果或搜索参数
- 单个或同时使用多关键词检索与过滤搜索
- 搜索全文内容



- ✓ 节省时间
- ✓ 发现意想不到的搜索条件搭配方式
- ✓ 为不常使用的用户简化了检索

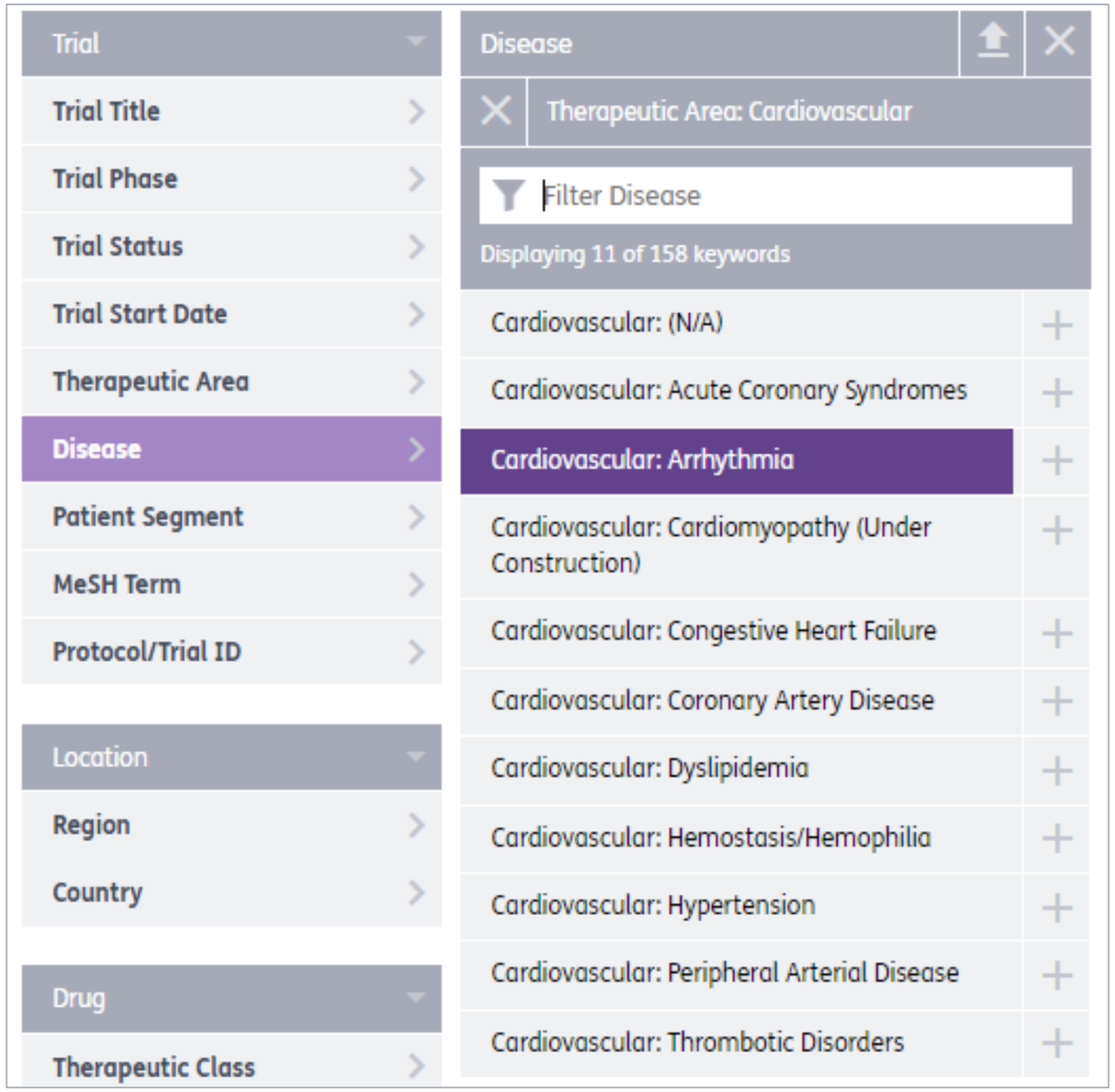
动态搜索与筛选

快速、轻松地搜索与筛选结果

- 通过扩展或缩小搜索条件列表轻松地查询结果
- 从列表中选择或通过关键词搜索快速找到搜索条件
- 实时查看查询结果

✓ 更快、更精准的搜索方式

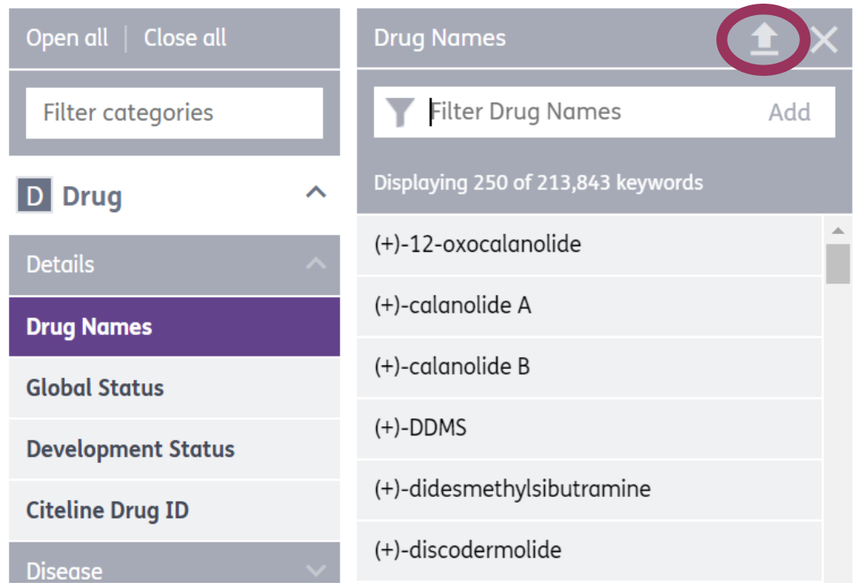
✓ 对初用者或不常用用户来说更便捷，同时保留了资深用户的需求

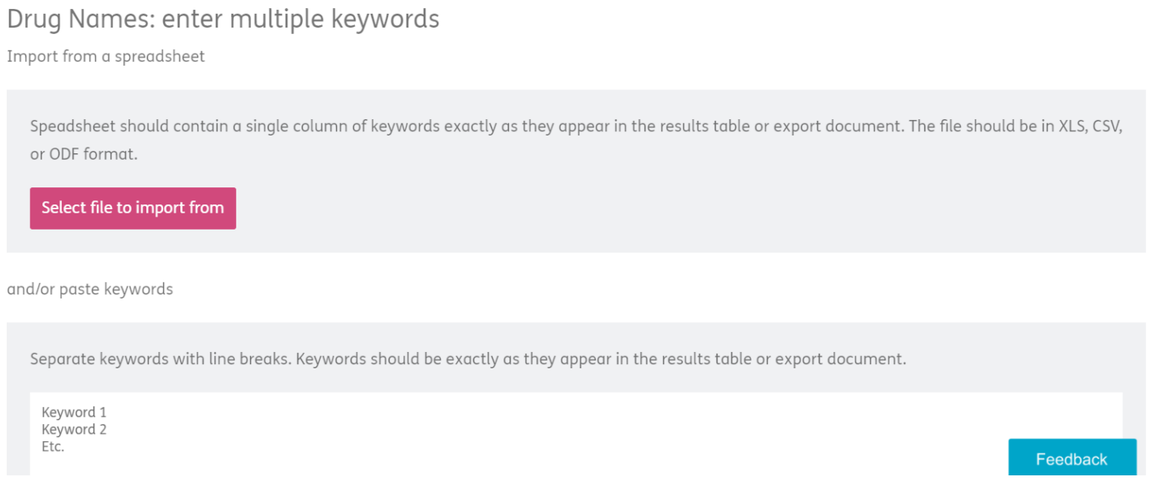


大量导入搜索条件

轻松建立复杂的搜索列表

- 输入或上传搜索词列表
- 可用于MeSH、临床研究名称、疾病、患者群体、Protocol或Trial编号、国家等



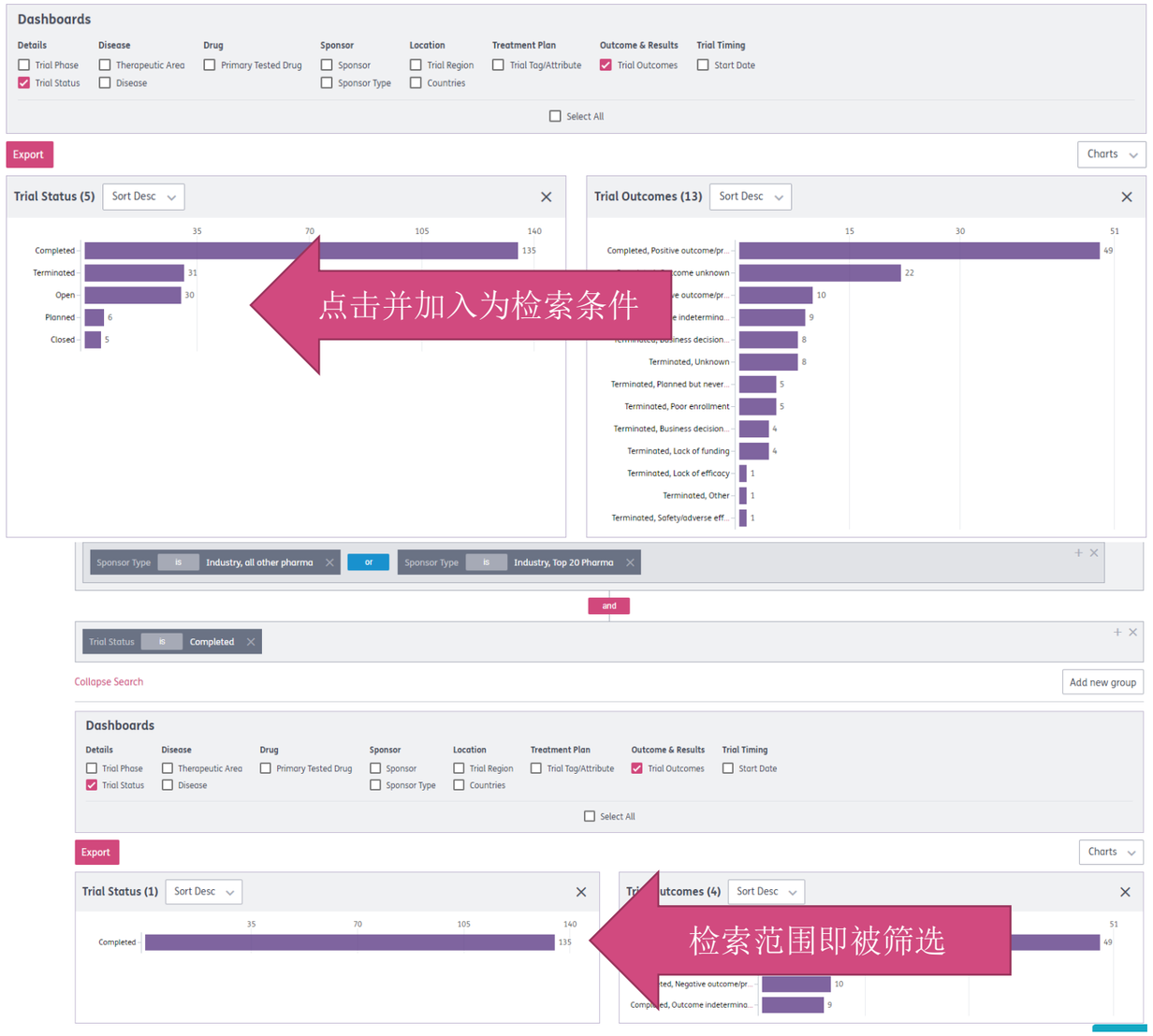


- ✓ 节省时间
- ✓ 提升可靠性
- ✓ 导出结果后轻松自定义建立新的搜索列表，以便创建新的搜索

可下载的交互式图表显示功能（Interactive Dashboards）

分析 > 修正 > 导出

- 随意选择显示部分或全部图表内容
- 随意切换图表或列表模式、以及选择显示前20或所有结果
- 一键导出至Excel格式以便修改或直接复制图表至演示资料
- 每当修改检索条件，图表即刻自动同步更新
- 点击图表内容即可加入至检索条件并同步更新



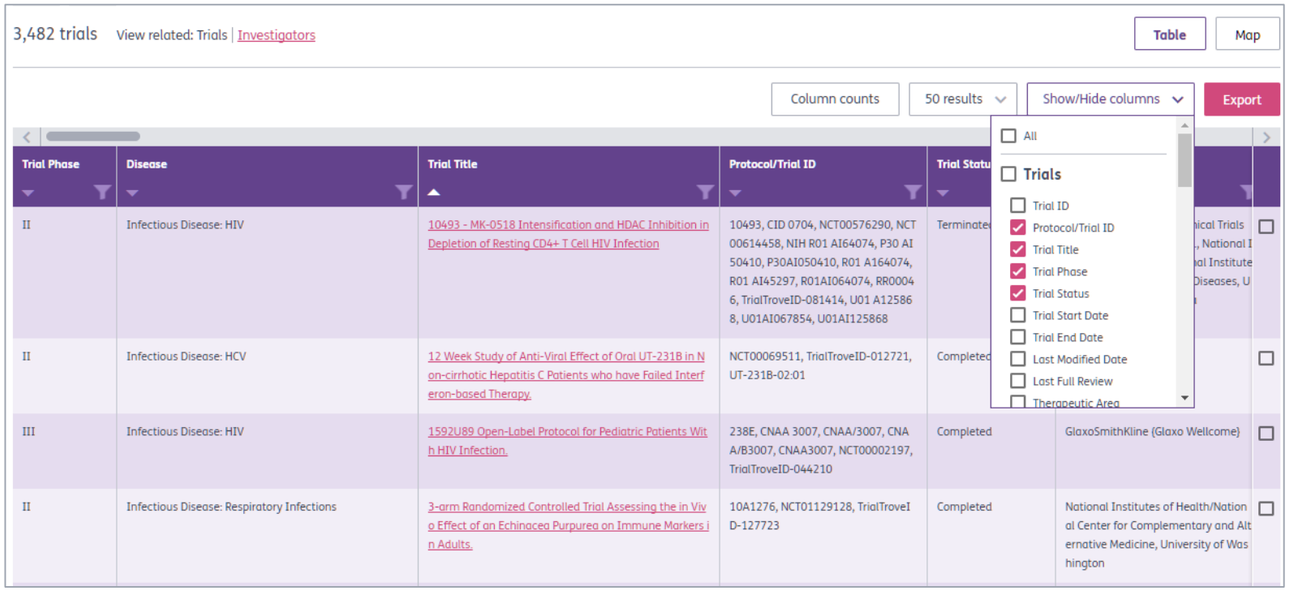
✓ 分析数据并快速优化检索及结果

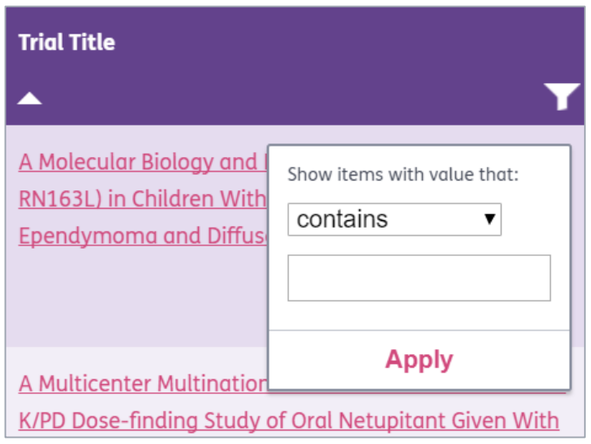
✓ 立即更新您的演示资料

自定义视图选择与数据导出

自行定制观看结果方式

- 添加、删减或重新排列搜索结果栏目
- 导出所有或已选的栏目数据
- 向右滑动查看更多信息栏目
- 导出所有或已选信息
- 选择以表格或地图方式查看
- 搜索结果栏目内进一步筛选





✓ **节省时间 – 无须导出内容再查看数据，也无须返回至筛选结果界面**

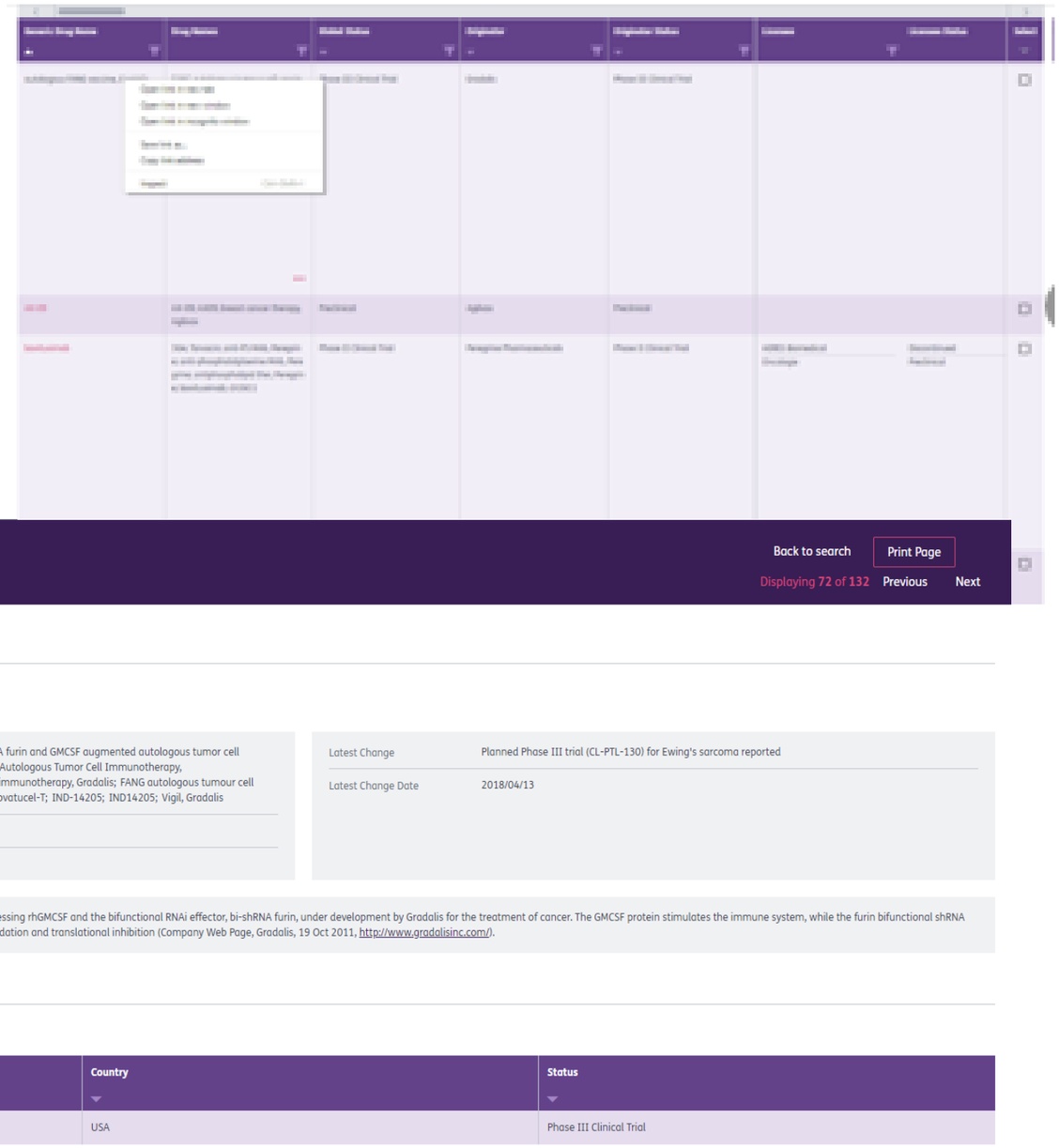
✓ **提升准确性 – 通过同时查看关键数据、搜索条件，以及能随时调整搜索**

资料连接

快速浏览相关记录

- 直接从临床研究名称右键点击另开网页，并直达相应资料

- 使用Navigation快速跳到所需信息

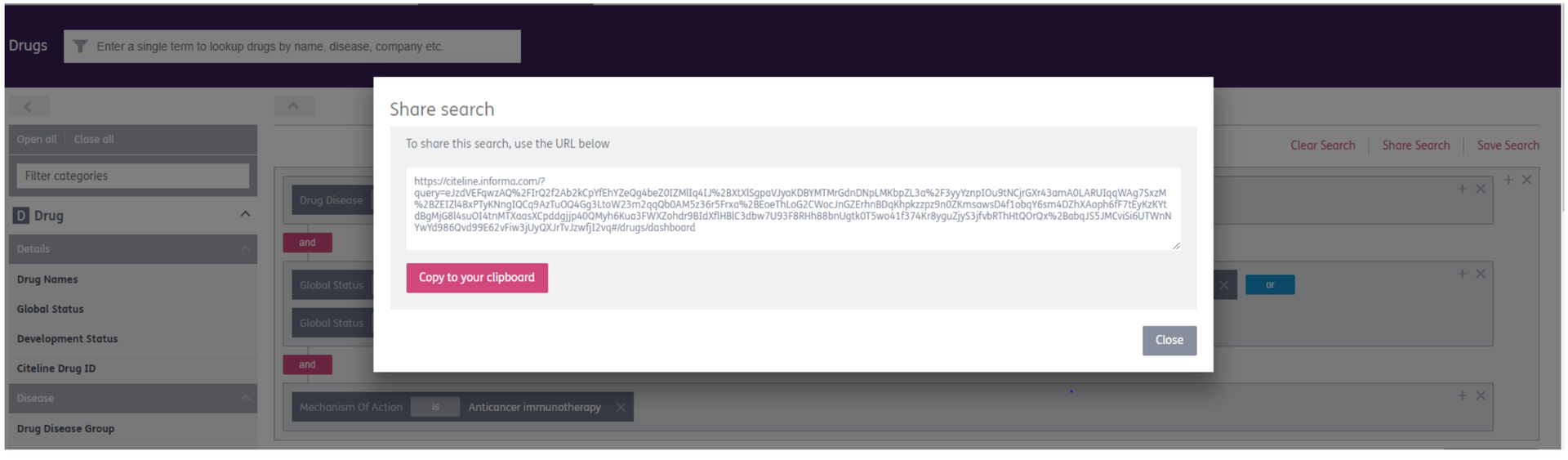


保存与分享

随时随地分享及使用

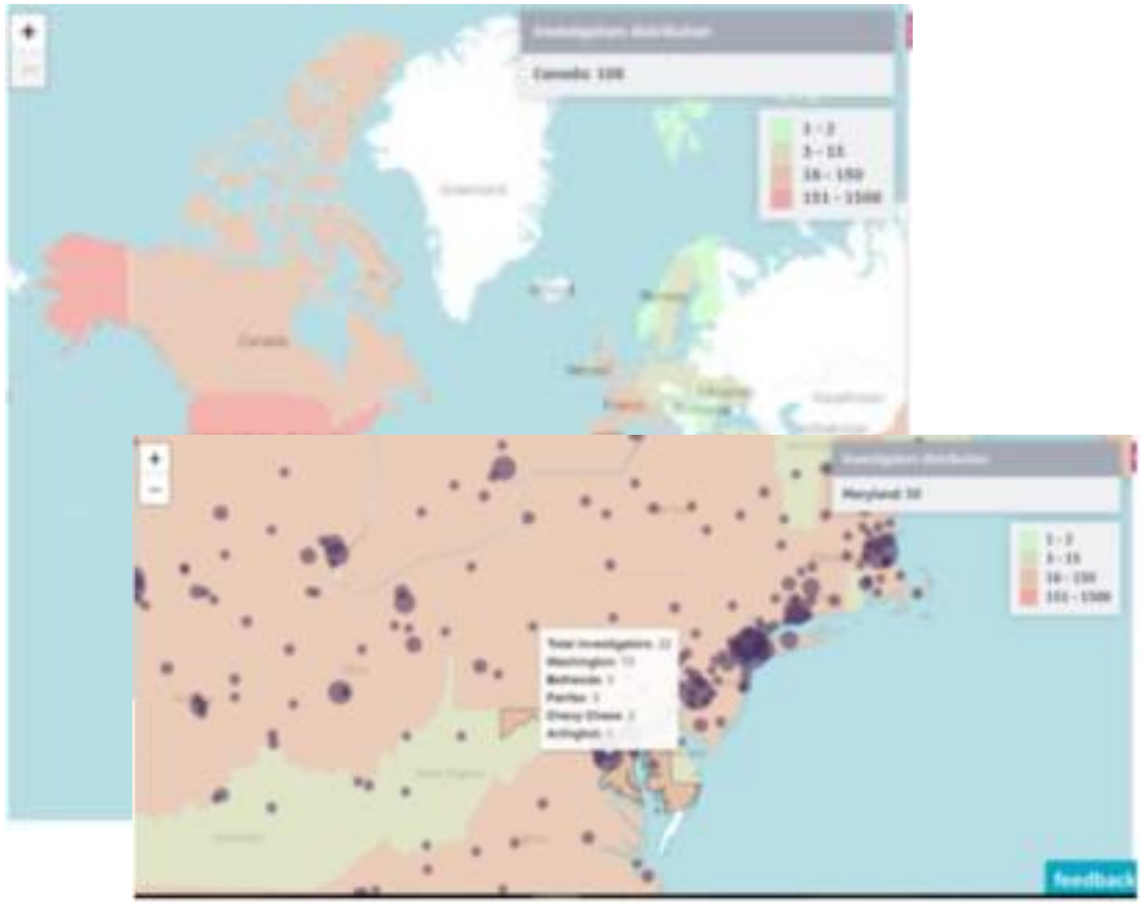
Next Gen版本

- 只保存您觉得重要的搜索
- 可以对已存搜索起名
- 同一地方管理Trialtrove与Sitetrove的已存搜索



Trialtrove & Sitetrove
交互性地图功能（Maps）

现即可查阅各国或地区在临床试验、研究人员或地点的情况及密度

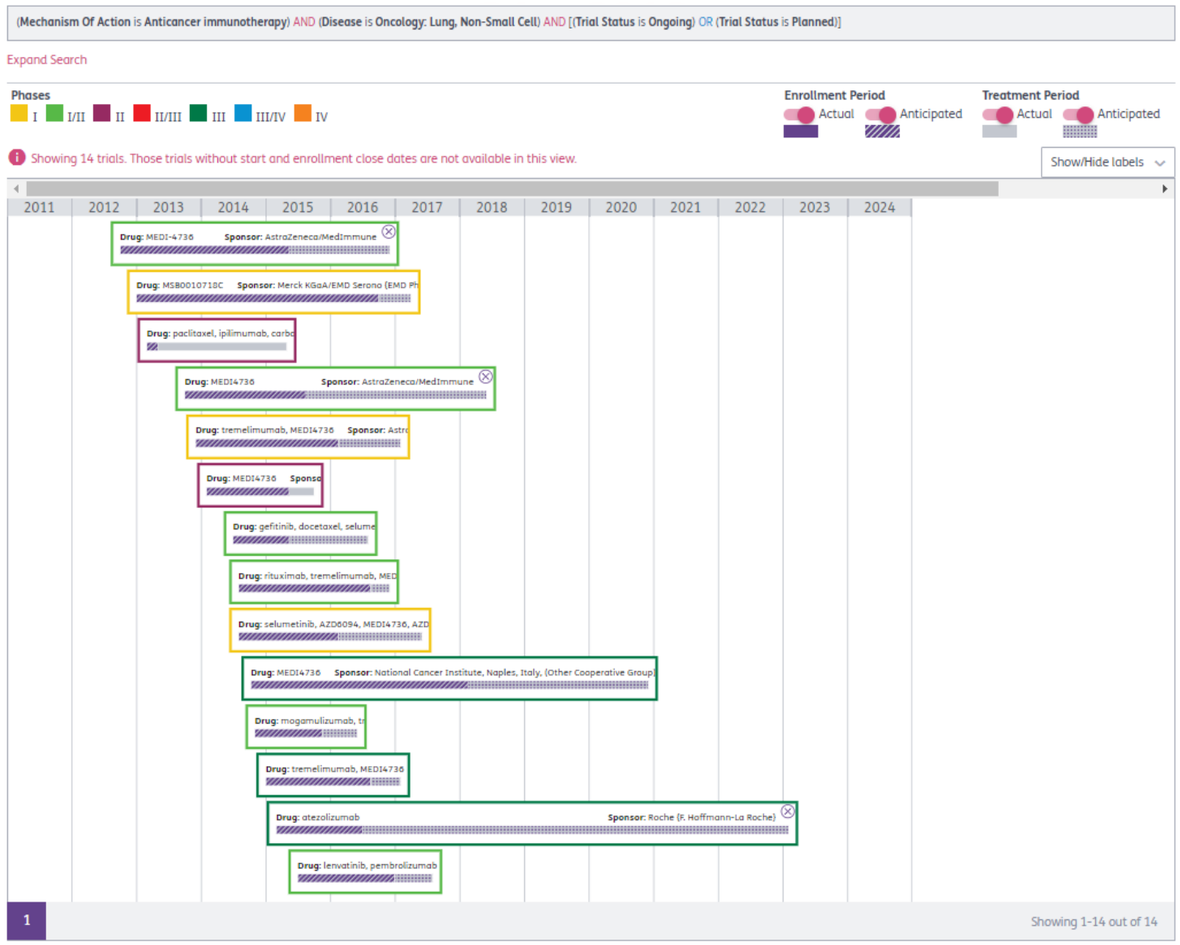


- 通过各种检索条件（如：适应症或患者人群）准确识别出与您的研发方案匹配的完整竞争市场格局
- 发掘符合您要求并可用的研究人员或地点的集中地
- 查看各国或城市的结果数量
- 通过热点地图（Heat Map）完善您的检索范围

For more information on Citeline Next Generation contact your Account Manager or Client Success Manager

Trialpredict
时间线图表模式（Timeline Dashboard）

快速查阅及评估临床试验竞争格局



- 通过临床阶段、预期或实际患者募集期、治疗期等信息，立即查阅所有符合要求的临床试验
- 快速识别有竞争力的研发时间段、评估临床研究战略、分析潜在患者人数
- 通过药物、作用机制、临床阶段、入选或去除条件、患者人群、申办方等条件，筛选并优化检索范围
- 通过药物、适应症、临床阶段、临床研究编号、研究状态，以及申办方Label，随意对图表进行修改

For more information on Citeline Next Generation contact your Account Manager or Client Success Manager

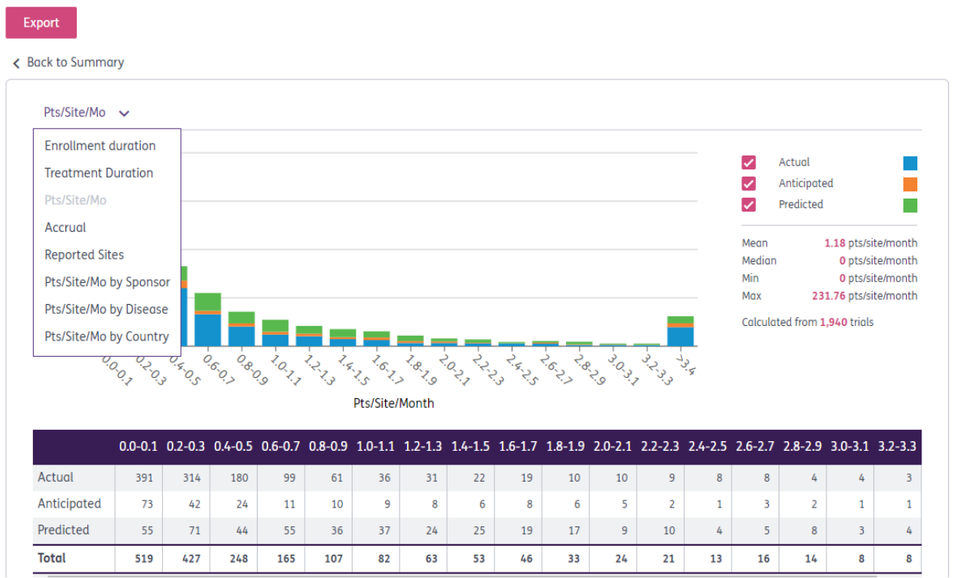
Trialpredict
全新比照分析及图表显示（Benchmarking & Dashboards）

一键分析相似临床方案，以便构建有效之临床试验设计及计划

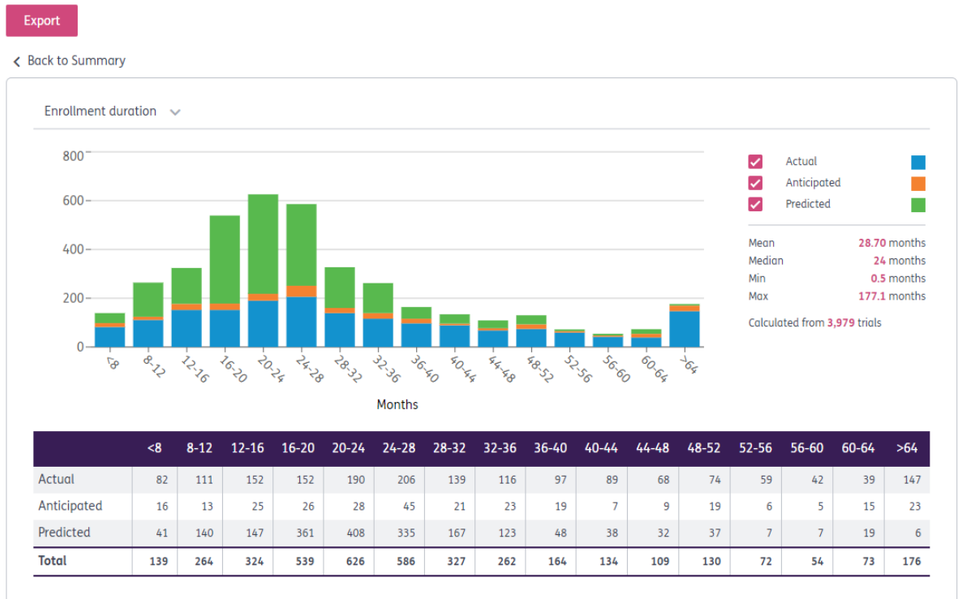
可下载的自订化分析功能包括：

- *受试者募集用时*
- *治疗用时*
- *受试者募集人数*
- *临床研究地点*
- *每月平均募集人数（Patient Site Per Month）*

- 统一计算及绘制所选临床试验的受试者募集信息与比对治疗用时
- 分析各类临床研究的募集成功率（每月平均募集人数【pts/site/mon】）
- 通过各检索条件（如：患者群体、适应症等），直接了解相似临床试验的受试者募集情况
- 快速掌握可比较临床试验的范围及平均研究地点数量



	0.0-0.1	0.2-0.3	0.4-0.5	0.6-0.7	0.8-0.9	1.0-1.1	1.2-1.3	1.4-1.5	1.6-1.7	1.8-1.9	2.0-2.1	2.2-2.3	2.4-2.5	2.6-2.7	2.8-2.9	3.0-3.1	3.2-3.3
Actual	391	314	180	99	61	36	31	22	19	10	10	9	8	8	4	4	3
Anticipated	73	42	24	11	10	9	8	6	8	6	5	2	1	3	2	1	1
Predicted	55	71	44	55	36	37	24	25	19	17	9	10	4	5	8	3	4
Total	**519**	**427**	**248**	**165**	**107**	**82**	**63**	**53**	**46**	**33**	**24**	**21**	**13**	**16**	**14**	**8**	**8**

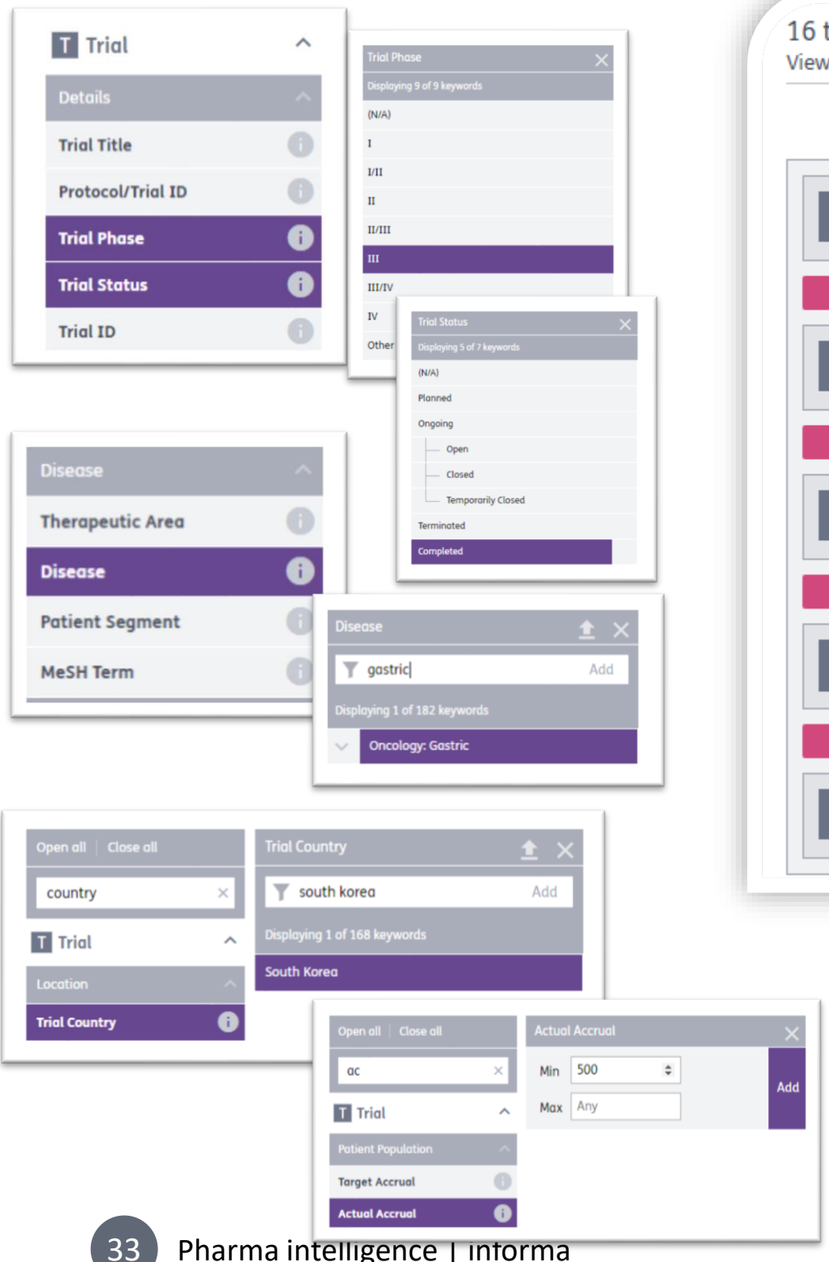


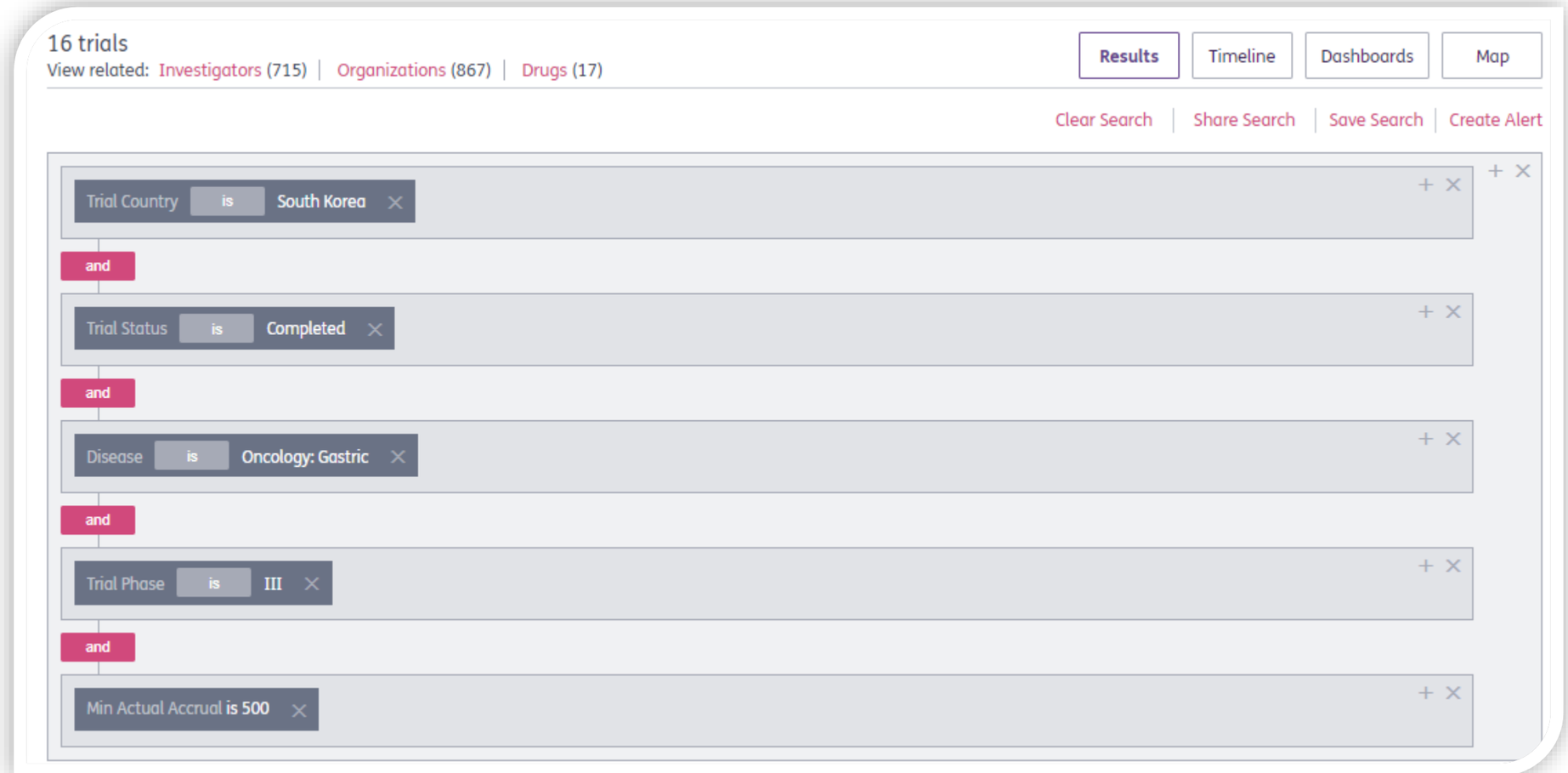
	<8	8-12	12-16	16-20	20-24	24-28	28-32	32-36	36-40	40-44	44-48	48-52	52-56	56-60	60-64	>64
Actual	82	111	152	152	190	206	139	116	97	89	68	74	59	42	39	147
Anticipated	16	13	25	26	28	45	21	23	19	7	9	19	6	5	15	23
Predicted	41	140	147	361	408	335	167	123	48	38	32	37	7	7	19	6
Total	**139**	**264**	**324**	**539**	**626**	**586**	**327**	**262**	**164**	**134**	**109**	**130**	**72**	**54**	**73**	**176**

Trialpredict
Pharma intelligence | informa

案例（Trialtrove）：

“如何检索所有在韩国已完成的临床三期胃癌临床试验（最少500名受试者）？”

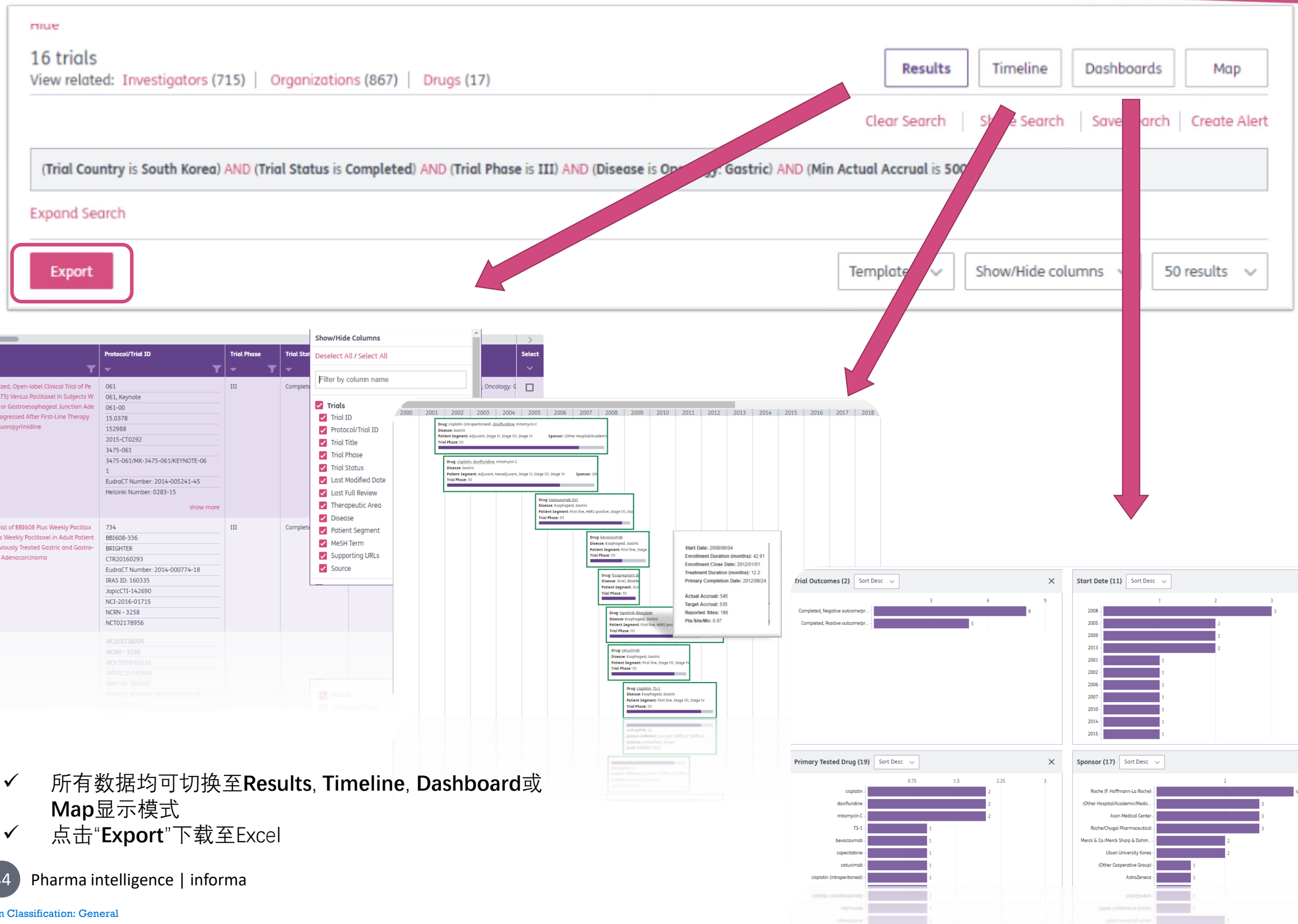




检索条件：

1. **Trial Phase & Status:** 选择“Phase III”与“Completed”
2. **Disease:** 检索并选择 “Oncology: Gastric”
3. **Trial Country:** 检索并选择 “South Korea”
4. **Minimum Enrolment (Actual):** 选择Actual并输入最少为 “500”名受试者

Note: Target Accrual (number of patients sought for) vs. Actual Accrual (number of patients enrolled) – Accrual numbers are based on reported information via the public domain with validation by Trialtrove analyst team. Final accrual information is searchable and provided in the Results table and exports. Interim accrual information is provided within the Trial Profiles when available.



- ✓ 所有数据均可切换至**Results**, **Timeline**, **Dashboard**或**Map**显示模式
- ✓ 点击“**Export**”下载至Excel

案例（Trialtrove）：

临床试验报告 – 查阅完整临床方案及研究经过

Trial

‹ Previous 10 / 16 Next ›

Back to search | Print Page | Download PDF | Share Trial | Create Alert

- Trial Summary
- Trial Outcomes
- Trial Objectives
- Trial Timing
- Patient Population
- Trial Locations
- Study Keywords
- Treatment Plan
- Trial Notes
- Results
- Supporting URLs
- Record Updates

Top

A Phase III, Randomized, Open-label Clinical Trial of Pembrolizumab (MK-3475) Versus Paclitaxel in Subjects With Advanced Gastric or Gastroesophageal Junction Adenocarcinoma Who Progressed After First-Line Therapy With Platinum and Fluoropyrimidine

Trial Summary

TrialTrove ID	TrialTroveID-252786	Phase	III
Source	Trialtrove	Sponsor	Merck & Co./Merck Sharp & Dohme (MSD)
Disease	Esophageal; Gastric	Primary Drugs	pembrolizumab
Patient Segment	HER2 positive; Second line; Stage III; Stage IV	Other Drugs	paclitaxel
MeSH Term			
Trial Tags/Attributes			

Trial Outcomes

Outcome	Completed, Negative outcome/primary endpoint(s) not met
Outcome Details	December 14, 2017

Treatment Plan

Study Design	Study Type: Interventional Study Design: Allocation: Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Treatment An active comparator, 1:1 rand
Treatment Plan	Arms: Experimental: Pembrolizumab Participants receive pembrolizu Arms: Active Comparator: Paclitaxel Participants receive paclitaxel 8 ESMO 2015: Patients will be randomized 1:1 decision. In the pembro arm, pt may continue pembro at the di central review and per RECIST c ASCO 2016: Eligible pts are randomized 1:1

Trial Notes

Enrollment Period: June 4, 2015 - July 26, 2016

https://www.ncbi.nlm.nih.gov/pubmed/29880231

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)31257-1/...

2018/07/19
July 19, 2018 [Sub-group Analysis]

Presented at the 16th Annual Meeting of Japanese Society of Medical Oncology (JSMO), July 19-21, 2018, Kobe, Japan.
Abstract Published online: July 19, 2018
Abstract No.: P5-4

Kohei Shitara, Kei Muro, Taroh Satoh, Takao Tamura, Keisho Chin, Nozomu Machida, Hiroki Hara, Shuichi Hironaka, Naotoshi Sugimoto, Carlos Maya, Shi Rong Han, Shinichi Shiratori, Atsushi Ohtsu

KEYNOTE-061: Pembrolizumab vs Paclitaxel for Previously Treated Advanced Gastric or Gastroesophageal Junction Cancer

Results:
Overall, 592 pts were enrolled; 395 had PD-L1 CPS >or=1 (pembro n=196; PTX n=199). 100 JPN pts were enrolled (pembro n=47; PTX n=53); 65 had PD-L1 CPS >or=1 (pembro, n=27; PTX, n=38). In the CPS >or=1 population, median follow-up was 8 mo for all pts and 10 mo for JPN pts. Primary endpoints of median OS and PFS were not statistically significant in all pts (OS, 9.1 vs 8.3 mo with pembro vs PTX [HR 0.82, <I>P</I>=0.04]; PFS, 1.5 vs 4.1 mo [HR 1.27, <I>P</I>=0.98]). Other <I>P</I> values were nominal. Median OS was 12.3 vs 9.8 mo in JPN pts (HR 0.67, <I>P</I>or=0.07); 12-mo OS rates were 40% vs 27% in all pts and 52% vs 34% in JPN pts; 18-mo OS rates were 26% vs 15% in all pts and 26% vs 16% in JPN pts. Median PFS was 1.6 vs 4.2 mo in JPN pts (HR 1.21, <I>P</I>or=0.75). ORR was 16% vs 14% in all pts and 7% vs 18% in JPN pts. In the overall population, grade 3-5 drug-related AE rate was 14% vs 35% in all pts and 4% vs 44% in JPN pts; treatment was discontinued for drug-related AEs in 3% vs 5% of all pts and 0% vs 6% of JPN pts.

Conclusion: Pembro (vs PTX) reduced risk for death by 18% in all pts and by 33% in JPN pts with previously treated G/GEJ cancer and PD-L1 CPS =1. Pembro had a better safety profile than PTX in all pts and in JPN pts.

https://www.micenavi.jp/jsmo2018/search/detail_program/id:541

2018/05/25
Mexico Clinical Trial Registry [Accessed on: May 25, 2018]

[Translated from Spanish]

PROTOCOL NUMBER:MK-3475-061
SPONSOR:Merck Sharp & Dohme Corp.

FULL TITLE OF STUDY: "Phase III, open-label, randomized clinical study of Pembrolizumab (MK-3475) compared to Paclitaxel in patients with gastric adenocarcinoma or advanced gastroesophageal junction that worsened after first-line treatment with Platinum and Fluoropyrimidine".