CERTARA®

accelerating medicines

Investor Day 2021

CERT
Nasdaq Listed

Disclaimer

Numerical figures in the presentation have been subject to rounding adjustments. Accordingly, numerical figures shown as totals in various tables may not be arithmetic aggregations of the figures that precede them.

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Non-GAAP Financial Information

This presentation contains "non-GAAP measures" that are financial measures that either exclude or include amounts that are not excluded or included in the most directly comparable measures calculated and presented in accordance with U.S. generally accepted accounting principles ("GAAP"). Specifically, we make use of the non-GAAP financial measures adjusted EBITDA, adjusted EBITDA margin, adjusted net income, and adjusted diluted EPS, which are not recognized terms under GAAP and should not be considered as alternatives to net income (loss) and GAAP EPS as measures of financial performance or cash provided by operating activities as a measure of liquidity, or any other performance measure derived in accordance with GAAP. The presentation of this measure has limitations as an analytical tool and should not be considered in isolation, or as a substitute for our results as reported under GAAP. Because not all companies use identical calculations, the presentations of these measures may not be comparable to other similarly titled measures of other companies and can differ significantly from company to company.

Adjusted EBITDA represents net income (loss) excluding interest expense, provision (benefit) for income taxes, depreciation and amortization expense, intangible asset amortization, equity-based compensation expense, acquisition and integration expense and other items not indicative of our ongoing operating performance. Adjusted EBITDA margin represents adjusted EBITDA divided by revenue. Adjusted net income and adjusted diluted EPS exclude the effect of the same items noted above with respect to adjusted EBITDA from GAAP net income (loss) and GAAP EPS, respectively, as well as adjust the provision for income taxes for such charges. You should refer to the appendix at the end of this document for a reconciliation of these non-GAAP measures in specific periods to their most directly comparable financial measures calculated and presented in accordance with GAAP for those periods.

Management uses various financial metrics, including total revenues, income from operations, net income, and certain non-GAAP measures, including those discussed above, to measure and assess the performance of the Company's business, to evaluate the effectiveness of its business strategies, to make budgeting decisions, to make certain compensation decisions, and to compare the Company's performance against that of other peer companies using similar measures. In addition, management believes these metrics provide useful measures for period-to-period comparisons of the Company's business, as they remove the effect of certain non-cash expenses and other items not indicative of its ongoing operating performance. Management believes that these metrics are helpful to investors, analysts, and other interested parties because they can assist in providing a more consistent and comparable overview of our operations across our historical periods. In addition, these measures are frequently used by analysts, investors, and other interested parties to evaluate and assess performance. In evaluating adjusted EBITDA, adjusted net income, and adjusted diluted EPS, you should be aware that in the future the Company may incur expenses similar to those eliminated in this presentation and this presentation should not be construed as an inference that future results will be unaffected by unusual items.

Agenda

- CEO Remarks
- Software: Innovating to Transform Traditional R&D
- Q&A
- Break
- Technology-driven Services: Customer Value Creation
- Q&A
- Financial Guidance
- Q&A

CERTARA

CEO Remarks

William Feehery, Ph.D.

Chief Executive Officer

Certara at a glance

BUSINESS

20+ Year
History of innovation

1,100+ Employees[1]

350+ with Ph.D.s, Pharm.D.s and M.D.s

15 Acquisitions

Track record of accretive, complementary acquisitions

END-TO-END PLATFORM

Software

- Biosimulation
- Regulatory & compliance
- Market access

Technology-Driven Services

- Drug discovery & development with biosimulation
- Regulatory science
- Market access

$13B TAM growing at **12-16%** CAGR[2]

CUSTOMERS[3]

1,650+
Customers across 61 countries

10+ Year
Average tenure for top 30 customers

261 customers with ACV > $100,000

53 customers with ACV > $1M

2021 Q1–Q3 FINANCIALS

$210.8M Revenue

18% YoY Growth

$75.5M
Adjusted EBITDA[4]
15% YoY Growth

36% Adjusted EBITDA Margin

Net Loss **($3.6M)**
PY $5.1M

(1) As of 11/30/2021
(2) Market research reports from Grand View and SpendEdge
(3) Customer data as of 12/31/2020
(4) See Appendix for reconciliation tables

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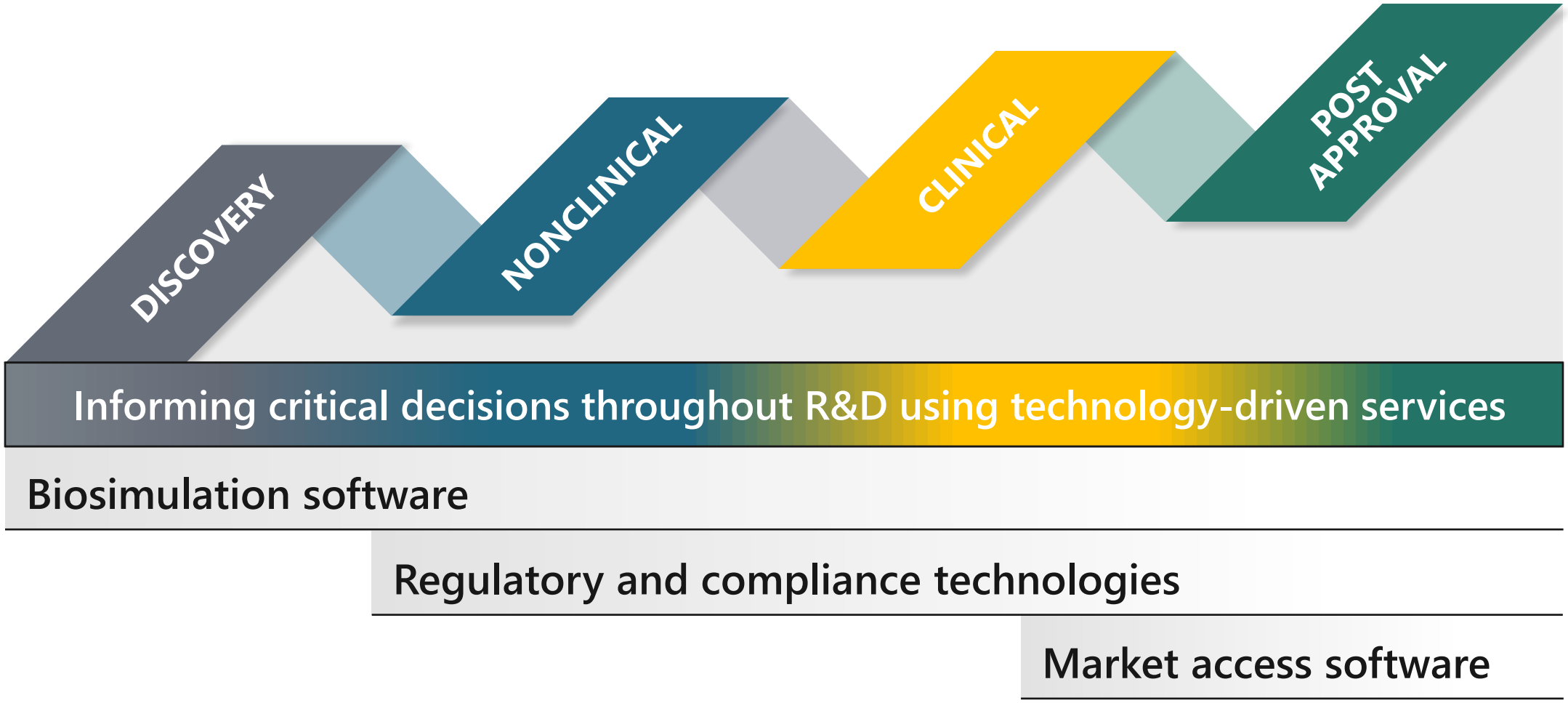
Accelerating medicines using biosimulation and technology



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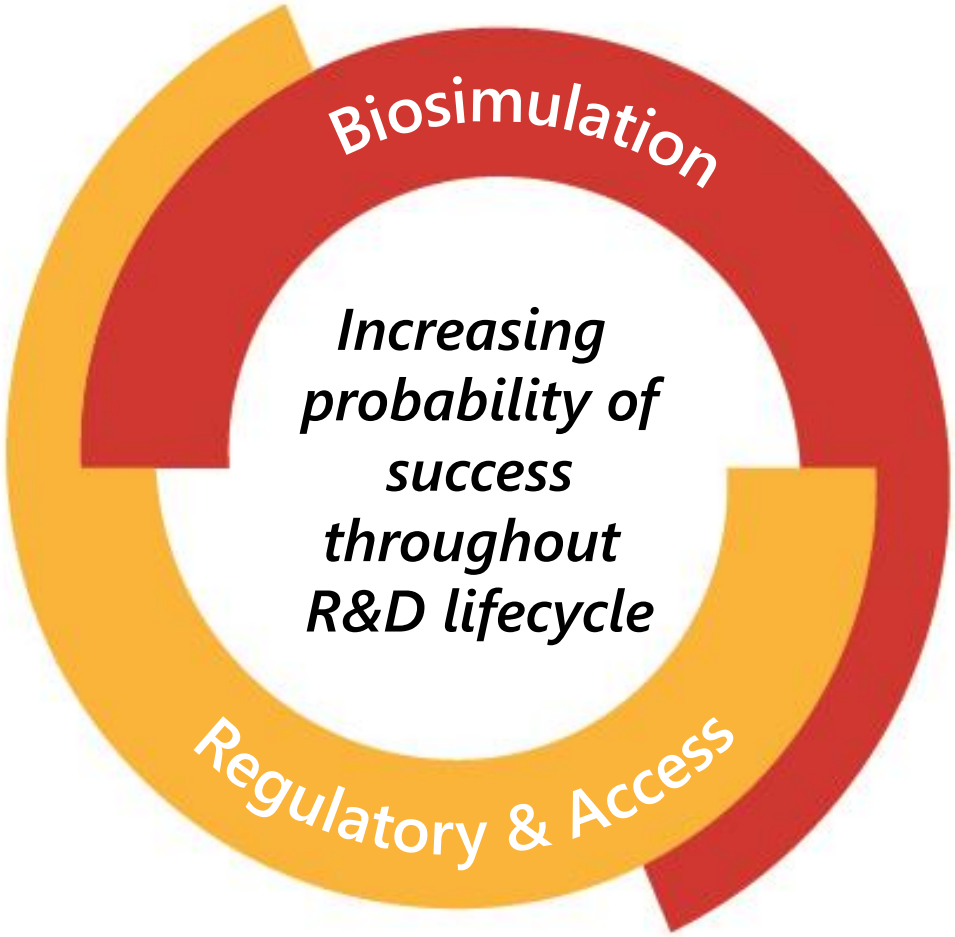
Advancing drug programs with our suite of solutions



Biosimulation is applied throughout R&D and integrated into regulatory strategy and submission

Technology-driven **regulatory science** improves quality, delivers scalability and expedites the submission process

Modeling and analytics help to understand and incorporate real-world impact in **value assessment** and **market access decisions**

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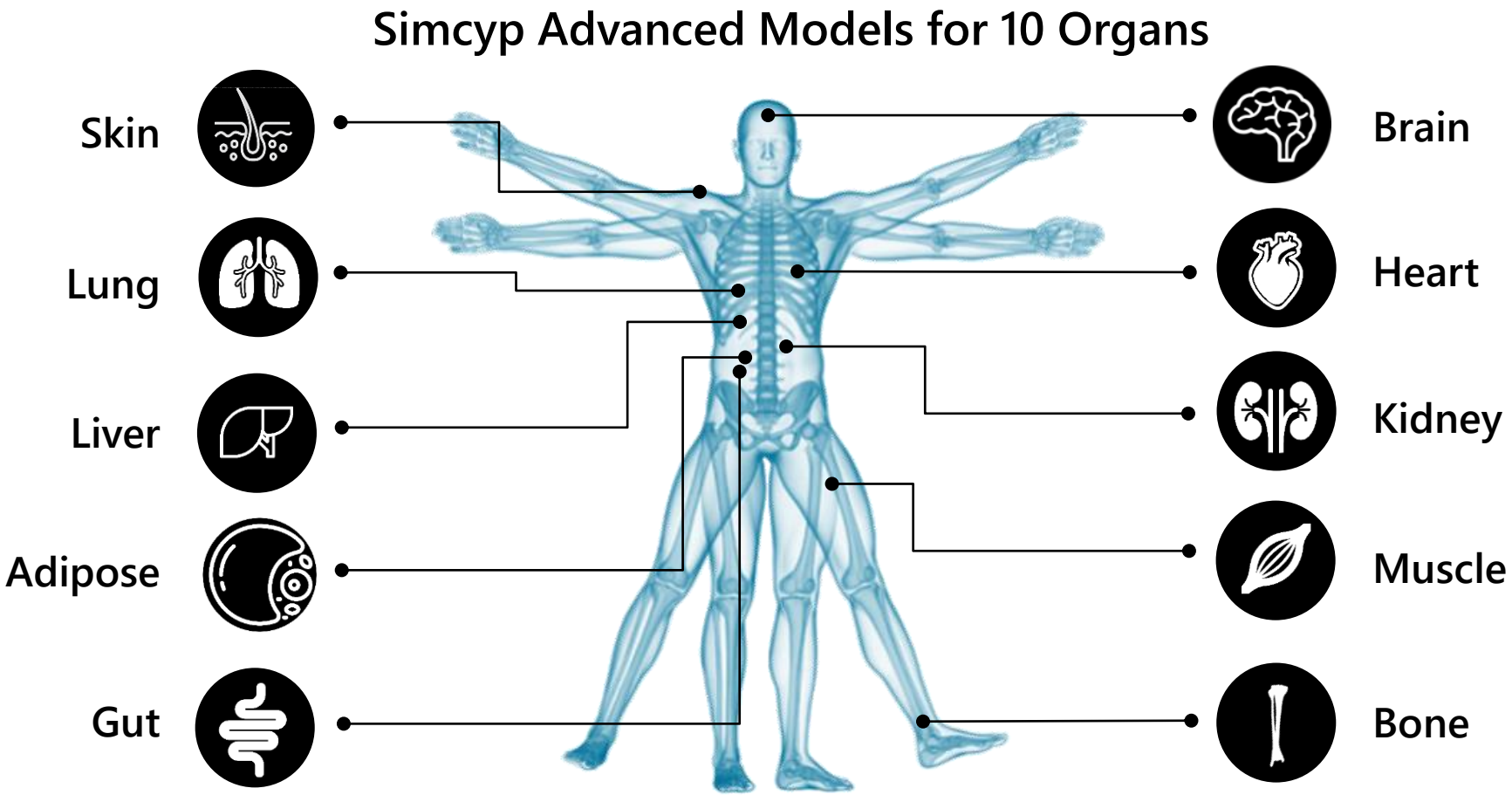
Predictive power of biosimulation

Biosimulation uses computer-based models of biological systems to predict how the body affects the drug and how the drug affects the body.



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Streamlining trials and optimizing outcomes

Biosimulation Use Case Examples

Discovery	• Improve target selection • Identify safety risks early
Nonclinical	• Replace, reduce and refine animal studies • Inform design of subsequent experiments
Clinical	• Determine first-in-human dosing • Waive drug interaction studies • Optimize dosing for special populations • Streamline or waive bioequivalence studies

Benefits

- ✓ Fail faster
- ✓ Streamline or waive animal and human studies
- ✓ Help increase safety and efficacy
- ✓ Cut time and cost

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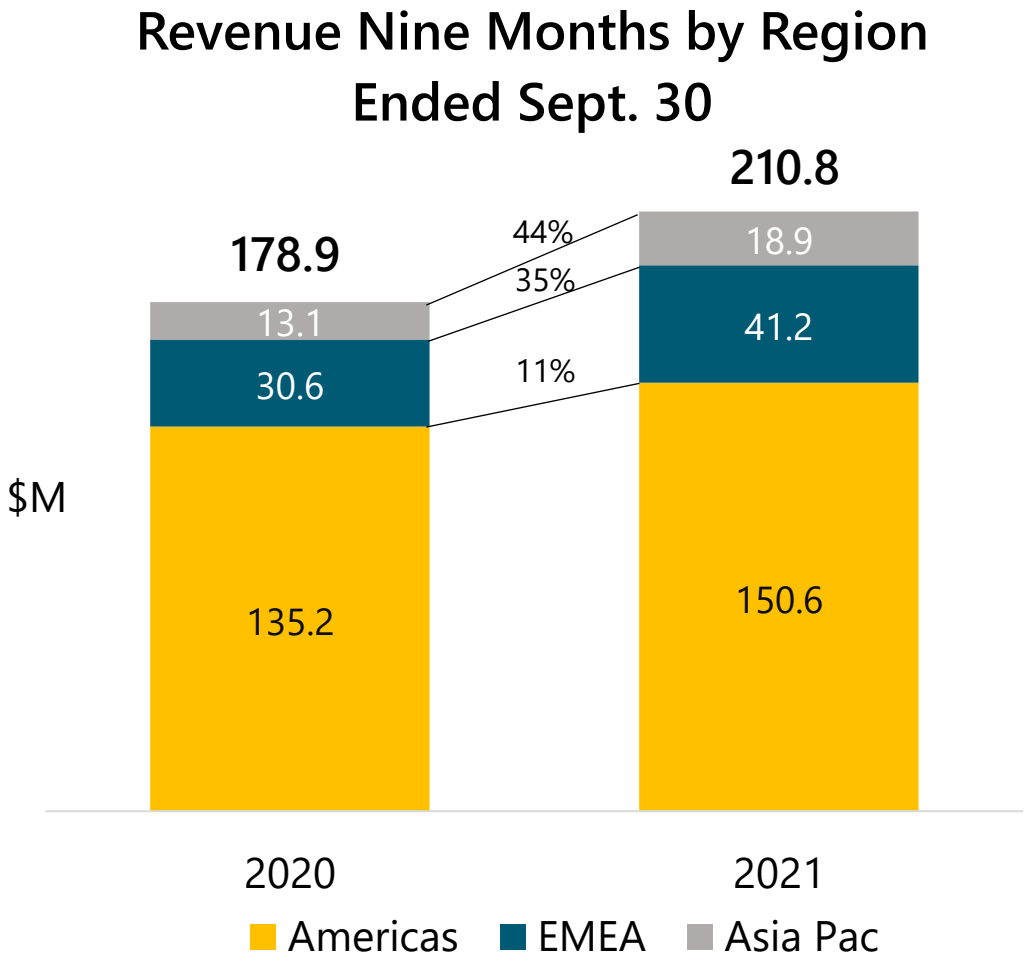
Differentiated strengths fuel global expansion

- Proprietary end-to-end software platform
- Biosimulation software adopted by 17 regulatory agencies
- Embedded in customers' R&D process with 90% renewal rate
- Scalable service model powered by technology and leading experts



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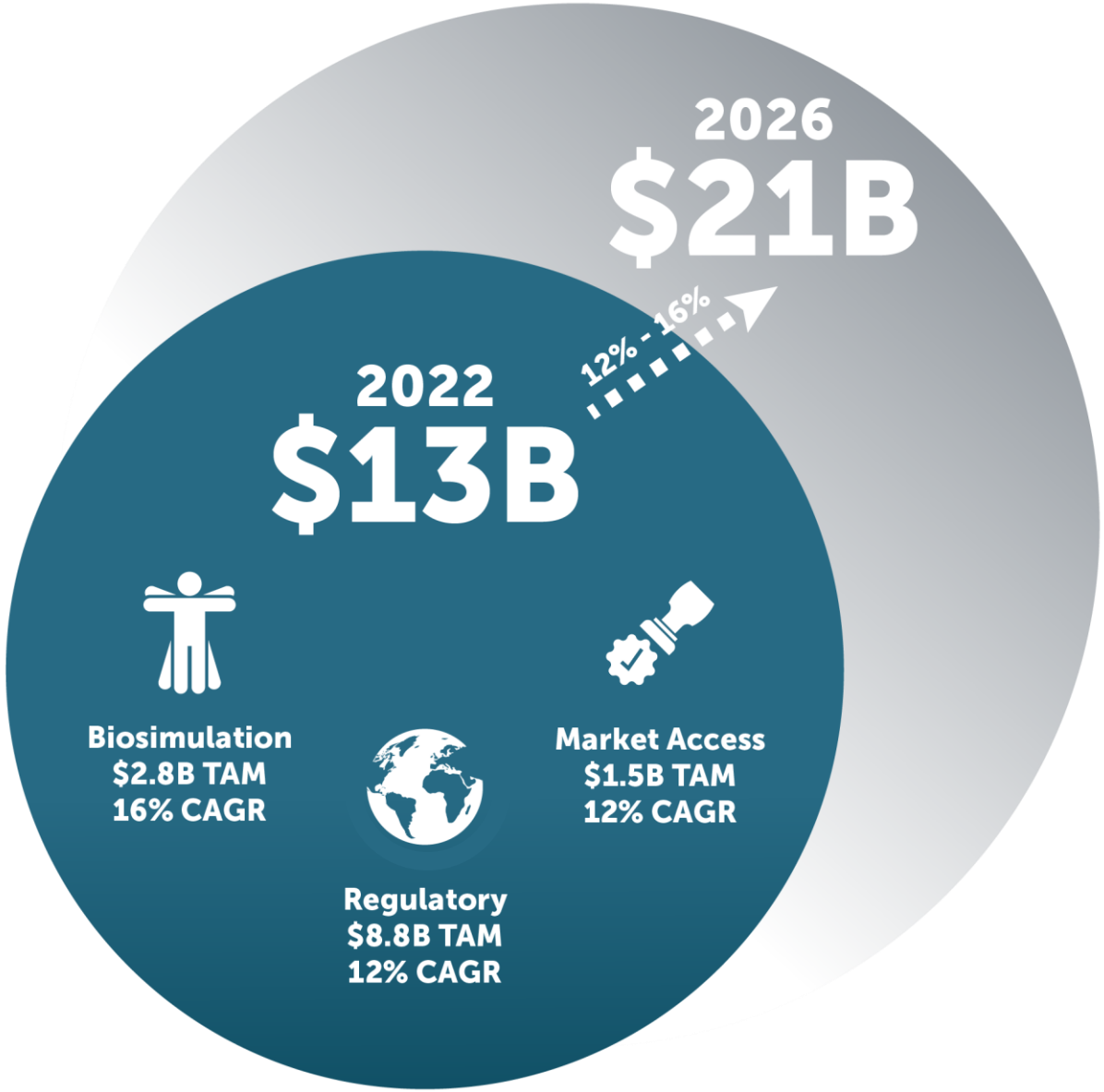
Large, growing end markets



Market Drivers

Global regulatory support

Biotech growth

Outsourcing

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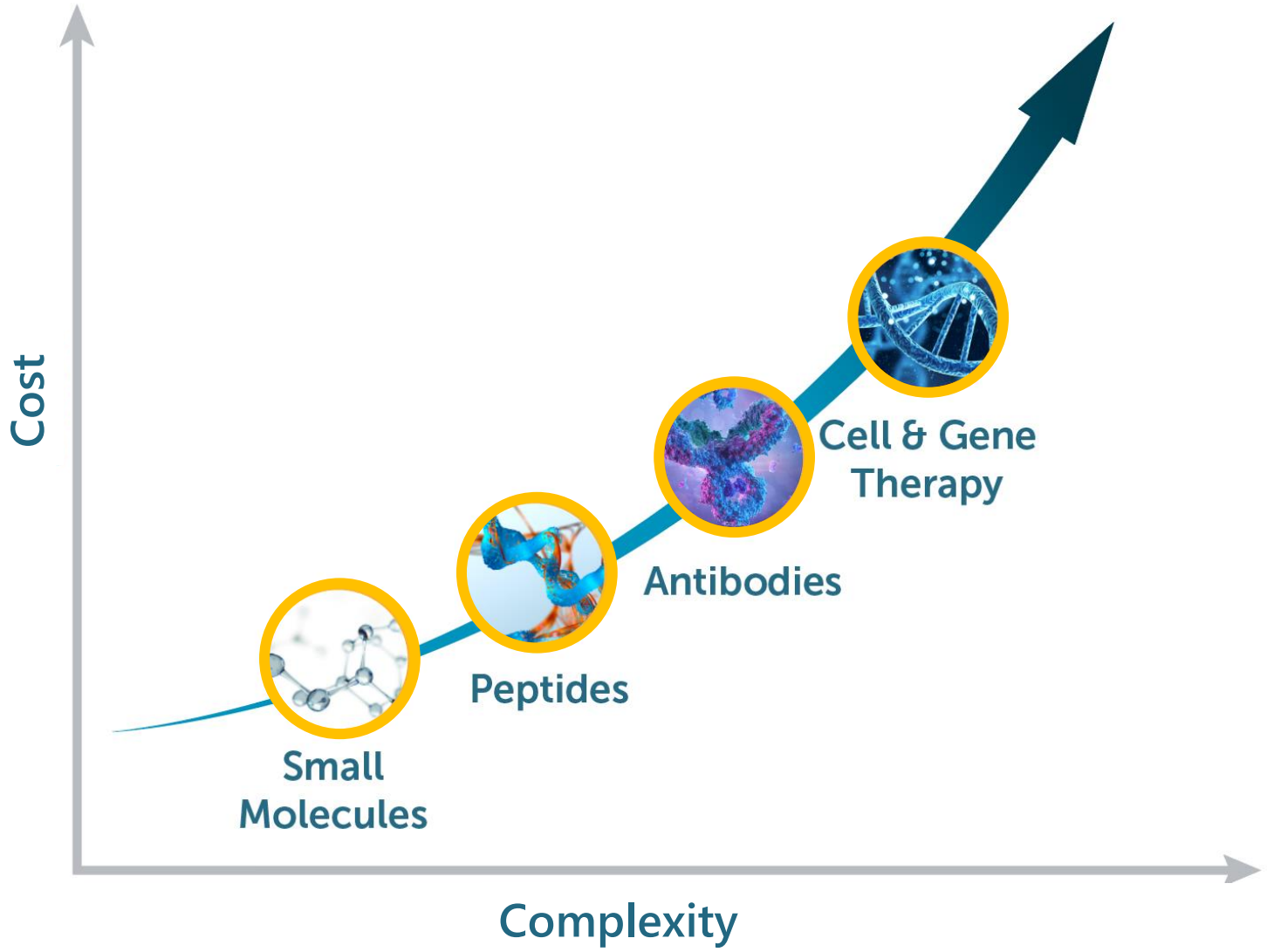
Drug R&D grows in complexity and cost



- Cost of development grows with complexity of compound
- Clinical phase times are increasing
- Biologics comprise 43% of the R&D pipeline
- Complex generics also pose development challenges

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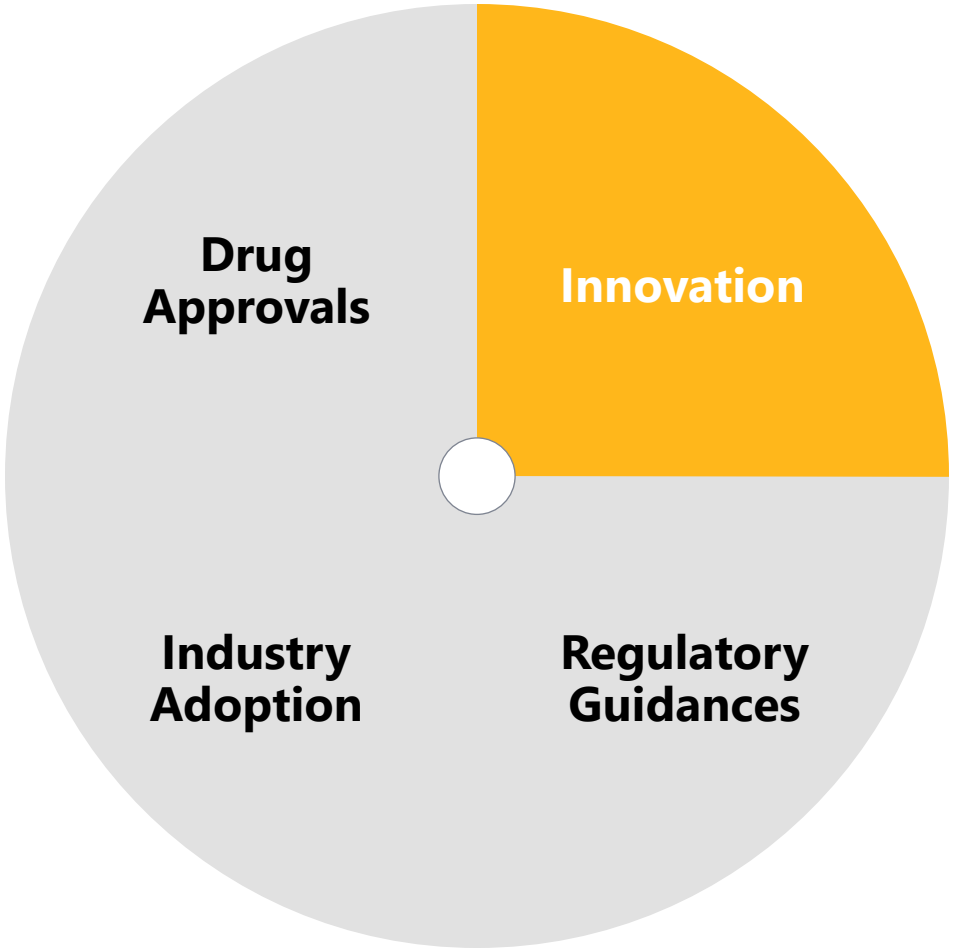
Powerful flywheel effect fuels momentum and adoption

Regulatory / Industry Flywheel Effect



New technology and biosimulation models **expand use cases**

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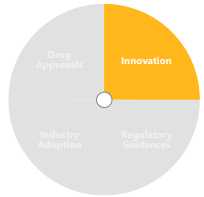
Driving innovation – 10 new products and updates in 2021



Regular cadence of new software launches and new capabilities to expand use cases

Simcyp™ Simulator
Versions 20 and 21

- Immuno-oncology
- Immunogenicity
- Vaccine Simulator

Quantitative Systems Pharmacology

Simcyp™ Secondary Intelligence

Synchrogenix™ Writer

PINNACLE 21

Pinnacle 21™ Enterprise

D360™ Platform

BaseCase™ Platform

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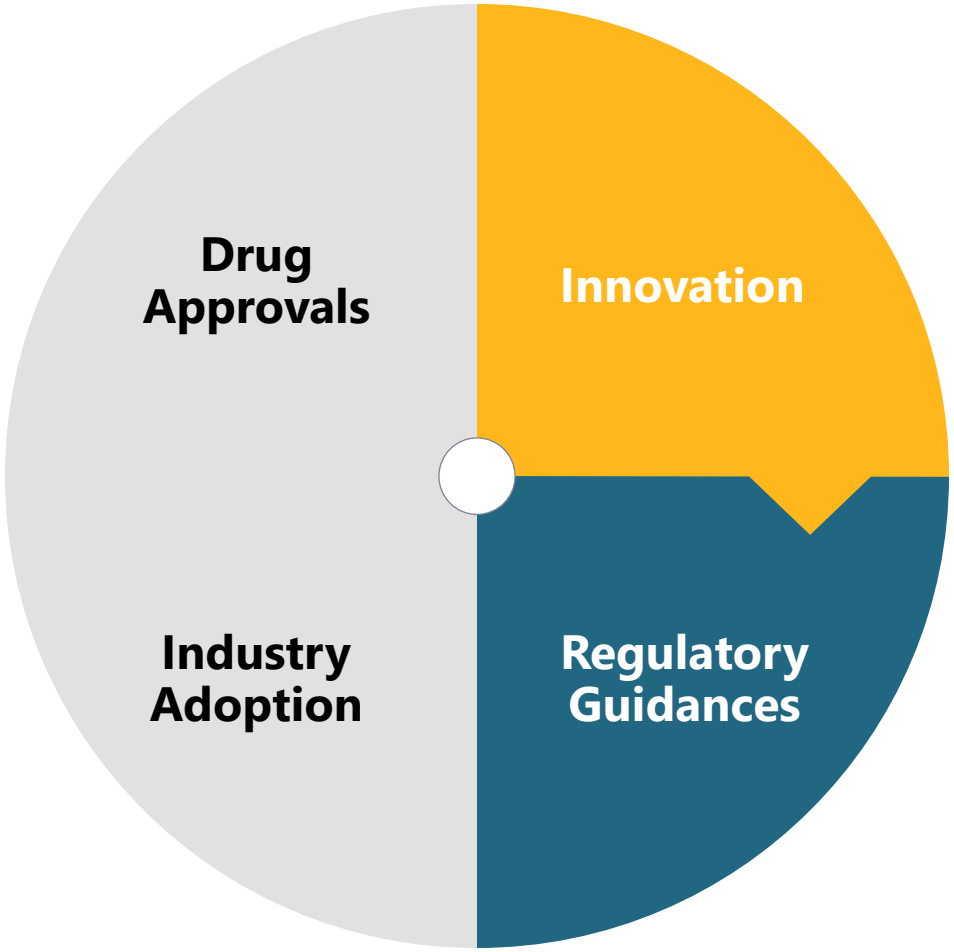
Powerful flywheel effect fuels momentum and adoption

Regulatory / Industry Flywheel Effect



New technology and biosimulation models **expand use cases**

Global regulatory guidances and workshops educate industry and advance use of biosimulation

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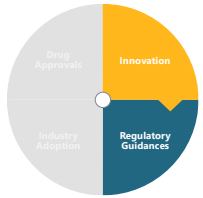
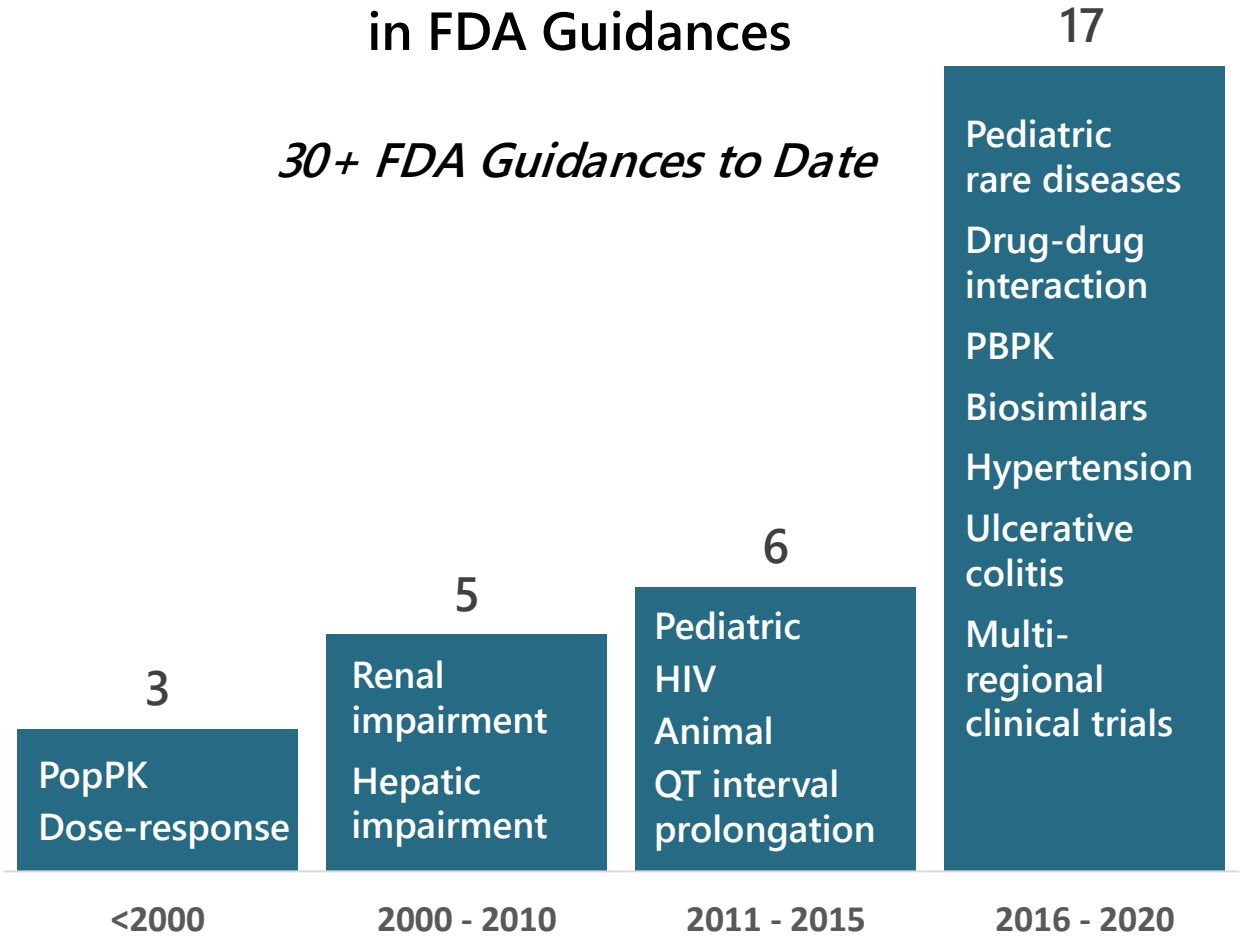
Increasing regulatory adoption



Incorporation of Biosimulation in FDA Guidances

30+ FDA Guidances to Date



2021 FDA Focus Areas of Regulatory Science

Model-informed product development aims to integrate information from diverse data sources to **help decrease uncertainty and lower failure rates, and to develop information that cannot or would not be generated experimentally.**

MIDD applications in the report include:

- Predicting clinical outcomes
- Informing trial designs
- Supporting evidence for efficacy
- Optimizing drug dosing
- Predicting product safety

https://www.fda.gov/science-research/advancing-regulatory-science/focus-areas-regulatory-science

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Powerful flywheel effect fuels momentum and adoption

Regulatory / Industry Flywheel Effect

New technology and biosimulation models **expand use cases**

Biopharmaceutical companies **use biosimulation and technology-driven services** to accelerate R&D programs

Global regulatory guidances and workshops educate industry and advance use of biosimulation

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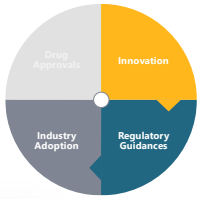
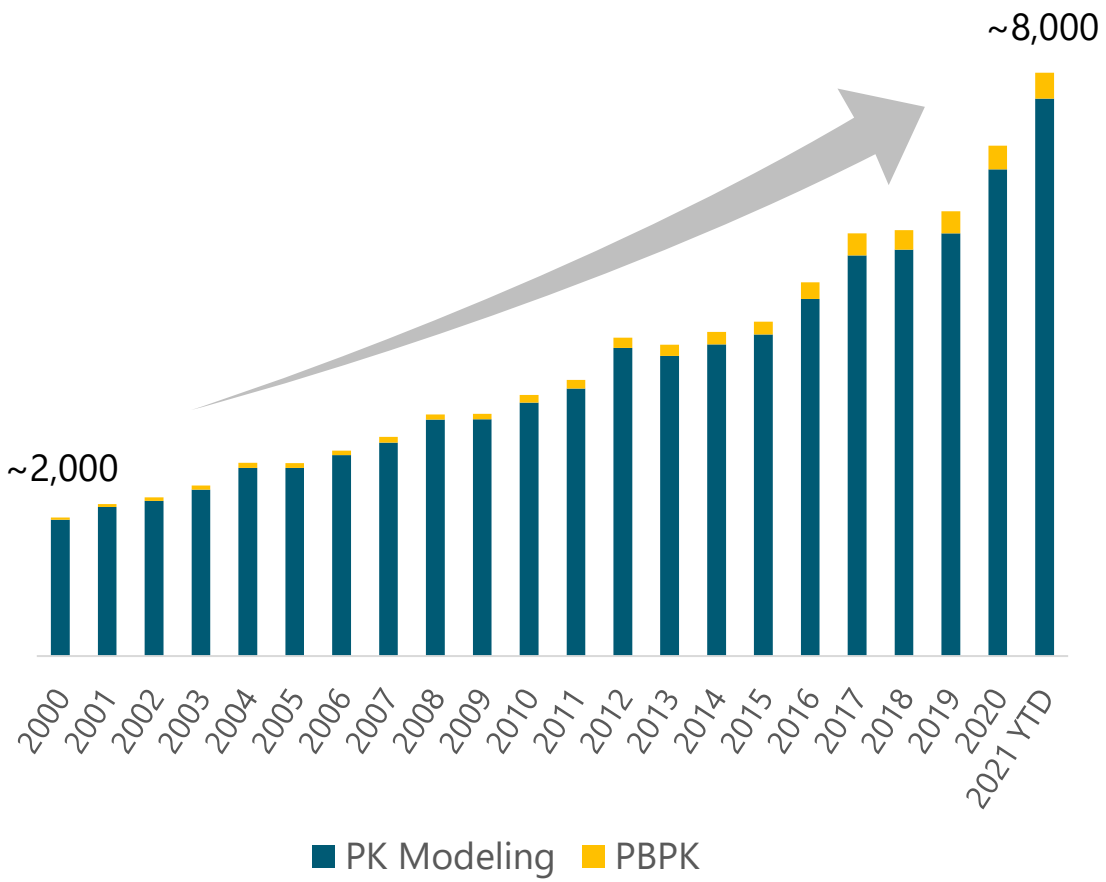
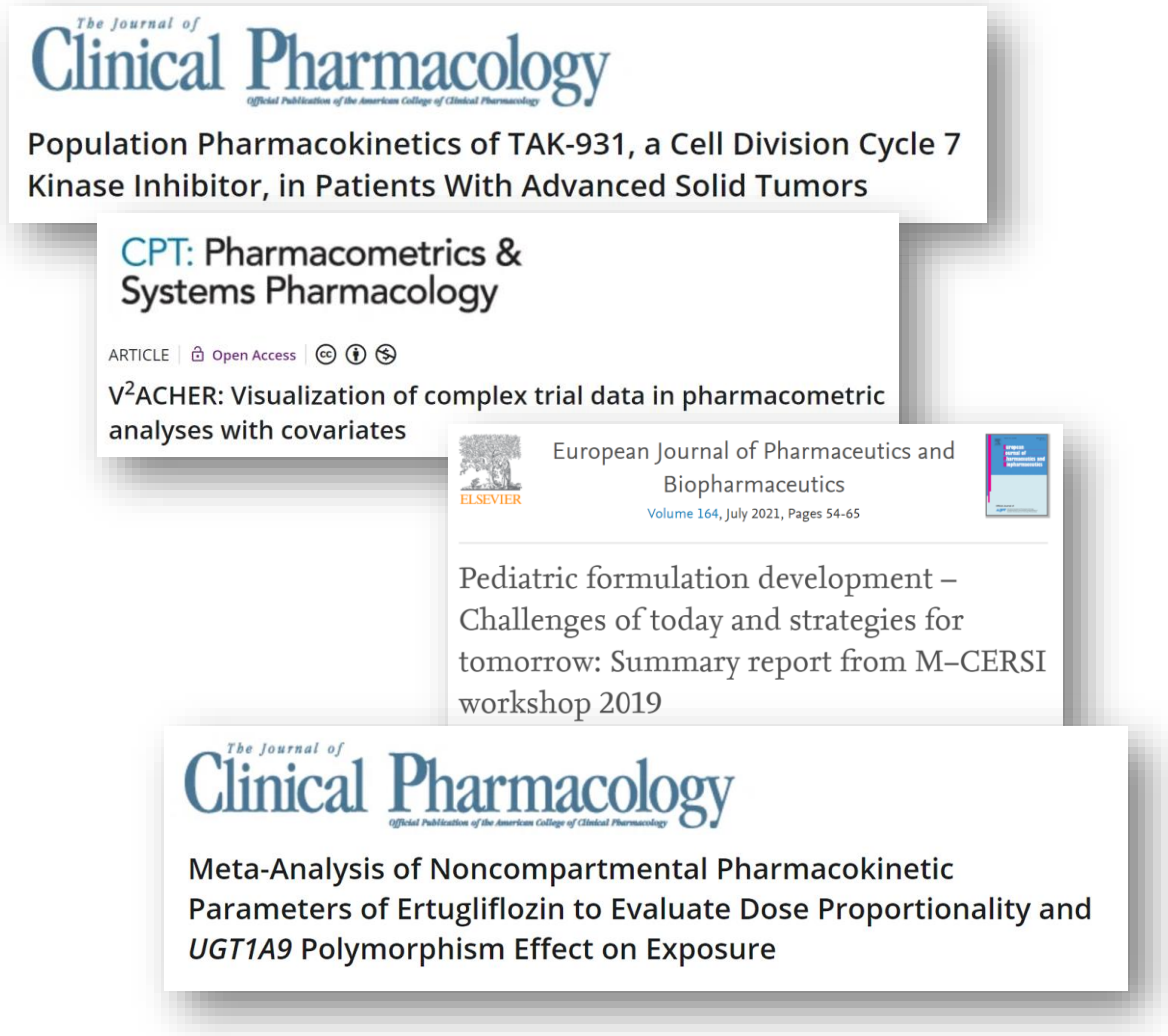
Growing number of publications by industry and academia







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Powerful flywheel effect fuels momentum and adoption

Regulatory / Industry Flywheel Effect

New drug approvals incorporating **biosimulation serve as proof points** and unlock more opportunities

New technology and biosimulation models **expand use cases**

Biopharmaceutical companies **use biosimulation and technology-driven services** to accelerate R&D programs

Global regulatory guidances and workshops educate industry and advance use of biosimulation

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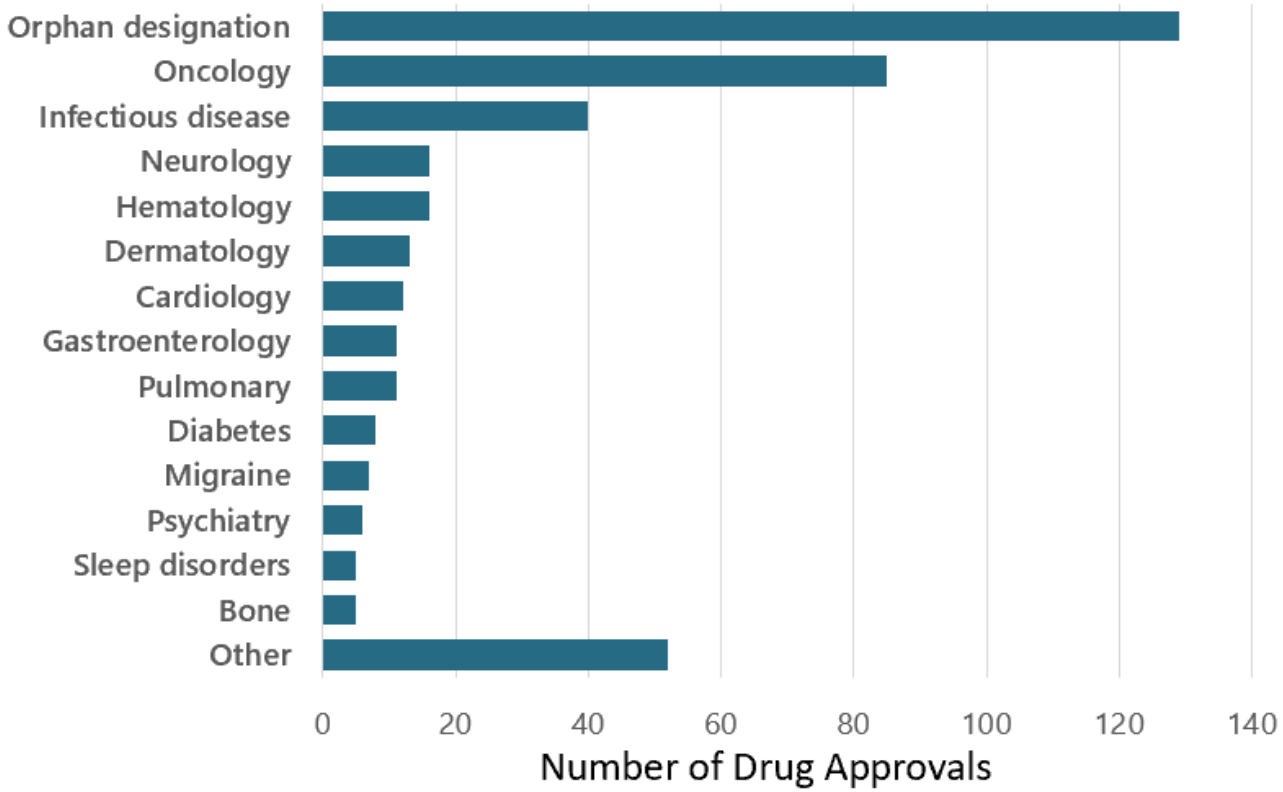
Drug approvals using biosimulation

Our customers, who use our software and technology-driven services, have received 90% of FDA drug approvals for 7 consecutive years.*

FDA Novel Drug Approvals Received by Our Clients 2014 - 2020



2021 Novel Drug Approvals Using Certara Solutions

illustrative examples

*Excludes diagnostics
Orphan designation applies across therapeutic areas

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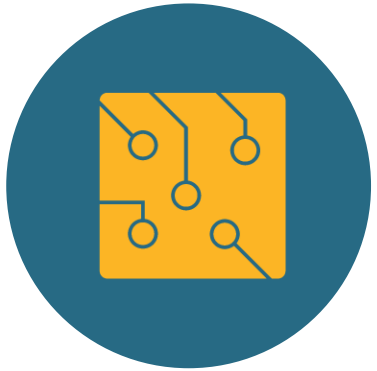
Disciplined, strategic approach to M&A

Proven track record of successfully acquiring and integrating businesses

Our strategy is highly disciplined and growth- and capability-focused.
We continually seek and assess a range of opportunities in:



Software and technology to build out the depth and breadth of our end-to-end platform

Services to strengthen and scale our technology-driven services and accelerate global expansion

We are uniquely well-positioned to be the acquirer of choice in the markets in which we compete.

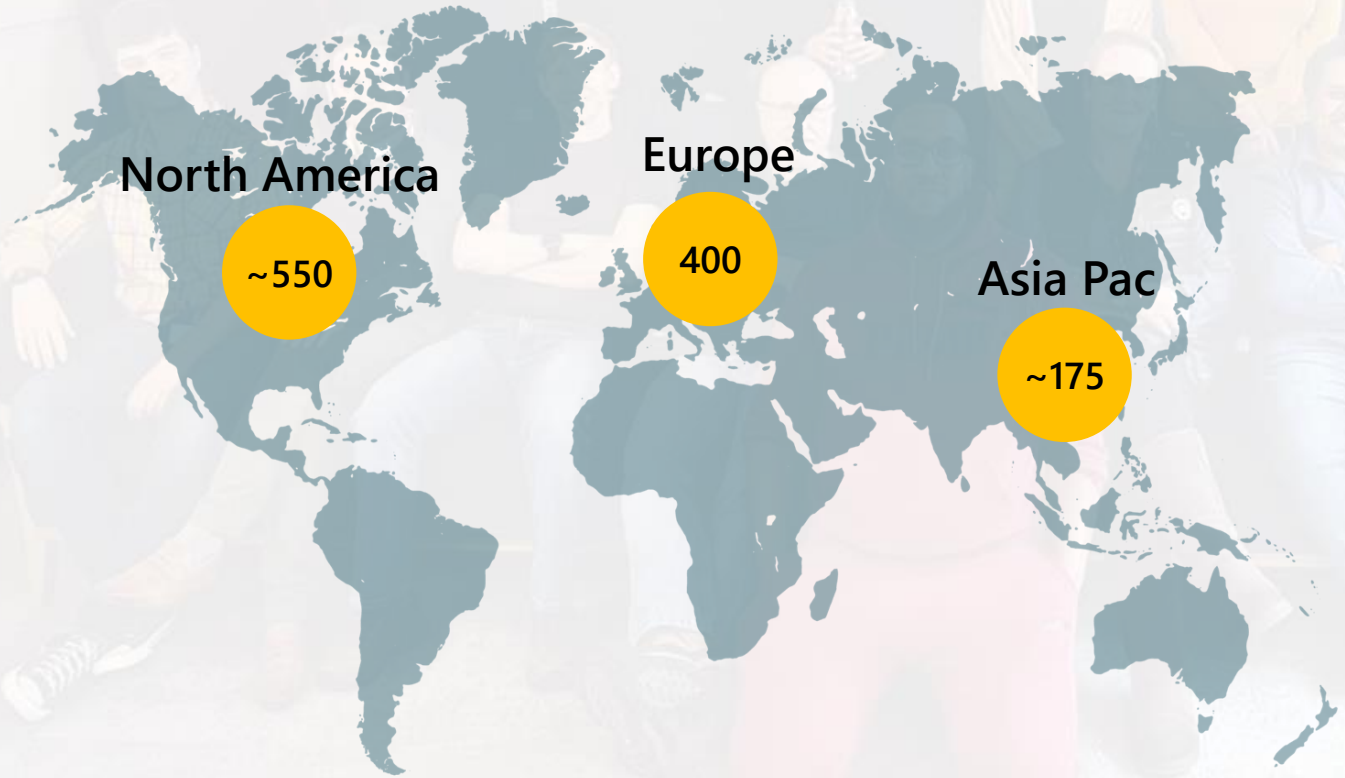
CERTARA

Diverse global team of leading experts

Diverse global team of leading experts

1,100+ employees

24% growth in people YTD



- 350+ with Ph.D.'s, Pharm.D.'s and M.D.'s
- 150+ scientific publications and presentations in 2021
- 7 of our scientists recognized as top 2% most cited

CERTARA

Proven growth strategy

Innovation

Technology leader with **90%+ renewal rate**

Land and Expand

Significant white space to **expand** with customers and **add new** ones

M&A

15 successful strategic acquisitions, **10 with software**

Global Expansion

Track record of **mid-teens** topline growth with EBITDA margins in **mid- to high-30s**

People

An employer of choice, attracting **leading experts**

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Our speakers today

Andrew Schemick
Chief Financial Officer

Robert Aspbury
President of Simcyp

Leif Pedersen
President of Software

Justin Edge
President of Regulatory and Access

Patrick Smith
President of Integrated Drug Development

Hannah Jones
VP, Simcyp Consultancy

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Software:
Innovating to Transform Traditional R&D

Leif Pedersen
President of Software

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Certara Software

Year to date as of September 30, 2021

YoY change	10%	19%	PY 91%

2021 Highlights

2 new software launches and **8** product updates

Pinnacle 21 acquisition

2021 R&D 100 Award for **COVID-19 Vaccine Model**

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Industry-leading software with more than 60,000 users

Biosimulation

Phoenix

Industry-leading software for PK/PD, toxico-kinetic, and non-compartmental analyses – required for regulatory submissions

36,000+ Google Scholar citations

Simcyp

Leading mechanistic biosimulation platform used to predict how drugs work, without human or animal studies

Supported >250 label claims for 85+ drugs

D360

Integrated discovery informatics software with self-service access and analytics

Used by 6,500+ discovery research scientists

CODEx

55 proprietary databases and analytics to compare drug's safety and efficacy relative to competitors'

Covers 10,000+ studies

Regulatory & Market Access

GlobalSubmit

BaseCase

PINNACLE 21 Enterprise

Synchrogenix Writer

Cloud-based applications to achieve regulatory compliance, prepare regulatory submissions and expand market access

40,000+ users

Certara Integral Repository

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Simcyp Platform Overview

Robert Aspbury, Ph.D.

President of Simcyp

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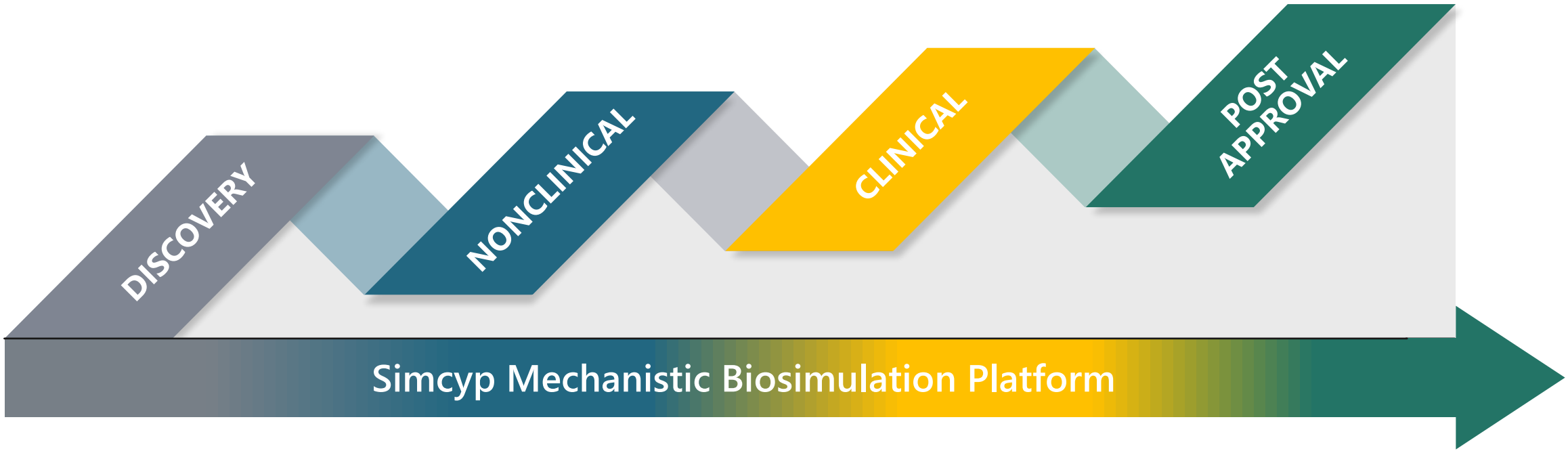
Simcyp platform spans discovery to post-approval support



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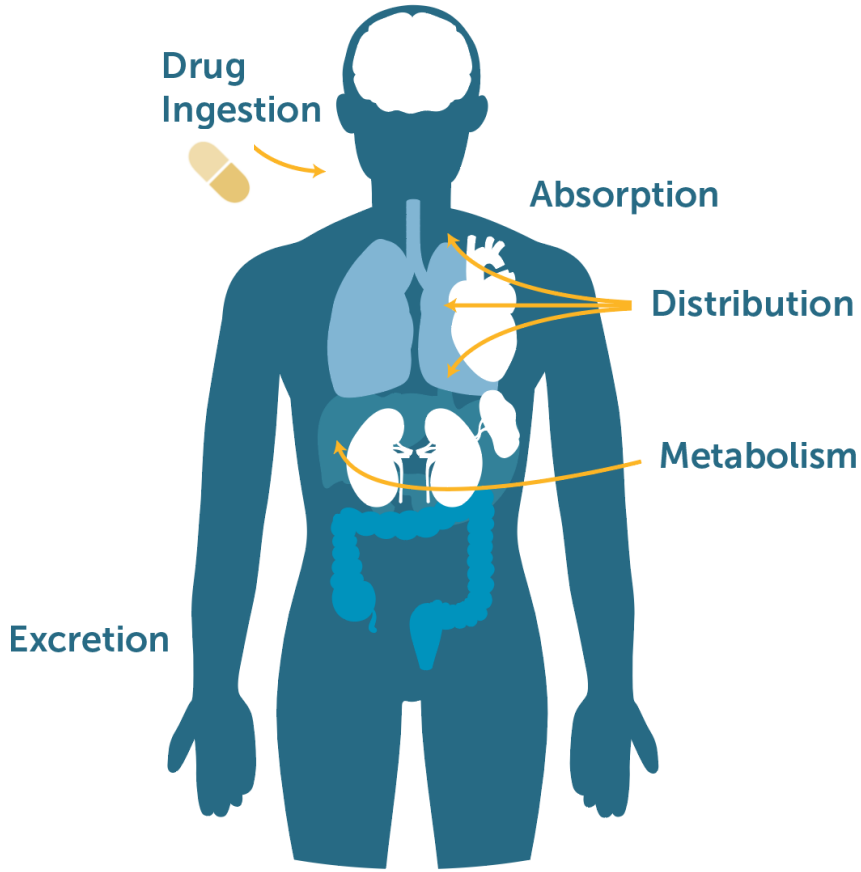
Mechanistic biosimulation is used to quantitatively predict, *without human or animal studies…*

What the body does to the drug

Physiologically-based pharmacokinetics (PBPK)
Simcyp Simulator



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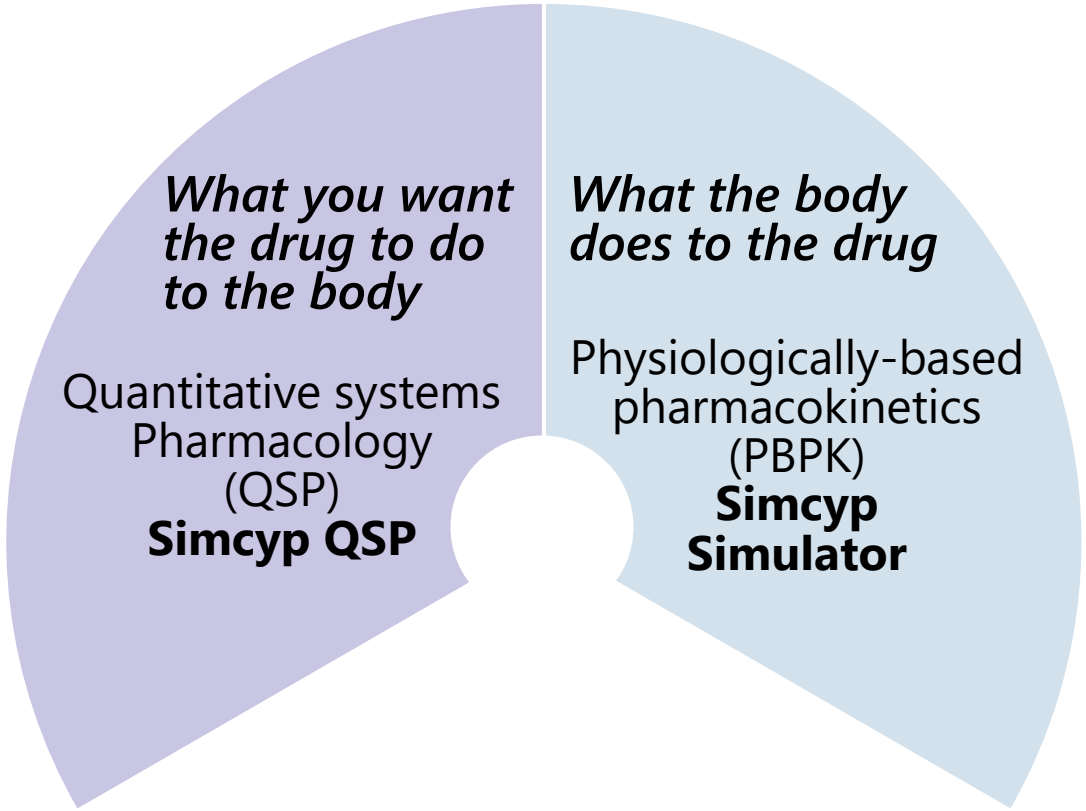
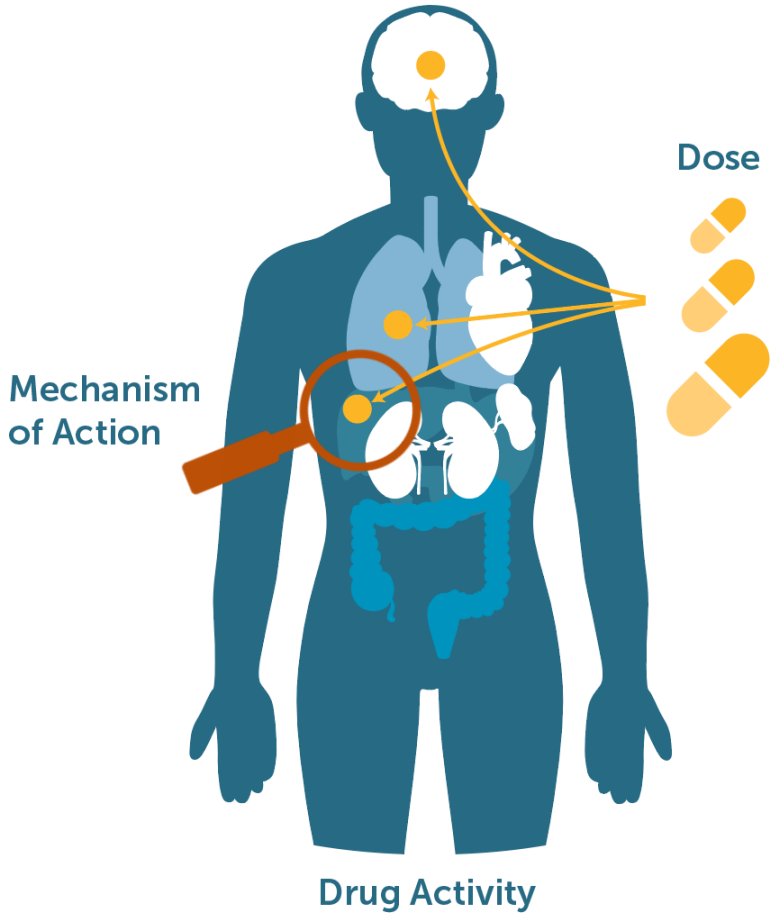
Mechanistic biosimulation is used to quantitatively predict, *without human or animal studies…*





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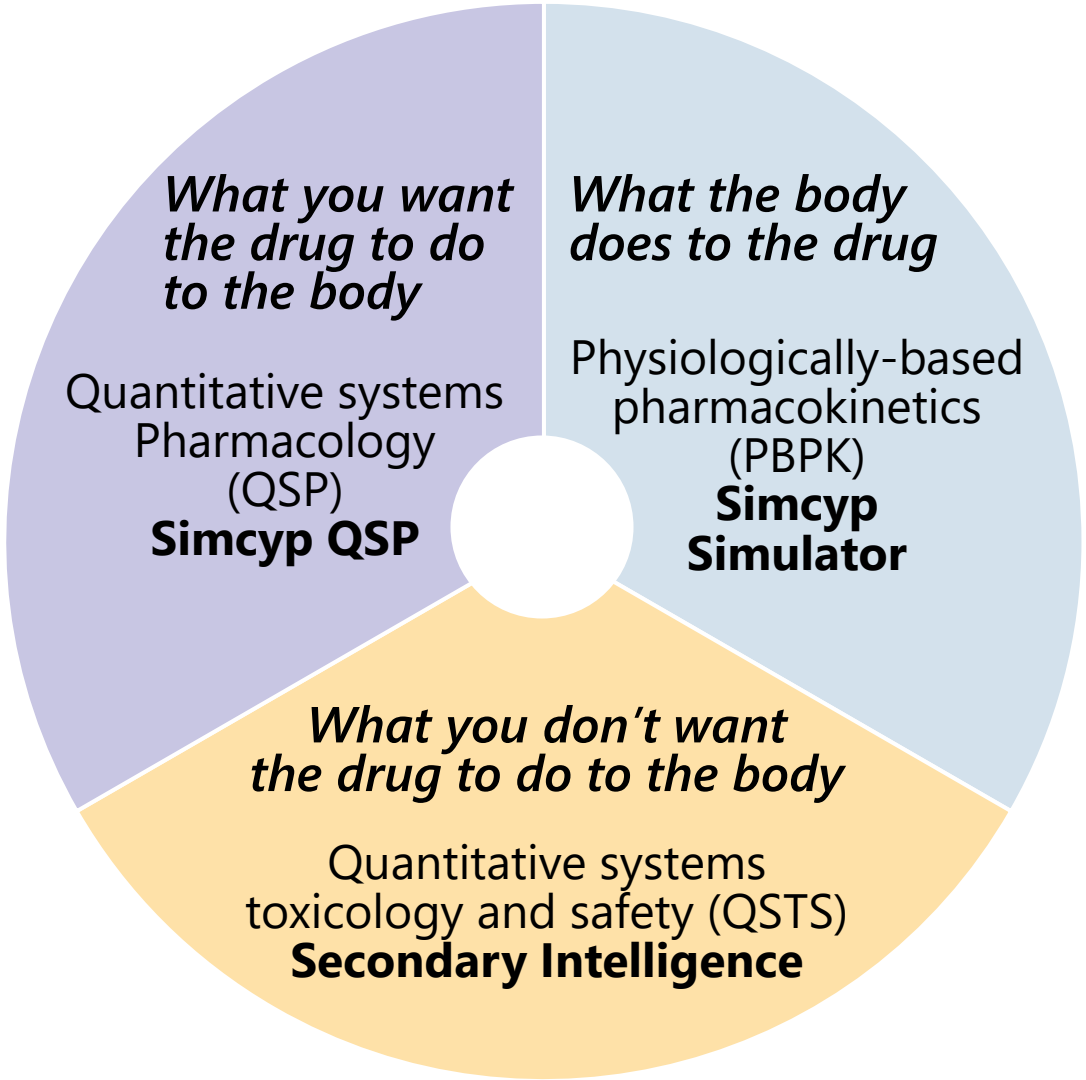
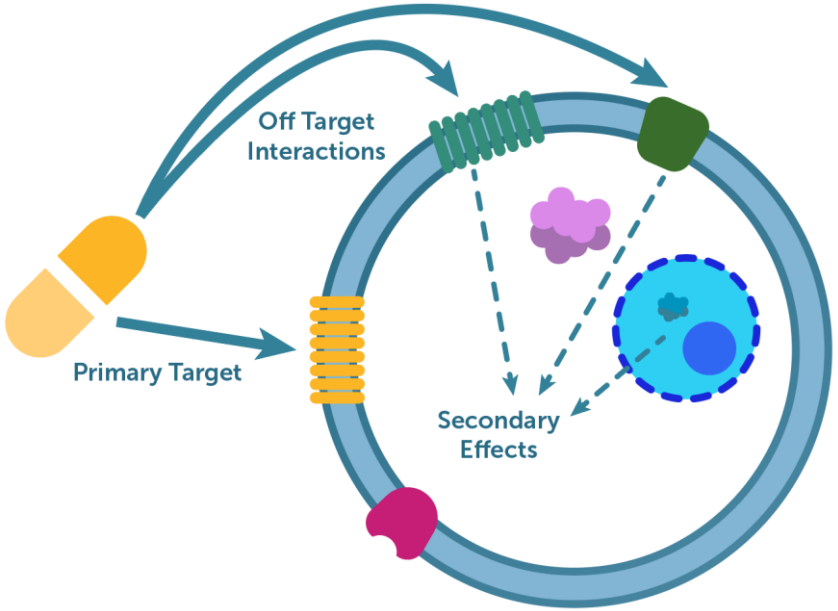
Mechanistic biosimulation is used to quantitatively predict, *without human or animal studies…*





Adapted from Jenkinson et al., 2020

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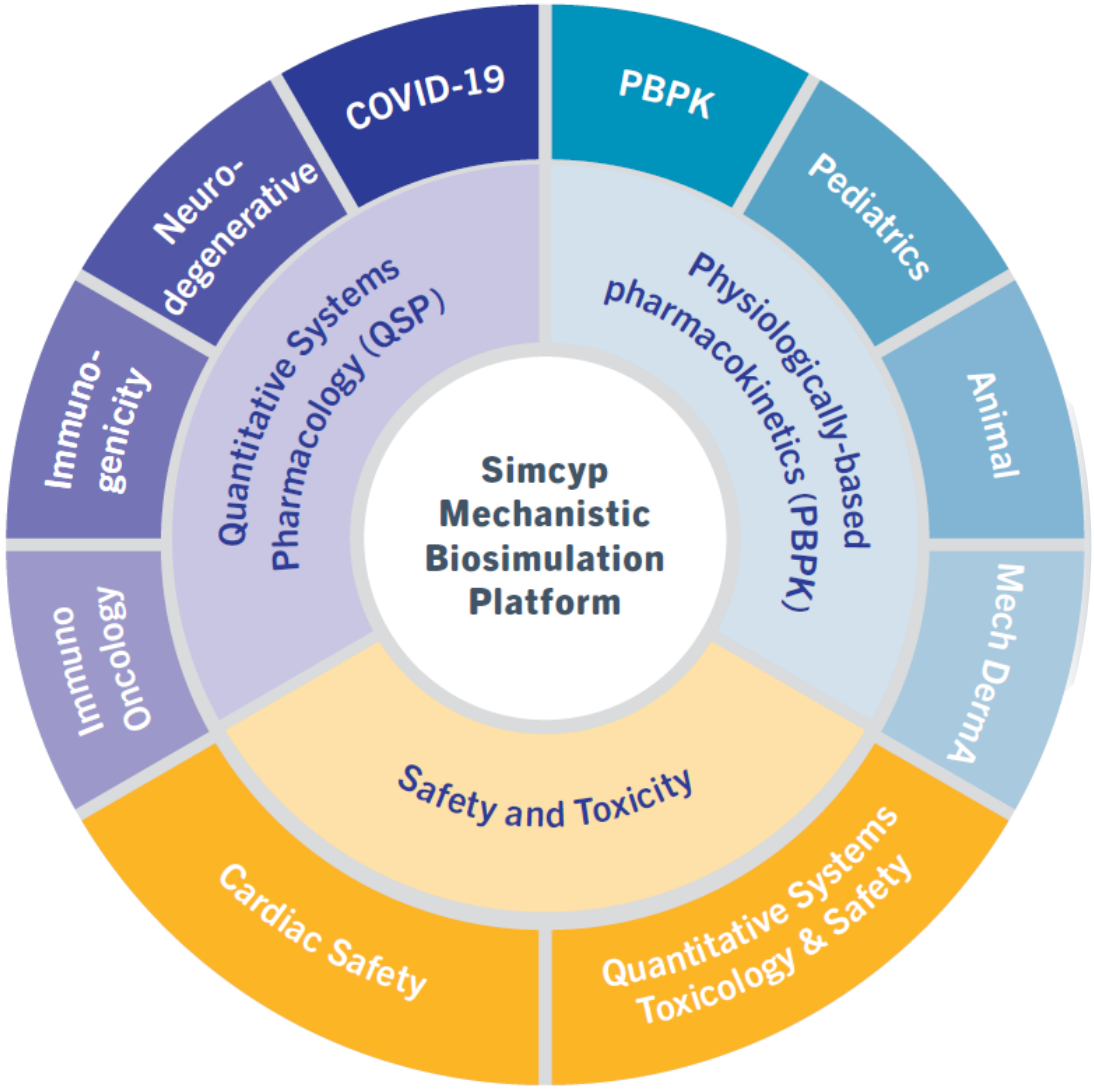
Simcyp Platform, leading mechanistic biosimulation software



- Built upon first principles of biology, chemistry and pharmacology
- Supported FDA approval of **85+ novel drugs** with **more than 250 label claims**
- **18 of the top 20** biopharma companies by R&D spend used the Simcyp Platform in 2021
- Used by **11 global regulatory agencies**
- Recipient of FDA cooperative R&D agreement, **6** FDA grants and **7** European grants
- Drives both software and tech-driven consulting

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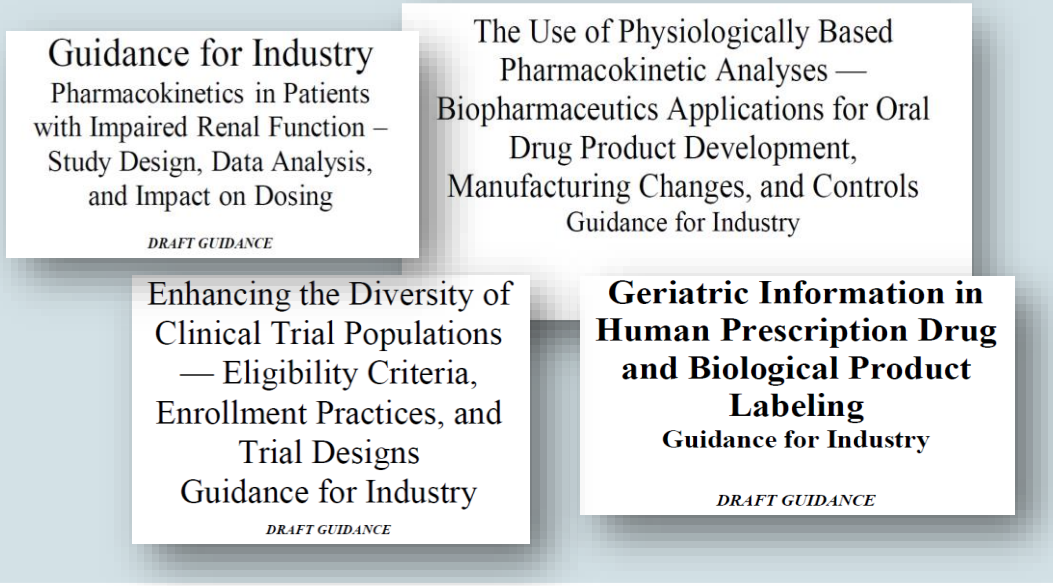
Growing regulatory adoption and support

Recent FDA Guidances



European Medicines Agency Guidances

- Investigation of drug interactions
- Use of pharmacogenetic methodologies in the pharmacokinetic evaluation of medicinal products
- Evaluation of the pharmacokinetics of medicinal products in patients with impaired renal function
- Evaluation of the pharmacokinetics of medicinal products in patients with impaired hepatic function
- Role of pharmacokinetics in the development of medicinal products in the paediatric population
- Reporting the results of population pharmacokinetic analysis
- Reporting of physiologically based pharmacokinetic modeling and simulation

Japan Pharmaceuticals and Medical Devices Agency

- Population pharmacokinetic and pharmacodynamic analysis
- Exposure-response analysis of drugs
- Analysis reports involving physiologically based pharmacokinetic models
- Drug interaction for drug development and appropriate provision of information

China National Medical Products Agency

- PK/PD research of antimicrobials
- Extrapolation of adult medication data to pediatric populations
- Biostatical analysis in clinical trials
- Drug interaction
- Rare disease drug development

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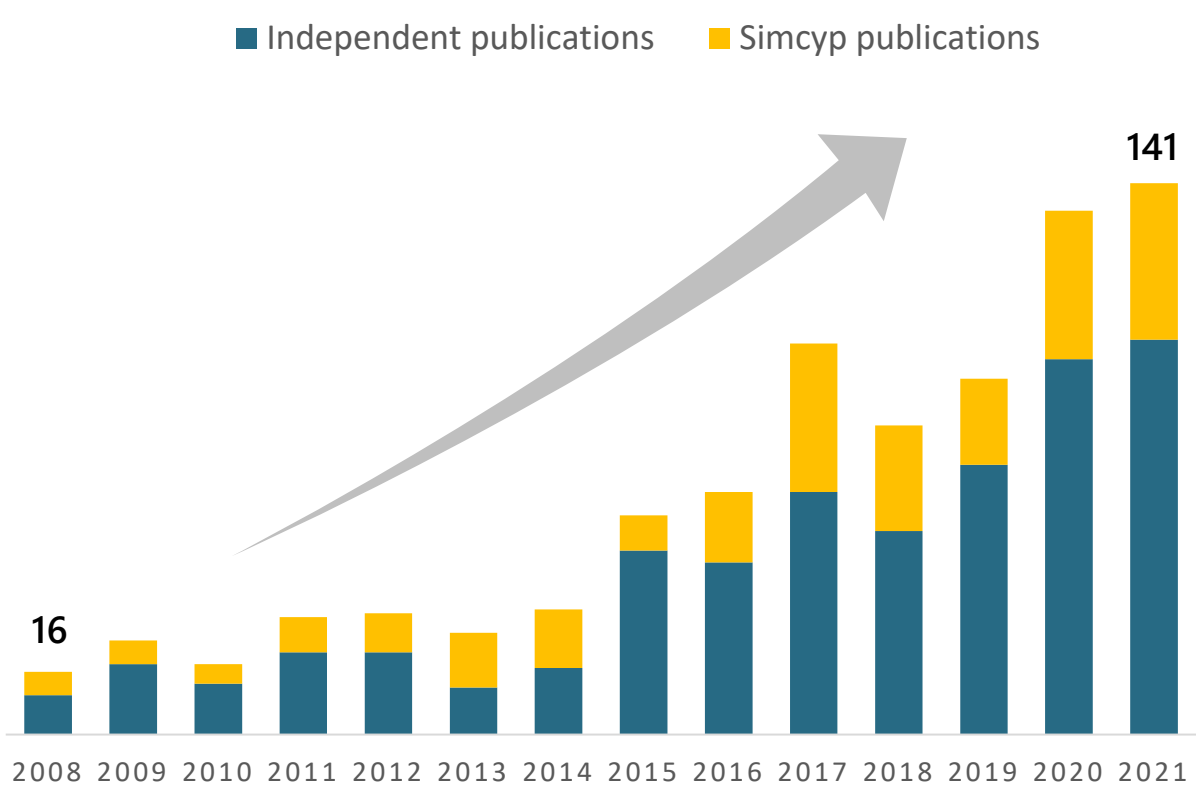
Industry and academic adoption

Simcyp Consortium

astellas, AstraZeneca, Biogen, VERTEX, ucb, Pfizer, gsk, NEKTAR, SANOFI, ono, SHIONOGI INC., GRÜNENTHAL, Lundbeck, MERCK, Sumitomo Dainippon Pharma, TAISHO PHARMACEUTICAL, Eisai, LEO, Incyte, idorsia, Mitsubishi Tanabe Pharma America, Otsuka

illustrative examples of consortium members

Number of Simcyp Scientific Publications



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Simulating virtual patients and waiving clinical studies

More than 250 label claims for 85+ novel drugs using the Simcyp Simulator

ONCOLOGY	Agios	Tibsovo *(ivosidenib)*	Genentech	Alecensa *(alectinib)*	Novartis	Odomzo *(sonidegib)*
	Amgen	Blincyto *(blinatumomab)*	Genentech	Cotellic *(cobimetinib)*	Novartis	Piqray *(alpelisib)*
	Ariad	Alunbrig *(brigatinib)*	Genentech	Polivy *(polatuzumab vedotin-piiq)*	Novartis	Rydapt *(midostaurin)*
	Ariad (Takeda)	Iclusig *(ponatinib)*	Genentech	Rozlytrek *(entrectinib)*	Novartis	Tabrecta *(capmatinib)*
	AstraZeneca	Calquence *(acalabrutinib)*	Incyte	Pemazyre *(pemigatinib)*	Novartis	Zykadia *(ceritinib)*
	AstraZeneca	Lynparza *(olaparib)*	Janssen	Balversa *(erdafitinib)*	Pfizer	Bosulif *(bosutinib)*
	AstraZeneca	Tagrisso *(osimertinib)*	Janssen	Erleada *(apalutamide)*	Pfizer	Lorbrena *(lorlatinib)*
	Beigene	Brukinsa *(zanubrutinib)*	Lilly	Retevmo *(selpercatinib)*	Pharmacyclics	Imbruvica *(ibrutinib)*
	BluePrint Medicines	Ayvakit *(avapritinib)*	Lilly	Verzenio *(abemaciclib)*	Sanofi	Jevtana *(cabazitaxel)*
	Celgene	Inrebic *(fedratinib hydrochloride)*	Loxo Oncology	Vitrakvi *(larotrectinib)*	Seattle Genetics	Tukysa *(tucatinib)*
	Daiichi Sankyo	Turalio *(pexidartinib)*	Novartis	Farydak *(panobinostat)*	Spectrum	Beleodaq *(tucatinib)*
	Eisai	Lenvima *(lenvatinib)*	Novartis	Kisqali *(ribociclib succinate)*	Takeda	Exkivity *(mobocertinib)*
	EMD Serono	Tepmetko *(tepotinib hydrochloride)*	Novartis	Scemblix *(asciminib)*	Verastem	Copiktra *(duvelisib)*
RARE DISEASE	AkaRx (Eisai)	Doptelet *(avatrombopag maleate)*	Global Blood Therapeutics	Oxbryta *(voxelotor)*	Novartis	Isturisa *(osilodrostat)*
	AstraZeneca	Koselugo *(selumetinib)*	Intercept	Ocaliva *(obeticholic acid)*	PTC Therapeutics	Emflaza *(deflazacort)*
	Auriana	Lupkynis *(voclosporin)*	Kadman	Rezurock *(belumosudil)*	Sanofi Genzyme	Cerdelga *(eliglustat tartrate)*
	Genentech	Enspryng *(satralizumab)*	Merck	Welireg *(belzutifan)*	Vertex	Symdeko *(tezacaftor/ivacaftor)*
	Genentech	Evrysdi *(risdiplam)*	Mirum	Livmarli *(maralixiba)*	Vertex	Trikafta *(elexacaftor/ivacaftor/tezacaftor)*
CENTRAL NERVOUS SYSTEM	AbbVie	Rinvoq *(upadacitinib)*	Eisai	Dayvigo *(lemborexant)*	Lilly	Reyvow *(lasmiditan succinate)*
	AbbVie	Qulipta *(atogepant)*	GW Research	Epidiolex *(cannabidiol)*	Novartis	Mayzent *(siponimod fumaric acid)*
	Alkermes	Aristada *(aripiprazole lauroxil)*	Janssen	Ponvory *(ponesimod)*	UCB	Briviact *(brivaracetam)*
	Alkermes	Lybalvi *(olanzapine; samidorphan)*	Kyowa Kirin	Nourianz *(istradefylline)*		
INFECTIOUS DISEASE	Gilead	Veklury *(remdesivir)*	Merck	Prevymis *(letermovir)*	Tibotec	Edurant *(rilpivirine)*
	GSK	Dectova *(zanamivir)*	Nabriva	Xenleta *(lefamulin acetate)*	VIIV	Cabenuva Kit *(cabotegravir, rilpivirine)*
	Janssen	Olysio *(simeprevir)*	Novartis	Egaten *(triclabendazole)*	VIIV	Vocabria *(cabotegravir sodium)*
	Merck	Pifeltro *(doravirine)*				
GASTROENTEROLOGY	AstraZeneca	Movantik *(naloxegol)*	Shionogi	Symproic *(naldemedine)*	Shire	Motegrity *(prucalopride)*
	Helsinn	Akynzeo *(fosnetupitant/palonosetron)*				
CARDIOVASCULAR	Actelion (J & J)	Opsumit *(macitentan)*	Johnson & Johnson	Xarelto *(rivaroxaban)*	Pfizer	Revatio *(sildenafil)*
OTHER	AbbVie	Orilissa *(elagolix)*	Janssen	Invokana *(canagliflozin)*	Merck	Steglatro *(ertugliflozin)*
	Galderma	Aklief *(trifarotene)*	Lilly	Olumiant *(baricitinib)*		

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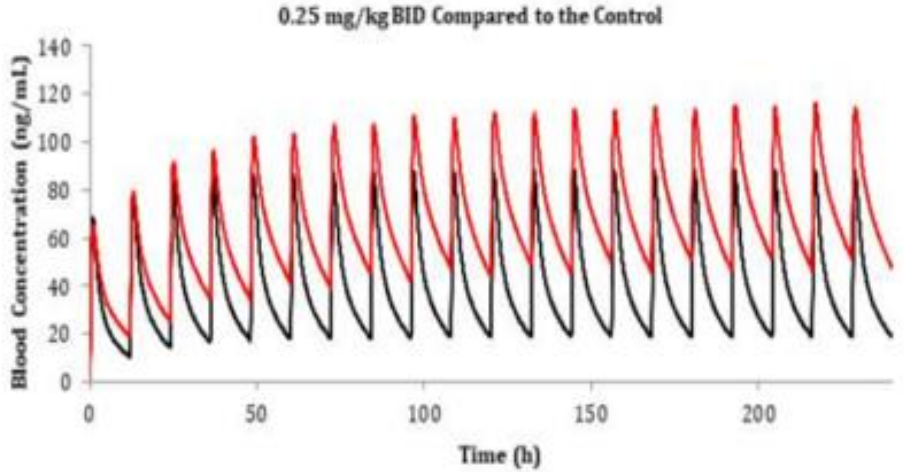
2021 novel drug approval using Simcyp Simulator

Multi-discipline Review for voclosporin
Center for Drug Evaluation and Research

All simulations were performed using the PK/PD Profiles mode in the Simcyp® Simulator (Version 17 Certara, Sheffield, UK). A scheme of the PBPK simulation strategy is shown in Figure 21, which summarizes the studies used for model development and verification, and model applications in DDI predictions.

Simcyp library files of ketoconazole, diltiazem, verapamil and nor-verapamil, fluconazole, fluvoxamine, cimetidine, rifampin MD, efavirenz, rosuvastatin and pravastatin were used for DDI simulations without any modification except that a P-gp Ki of 0.059 M was incorporated into the sim-ketoconazole 400 mg QD file and ketoconazole CL/F was reduced to 3.7 L/h (see comments in the Results section).

Simulated concentration-time profiles of voclosporin following difference dosing scenarios in the absence or presence of moderate CYP3A4 inhibitor fluconazole



Label for drug-drug interaction informed by Simcyp

----------DRUG INTERACTIONS----------

- Moderate CYP3A4 inhibitors: Reduce LUPKYNIS daily dosage to 15.8 mg in the morning and 7.9 mg in the evening. (2.5, 7.1, 12.3)
- Strong and moderate CYP3A4 inducers: Avoid co-administration. (7.1, 12.3)
- Certain P-gp substrates: Reduce dosage of certain P-gp substrates with a narrow therapeutic window when co-administered with LUPKYNIS. (7.2, 12.3)

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/213716Orig1s000MultidisciplineR.pdf

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3 areas of significant impact with Simcyp Simulator

Clinical Trial Waivers

Extrapolation to Special Populations

Reduction in Study Patients

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Regulatory priority to increase access to generics

Simcyp Simulator can advance development of complex generics

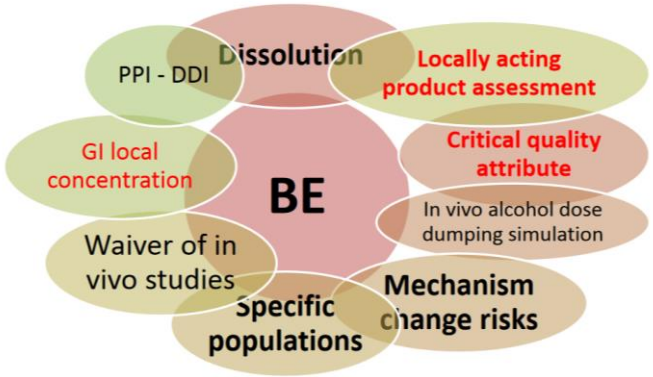
Increasing Access to Generic Alternatives for Complex Drugs

Importance to FDA

FDA supports the development of generic versions of complex drug products because they represent nearly one-third of drug products currently used but have less generic competition than non-complex drugs. The presence of generic drugs on the market helps to ensure availability of quality medicines at a lower cost to the American public.

2021 Advancing Regulatory Science at FDA

General PBPK Model Applications for Generic Products



Increasing trends in using PBPK models to support regulatory decision making in the realm of generic drug development

Zhao, Generic Drug Research Public Workshop May 2017, MD, USA

Milestone FDA Approval of Diclofenac Gel

First complex generic approved using the Simcyp Simulator to establish *virtual bioequivalence in lieu of a clinical trial, saving significant time and money.*

Research Highlight

Physiologically-based pharmacokinetic modeling supported approval of a locally acting drug based on an efficient alternative bioequivalence approach.

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Emerging technologies in biosimulation

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Platform approach to quantitative systems pharmacology

QSP combines computational modeling and experimental data to examine the relationships between a drug, the biological system and the disease process.

Immunogenicity	Immuno-oncology	Vaccines	Neurodegenerative diseases	Gene therapies
				
Increasing complexity				
• Monoclonal antibodies • Bi-specifics • Complement system • Neuro-immunity	• Combination therapies • IL-2 • TIGIT • CAR T-cell therapies	• COVID vaccines • Respiratory syncytial vaccine • Oncology vaccine	• Alzheimer's • Parkinson's • Multiple sclerosis • Schizophrenia	• AAV vector delivery • Hemophilia • Fabry disease • Gaucher disease

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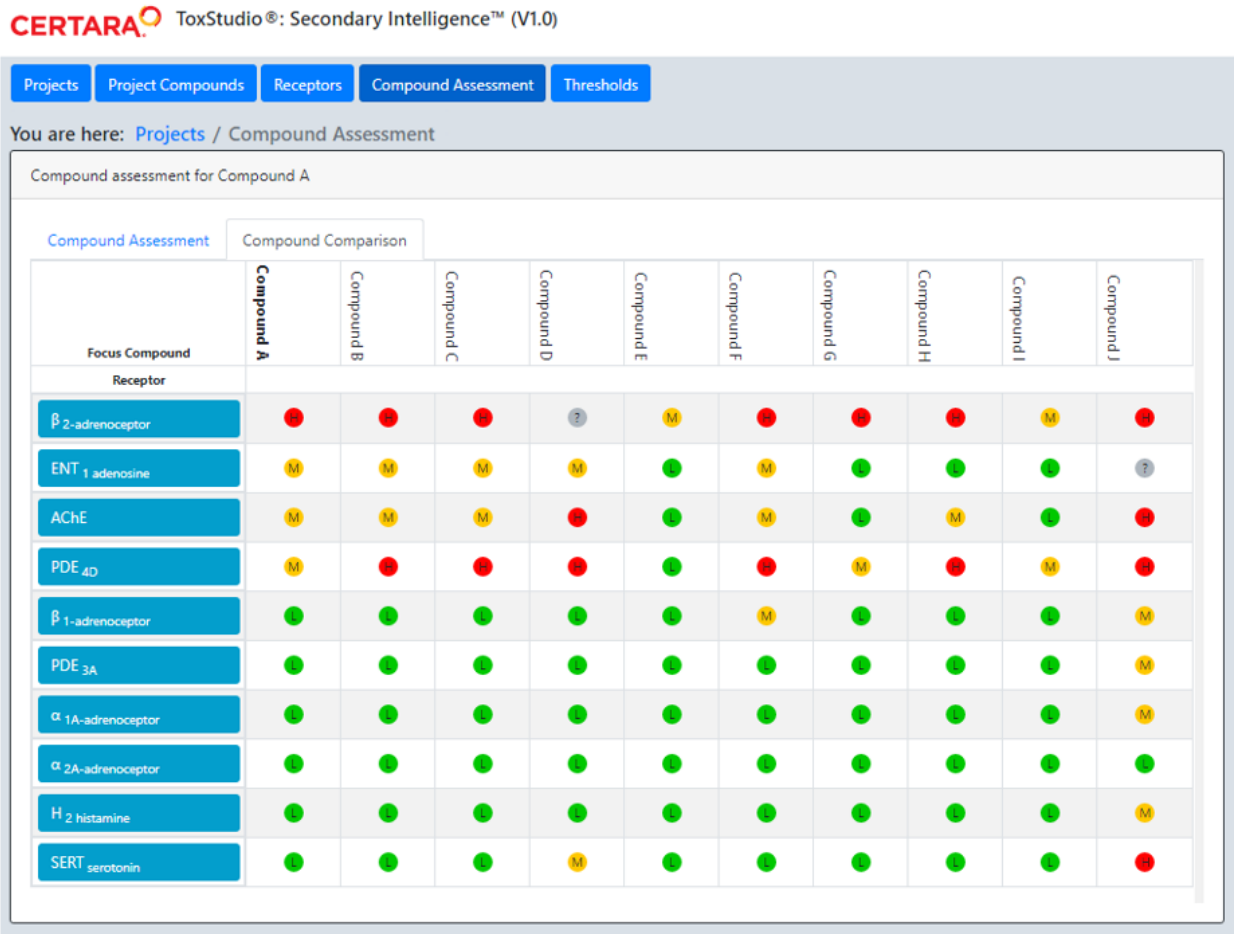
Addressing safety issues consistently and earlier

Secondary Intelligence v1



- Toxicology and safety pharmacology impact organ-specific drug exposure
- Biosimulation tools can simulate and predict safety issues
- More efficient and consistent than traditional method
- Reduction in animal use
- Relevant for adjacent industries

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Simcyp Simulator Demo

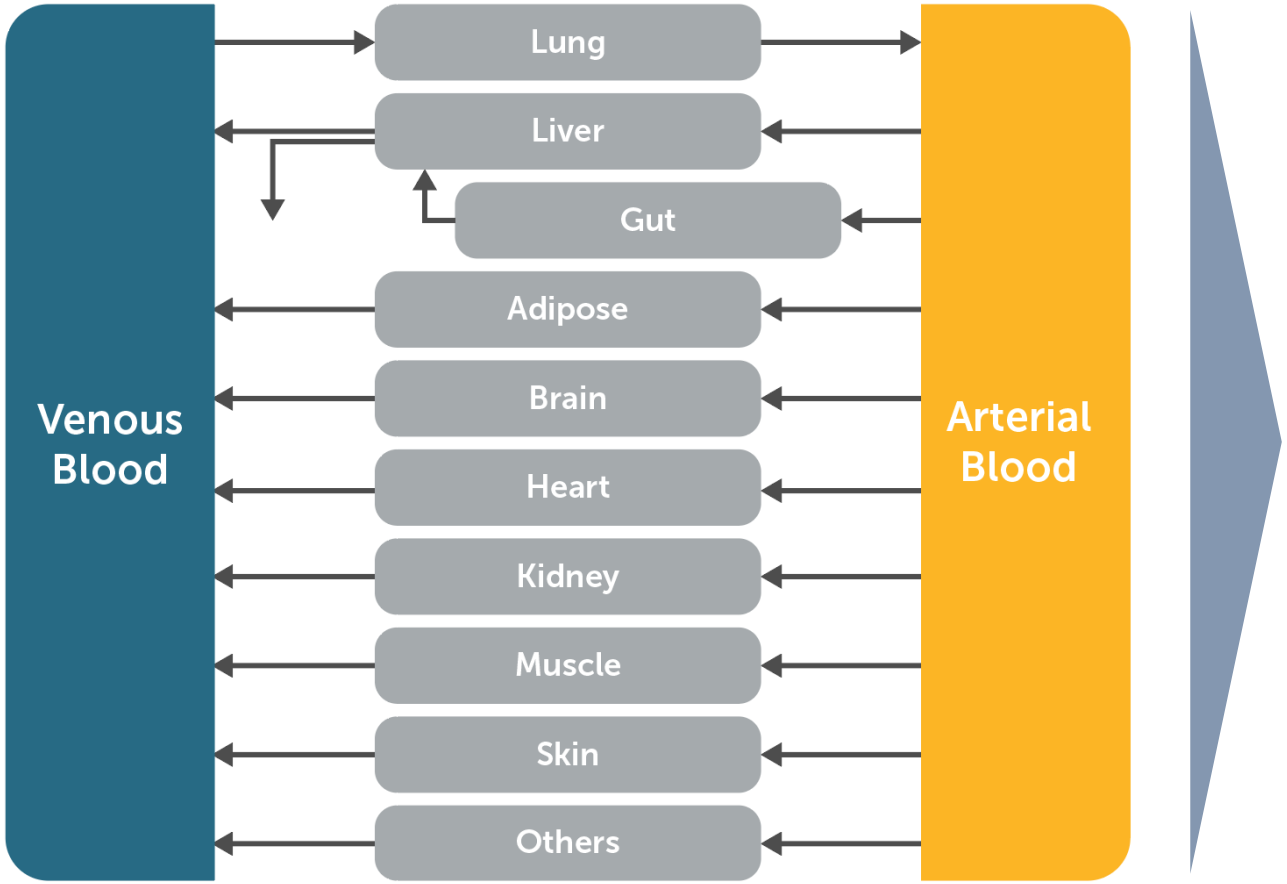
Hannah Jones, Ph.D.

Vice President of Simcyp Consultancy

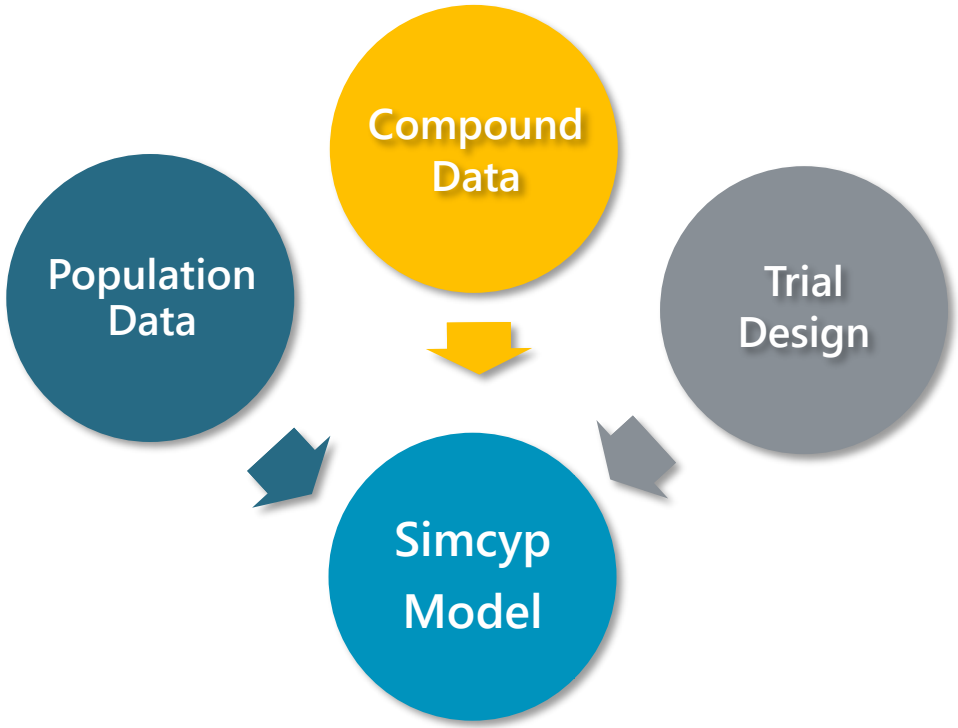
CERTARA

Simcyp Simulator framework with virtual patients

10 Advanced Mechanistic Organ Models



Simcyp Simulator Model Structure



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Numerous applications across R&D lifecycle

Discovery/Nonclinical

- Animal to human extrapolation
- Early formulation assessment
- Early drug interaction risk assessment
- First-in-human dose prediction

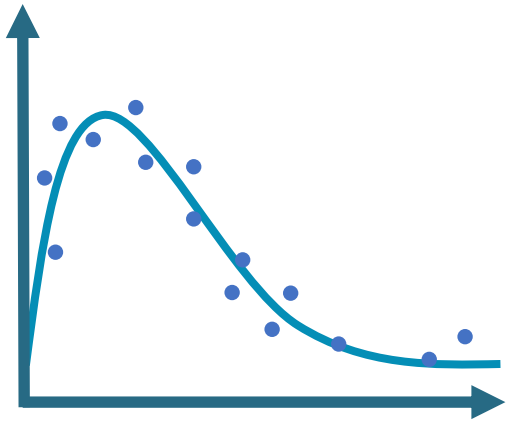
Early Development

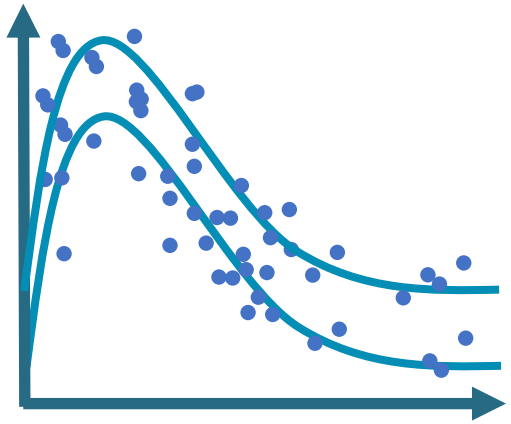
- First-in-human single/multiple dose exposure
- Drug-drug interactions
- Absorption, food effect and formulation modelling

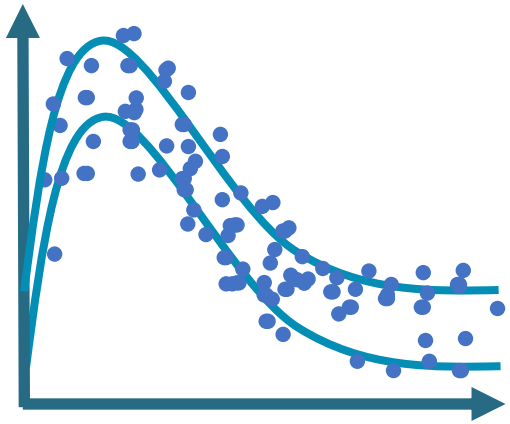
Late Development

- Drug-drug interactions
- Pediatric and special populations
- Organ impairment modelling
- Label claims in lieu of clinical study

"Learn and confirm" with continuous Model Refinement, Verification and Validation







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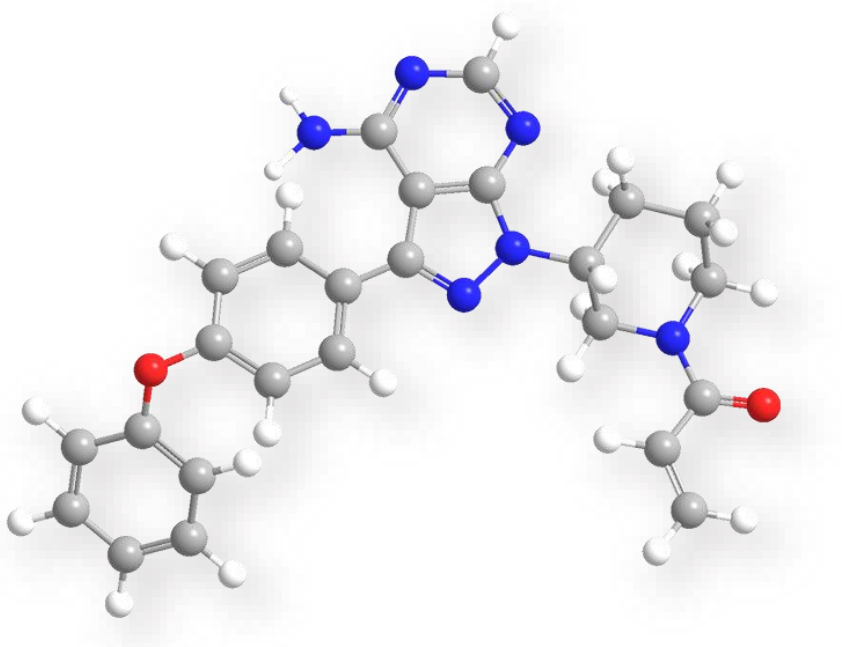
Ibrutinib case study using Simcyp Simulator

Ibrutinib for the treatment of mantle cell lymphoma



Source: American Chemical Society

Simcyp Modelling Strategy

Simcyp model developed in healthy adults using lab and clinical data

↓

Simcyp model verified using clinical data with strong CYP3A4 inhibitor & inducer

↓

Simulated DDI with moderate CYP3A4 inhibitors & inducers in cancer patients -> recommended dose adjustments

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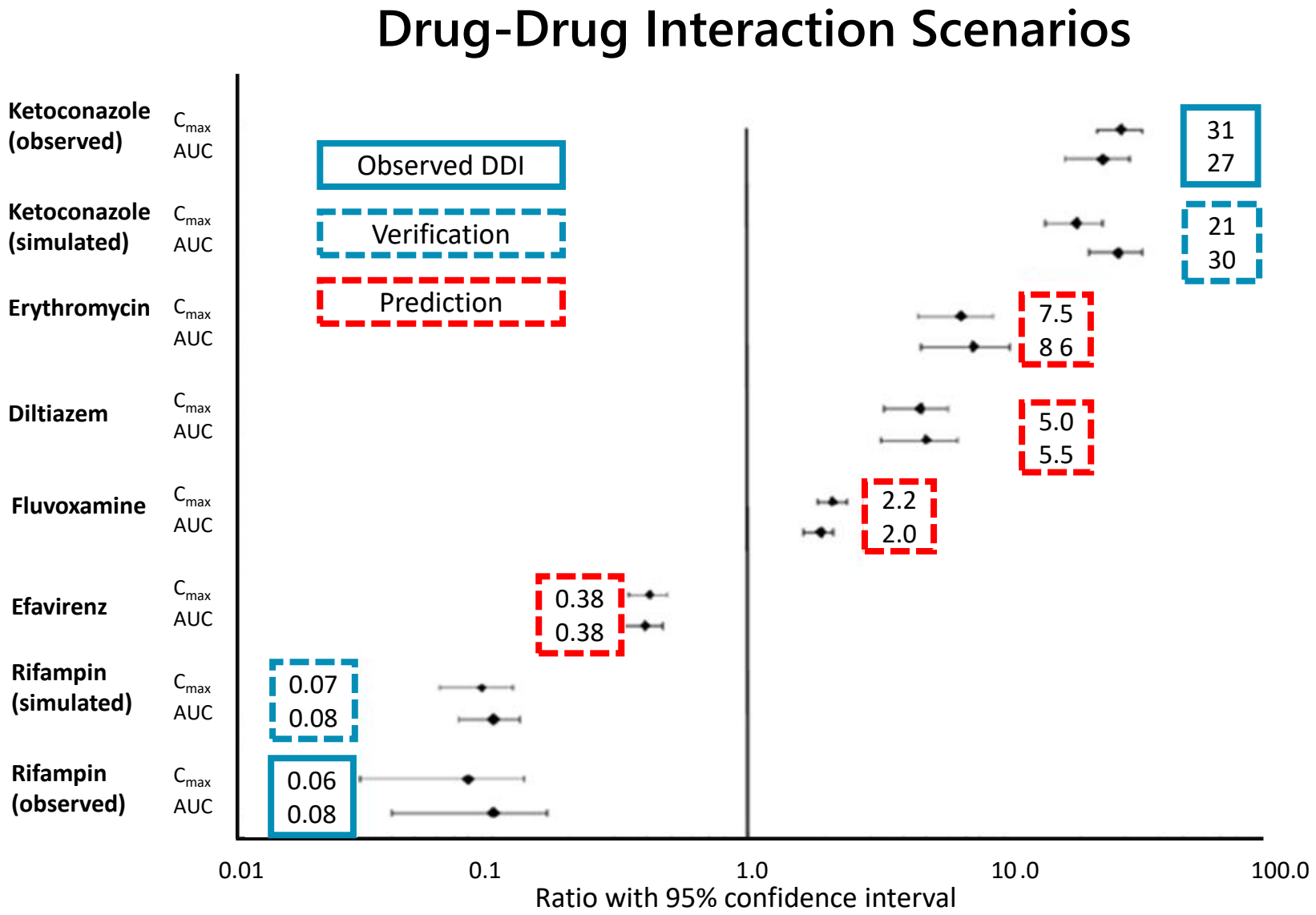
Ibrutinib model predicted untested scenarios



The Simcyp Simulator accurately predicted observed drug interactions and was used to study new scenarios, avoiding several DDI studies.

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Ibrutinib model used to inform dose adjustments in label

"The simulations of PBPK model provided a dose optimization strategy for combined use of ibrutinib with specific CYP3A inhibitors or inducers."

- from the FDA label report, June 28, 2013

CYP3A modulators	Goal	CYP3A interaction mechanisms of co-medications	Ibrutinib dosing
Inhibitors	Simulated ibrutinib exposure vs. that of 560 mg without inhibitor should be <2 fold	Strong, reversible, minimal accumulation (e.g. ketoconazole)	Reduce to 140 mg and give 2 hours before inhibitor
		Strong, time-dependent (e.g. ritonavir)	Do not use
		Moderate	Reduce to140 mg
Inducers	Simulated ibrutinib exposure vs. that of 140 mg without inducer should be >1	Moderate	No dose adjustment
		Strong	Do not use

Track record of scientific and regulatory milestones

- First PBPK workshop to FDA
- First FDA approval with virtual bioequivalence for complex generic
- First FDA acceptance of Simcyp simulation in lieu of DDI trial
- Gene therapy regulatory submission with QSP
- Simcyp used to enable drug to come off FDA clinical safety hold
- COVID-19 Vaccine Model wins R&D 100 Award

Yesterday

- Drug-drug interaction model
- Pediatrics module
- Animal module
- Cardiac safety simulator

Today

- Virtual bioequivalence
- Vaccine simulator
- Immuno-oncology
- Immunogenicity

Tomorrow

- Secondary pharmacology
- Long-acting injectables
- Gene therapy
- Neurodegenerative diseases

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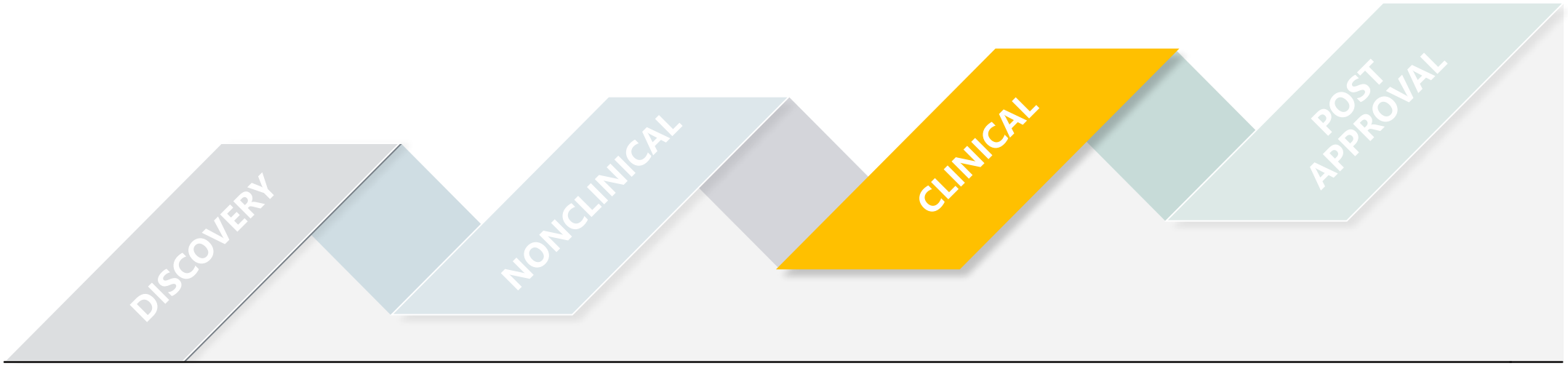
Clinical development opportunity



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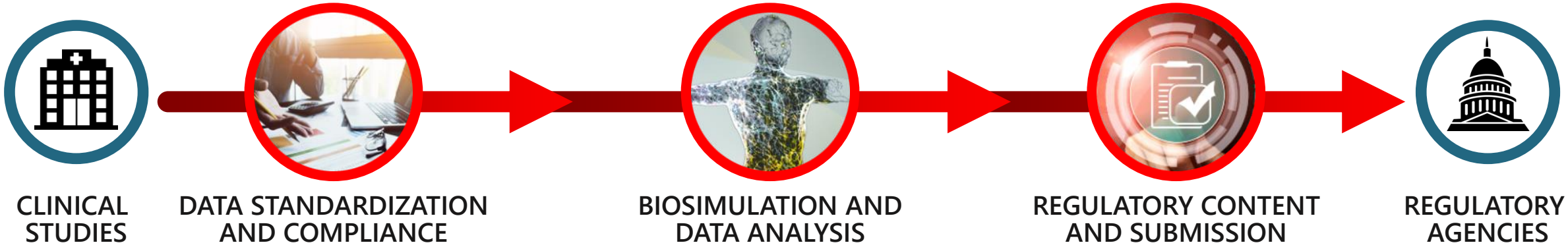
Pain points in clinical phase ➡ significant opportunity

Clinical Data Workflow



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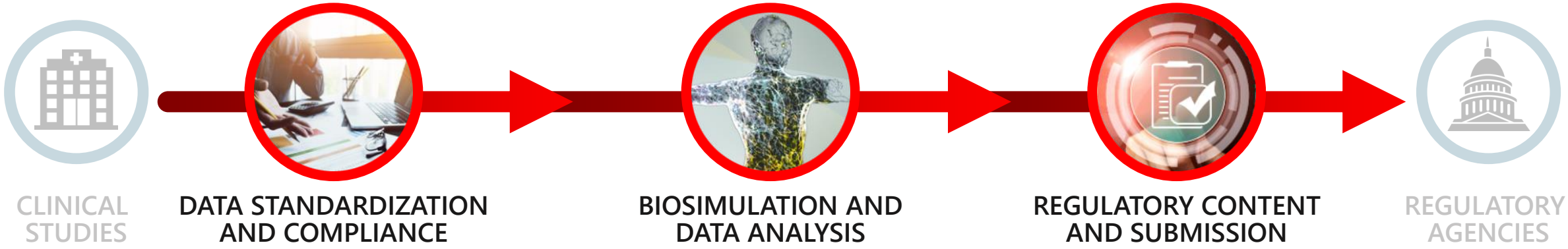
Pain points in clinical phase ➡ significant opportunity

Clinical Data Workflow



Customer Pain Points and Opportunities

- Growing number and diversity of data sources --> longer database lock cycle times
- Lack of data governance
- Manual data management

- Sub-optimal trial design
- Patient recruitment challenges
- ~50% of compounds fail due to safety, efficacy or funding
  - Get the dose right for the right patient

- Evolving regulatory and compliance landscape
- Global regulatory filings

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Reducing errors, ensuring quality and increasing speed

Clinical Data Workflow

PINNACLE 21

Integral Repository

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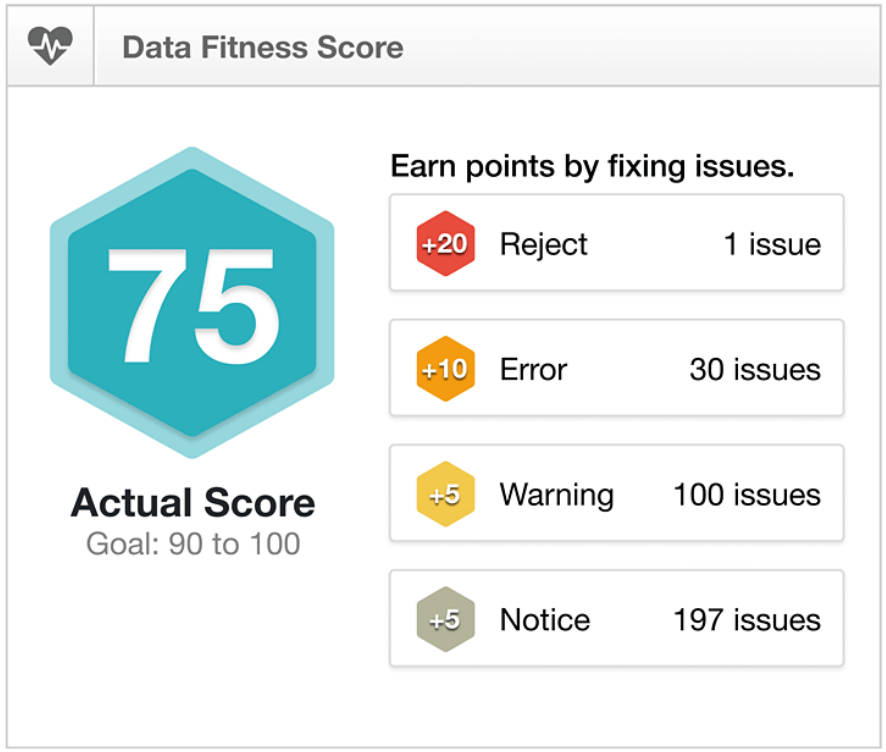
Validating all clinical data submitted to FDA and PMDA

Pinnacle 21 Enterprise



- The US FDA and Japan's Pharmaceutical and Medical Devices Agency use Pinnacle 21 Enterprise to validate all clinical data submitted by sponsors
- 22 of the top 25 biopharmaceutical companies by R&D spend and 6 of the top 10 CRO's license Pinnacle 21 Enterprise
- Software integration with Integral Repository
  - CFR Part 11 compliant repository with audit trail
- Rollout of services powered by Pinnacle 21 Enterprise

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Mining insights to inform critical decisions

Clinical Data Workflow

PINNACLE 21

Integral Repository

Phoenix Platform

Simcyp Simulator

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Regulatory-adopted software for required analyses

Phoenix PK/PD Software

Exposure-response information is at the heart of any determination of the safety and effectiveness of drugs.

FDA Guidance for Industry, Exposure-Response Relationships, 2003

- Leading software for non-compartmental analysis, pharmacokinetic/pharmacodynamic (PK/PD) and toxicokinetic modeling with **13,000+ users**
- **Multiple integrated modules** for the full empirical biosimulation workflow with data processing, graphing and report generation
- Adopted by key regulatory agencies, including **US FDA, Japan PMDA and China NMPA** and used by **37 of the top 40** biopharma companies
- Customers can be confident they are using the same tools used by regulators to evaluate their products

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Assuring and accelerating regulatory success

Clinical Data Workflow

PINNACLE 21

Phoenix Platform

GlobalSubmit Software

Integral Repository

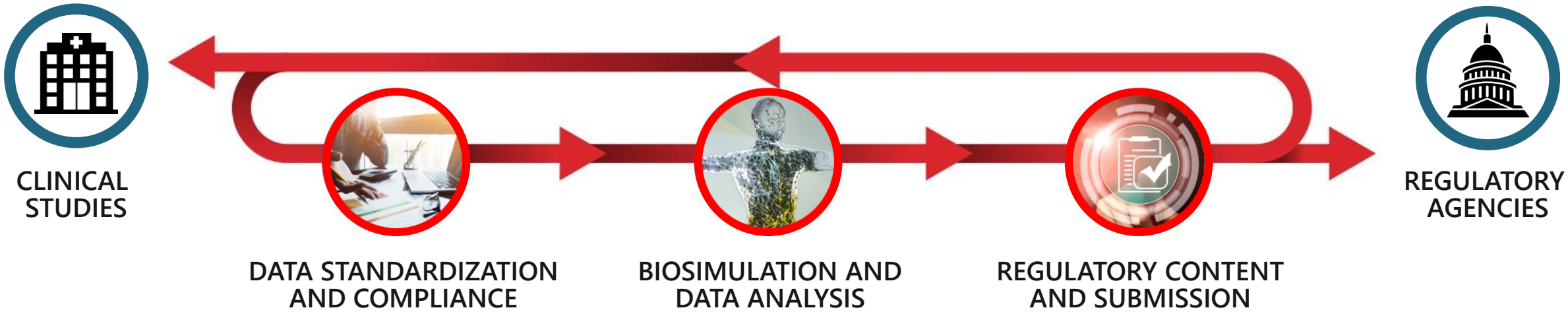
Simcyp Simulator

Synchrogenix Writer

CERTARA

Next study is informed by biosimulation

Clinical Data Workflow



PINNACLE 21

Phoenix Platform

GlobalSubmit Software

Integral Repository

Simcyp Simulator

Synchrogenix Writer

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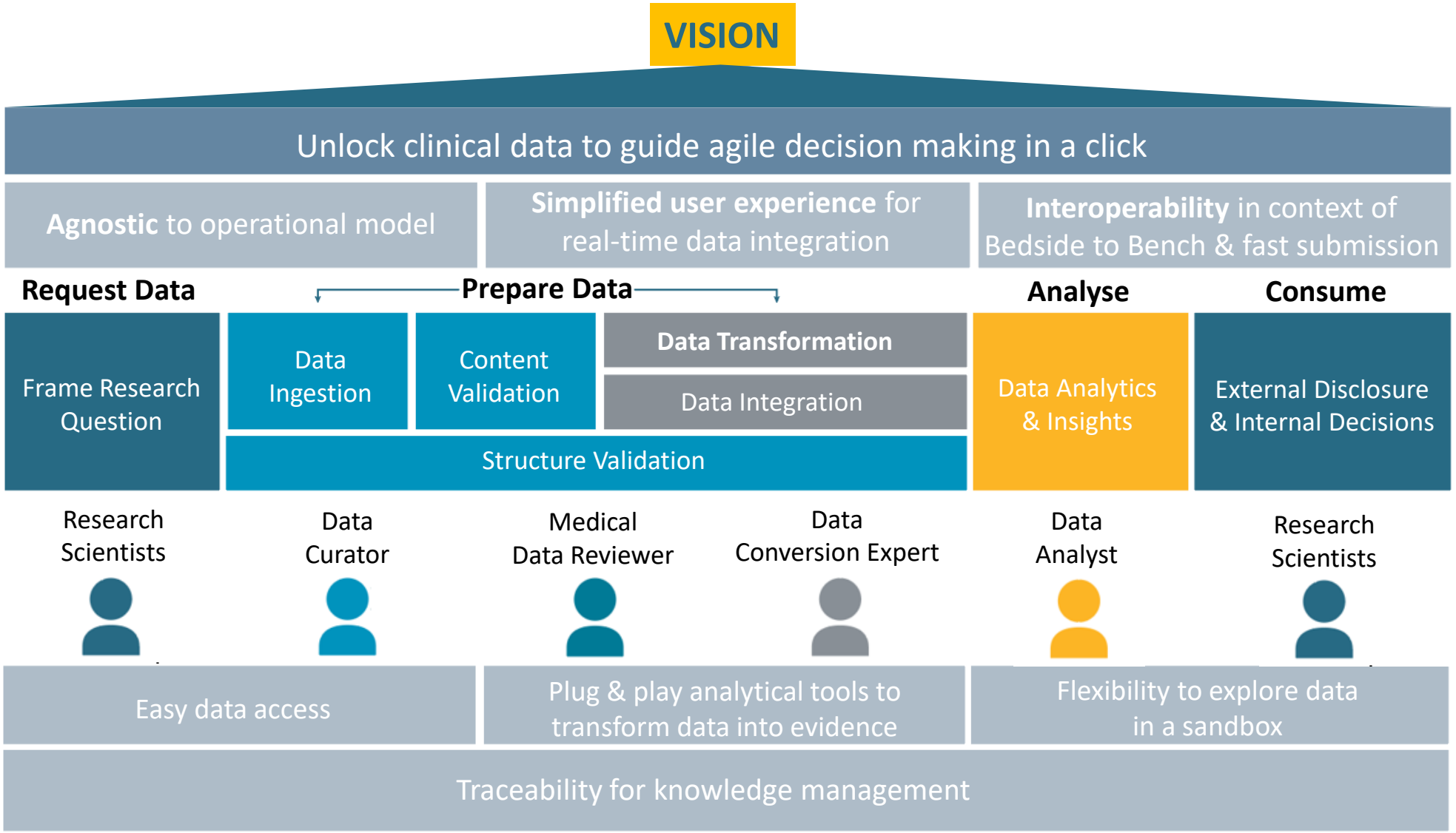
Use case from top 10 biopharmaceutical company



Adapted from client

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Technology-driven Services:
Maximizing Client Value Creation

Justin Edge
President of Regulatory & Access
Patrick Smith, Pharm.D.
President of Integrated Drug Development

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Certara Technology-Driven Services

Year to date as of September 30, 2021

YoY change	22%	10%	PY 115%

2021 Highlights

- Advanced **1,200+** projects YTD
- Supported more than **250** regulatory submissions in past 4 years
- Grew global team of scientists and experts by **18%** YTD

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Sustained drivers of our growth

Biotech Investment

- Healthcare investment in 1H 2021 reaches $47B
- Expanding biotech needs
- China growth

Global Regulatory Tailwinds

- Parallel global filings
- EU Policy 70
- Project Optimus

Technology-driven Differentiation

- Technologies spanning entire life cycle to increase speed and quality
- Proprietary biosimulation tools

CERTARA

Integrated suite of services powered by technology

Full spectrum of technology-driven services from discovery and clinical development to regulatory and commercial success

Drug Development and Regulatory Strategy

CODEx

Mechanistic Biosimulation Consulting

Simcyp Simulator, QSP & Secondary Intelligence

Clinical Pharmacology and Pharmacometrics

Phoenix Software

Regulatory Writing

Synchrogenix Writer

Regulatory Submissions

GlobalSubmit, Pinnacle 21

Real World Evidence and Market Access

BaseCase

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Accelerating patient safety narratives with technology

Patient safety narratives are critical to clinical study reports

- Summary of adverse events that occurred with a patient
- Required in all clinical phases across every therapeutic area

3 Key Challenges in the Narrative Process

Quality

Speed

Scale

Synchrogenix Writer automates and accelerates the patient safety narrative process.

Certara's regulatory team uses **Synchrogenix Writer** to generate quality narratives at speed and scale for many of our biopharmaceutical clients.

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CODEx for model-based meta-analysis (MBMA)

- CODEx Databases cover more than 55 therapeutic areas and 10,000+ studies
- Influences critical decisions in drug development
- Used by 9 out of the top 15 global biopharmaceutical companies

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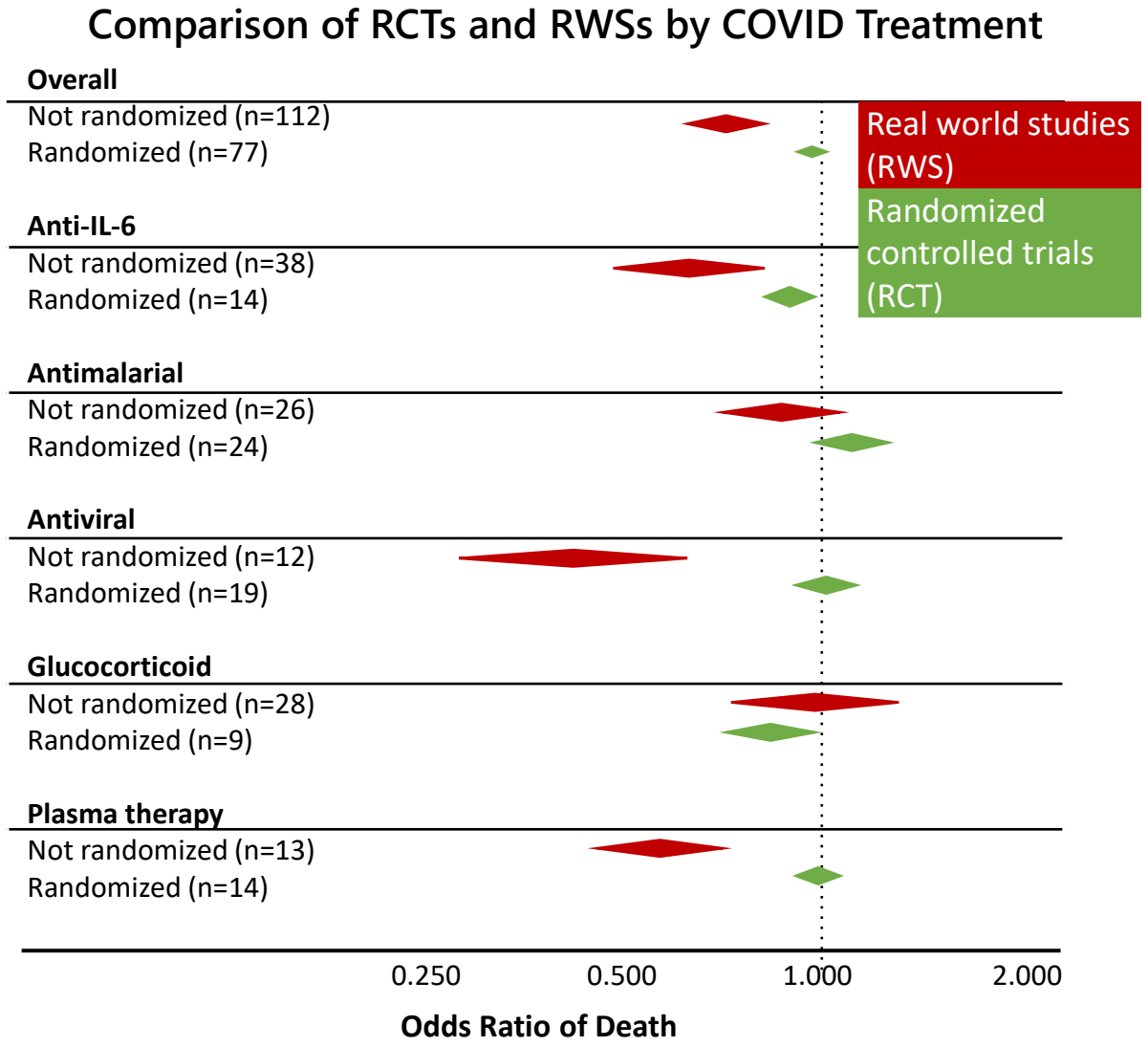
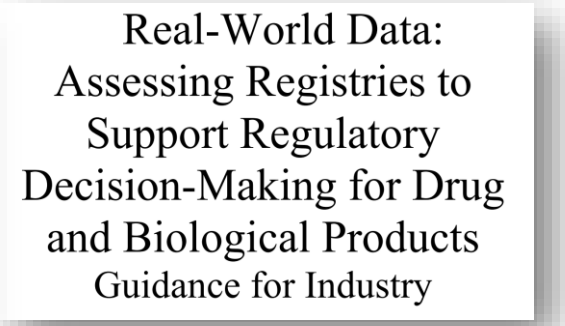
Insights from the COVID-19 CODEx database

Funded by the Bill and Melinda Gates Foundation, now includes 482 COVID-19 trials and real-world studies



- Real world studies overestimated COVID treatment effects compared to randomized controlled trials
- Sheds important insights on how to bridge between real world studies and RCTs
- Valuable across all areas from rare diseases to viral pandemics
- CODEx can be used to create synthetic control arms
- Growing regulatory support for real-world evidence



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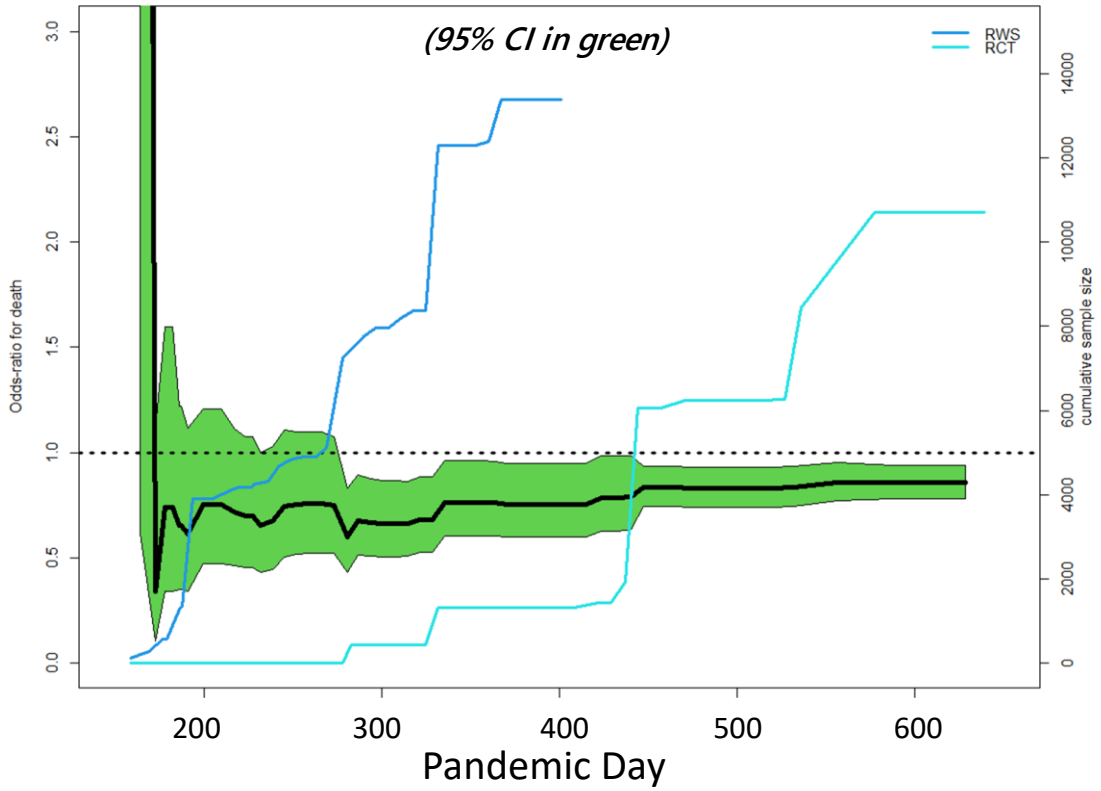
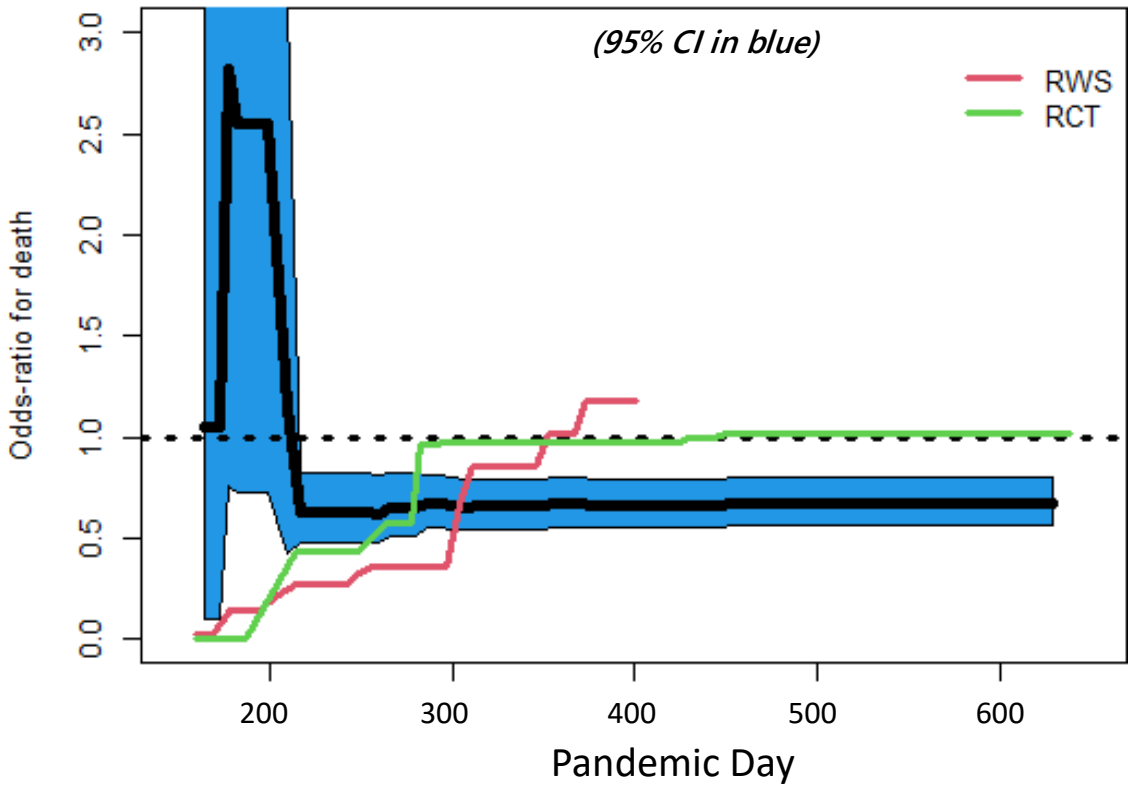
Tale of two COVID-19 repurposed therapies

Learning on Anti-Interleukin-6



Learning on Glucocorticoids (critical/severe patients)



For new drugs to be commercially successful, they must differentiate themselves from the standard of care.

Model-based meta-analysis using **CODEx** can help predict how a new drug's safety and efficacy profile might compare to competitor drugs, informing critical go/no-go decisions.

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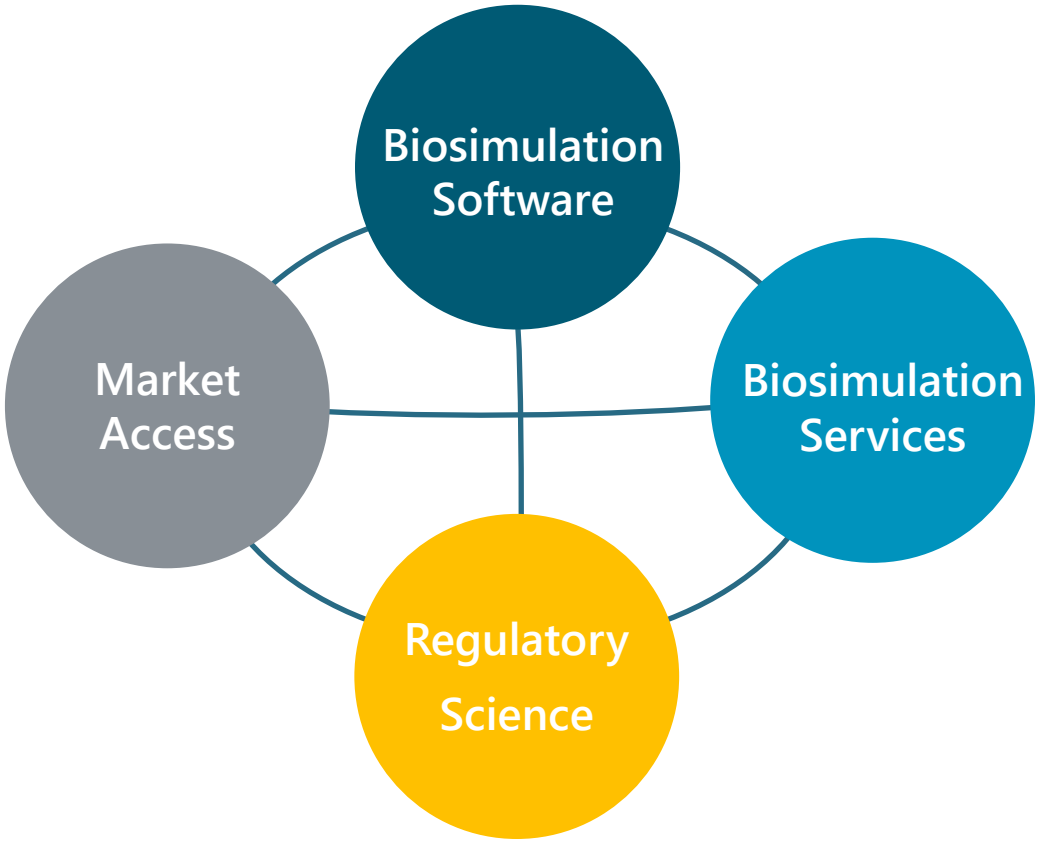
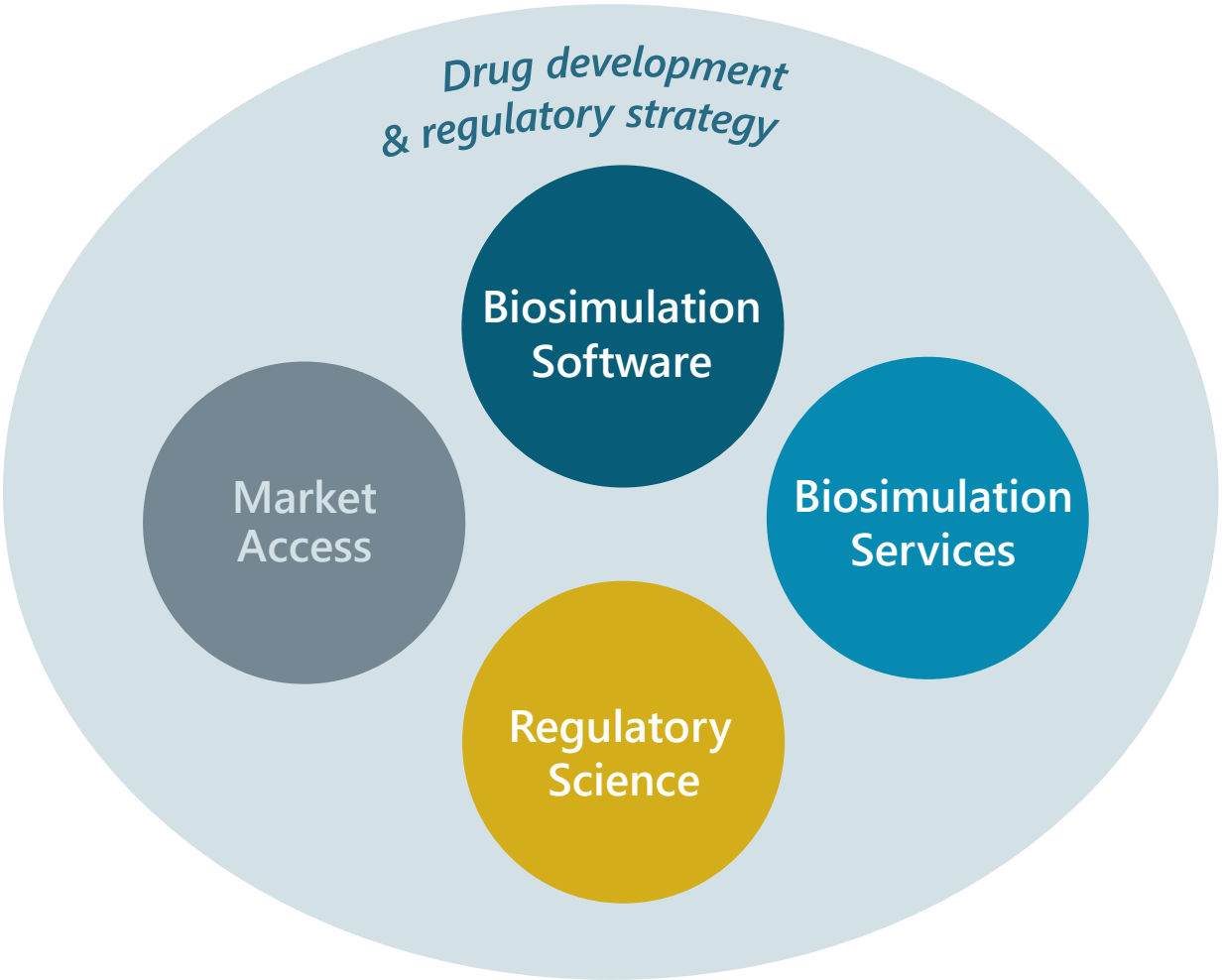
Different customer journeys depending on their needs

Land and Expand



Lift and Shift



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Practice areas with differentiated tools and support

Global Health

Pediatrics

Complex Biologics

Cell and Gene Therapy

CERTARA

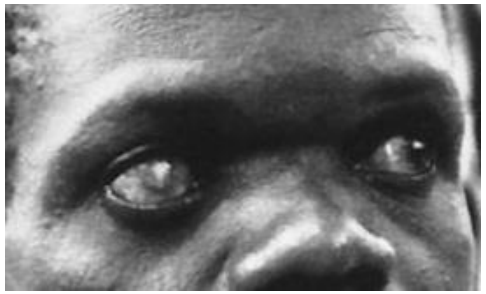
Advancing a novel, rare pediatric drug to FDA approval

Mirum, a start-up biotech, needed support to advance maralixibat, its novel therapy aimed at treating a rare pediatric disease, and chose to partner with Certara.

- Clinical pharmacology
- Clinical protocol design
- Regulatory strategy
- Non-compartmental PK analysis
- **Phoenix Software**
- Represent client at FDA meetings
- Drug interaction modeling
- **Simcyp Simulator**
- Regulatory submission

- Approved by the FDA as the **first and only medication** for the treatment of cholestatic pruritus in patients with Alagille syndrome 1 year of age and older
- Client received a **rare pediatric disease priority review voucher**
- More than **35 scientists and regulatory experts** at Certara contributed to this program

Virtual drug development for a neglected, tropical disease



Certara formed a **virtual drug development team** with Medicines Development for Global Health to work on **moxidectin**, a treatment for onchocerciasis or river blindness. **River blindness** is the second leading cause of infectious blindness, affecting at least **25 million** people worldwide.

- Drug development and regulatory strategy
- Population PK/PD analysis and NCA
- **Phoenix Software**
- Clinical pharmacology
- Clinical trial design
- Epidemiology modeling

- Approved by the FDA as the **first medication in 20 years** to treat patients 12 and older
- Client received a **tropical disease priority review voucher**

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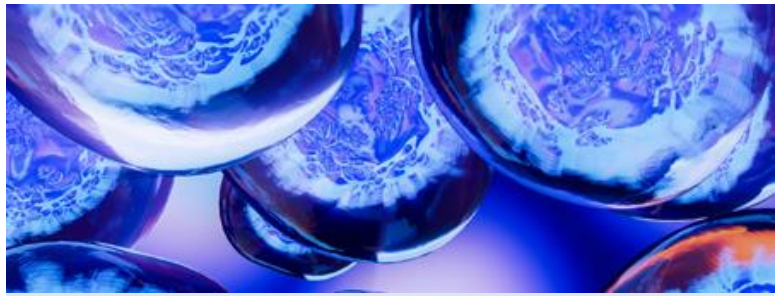
Meeting customers where they are

Hong Kong-based biotech seeks FDA approval

- Two cancer therapies in development
- Long-time Phoenix customer
- Simcyp and drug development consulting, regulatory writing and submission support, and HEOR modeling

Client granted 2 FDA Fast Track designations

Nasdaq-traded biotech needs major regulatory support



- Regulatory customer for 6 years
- Regulatory writing, including safety reports and narratives
- NDA and BLA submissions with GlobalSubmit eCTD publishing
- Simcyp and drug development consulting

Novel cancer drug approved by FDA in 2021

Top 3 pharma expands into evidence and access

- 10+ year partnership with Simcyp, Phoenix, R&D consulting
- Expansion with evidence and access support across immunology, neuroscience & oncology programs
  - Health economics models, health technology assessments, payer insights, dossier, value messaging

Successful coverage achieved in major and secondary EU markets

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People, passion and purpose

- Employer of choice in industry with **350+** experts with doctorate degrees
- Strong growth globally, especially in Europe and Asia Pac with nearly **30%** growth in people YTD
- Sales and marketing expansion with more than **40%** growth in people YTD

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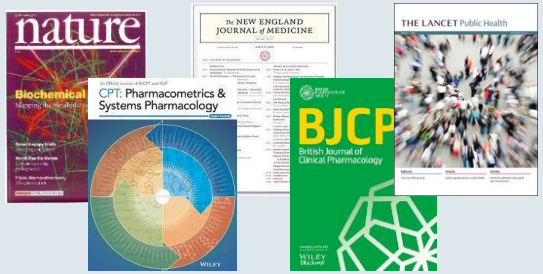
Educating to influence

Education and Certification

- **3,000+** scientists trained in 2021
- **48** scientific webinars in 2021 with **15,000+** attendees and recording views
- Academic fellowships, awards and grants

Scientific Publications and Presentations



- **150+** scientific publications and presentations at key industry conferences YTD

ASCPT aaps DIA RAPS ISPOR

- Recognition of our experts by industry organizations

Regulatory Engagement

- Experts invited to speak at FDA, European Medicines Agency, UK Medicines and Healthcare Products Regulatory Agency
- FDA Workshops in 2021
  - Model Informed Drug Development Approaches for Immunogenicity Assessments
  - Generic Drug Science and Research Initiatives Public Workshop

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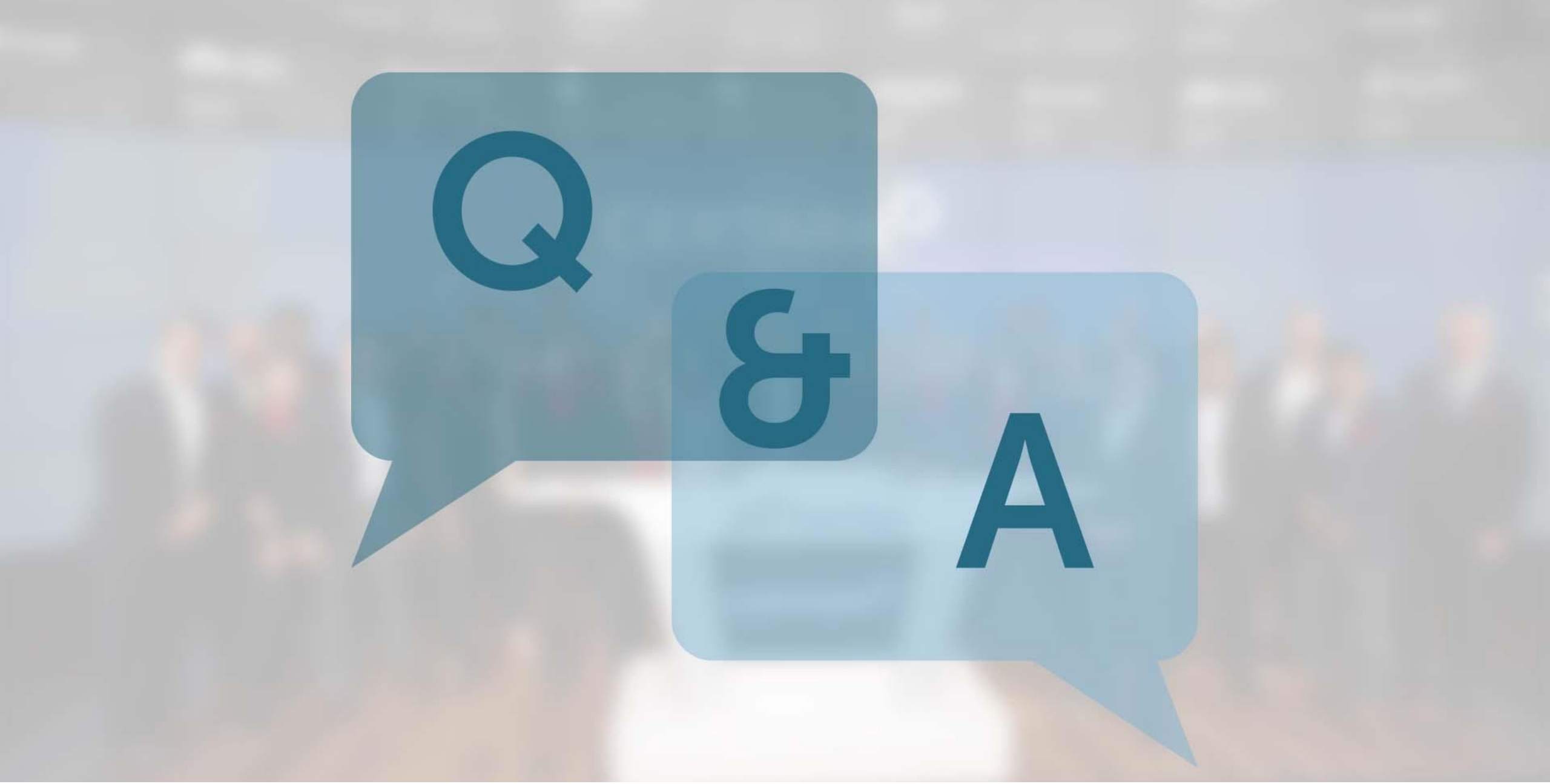

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Financial Update and Outlook

Andrew Schemick
Chief Financial Officer

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Track record of strong performance

Year to date as of September 30, 2021

YoY Change	18%	PY $5.1M	15%	PY $0.04	167%

See Appendix for reconciliation tables

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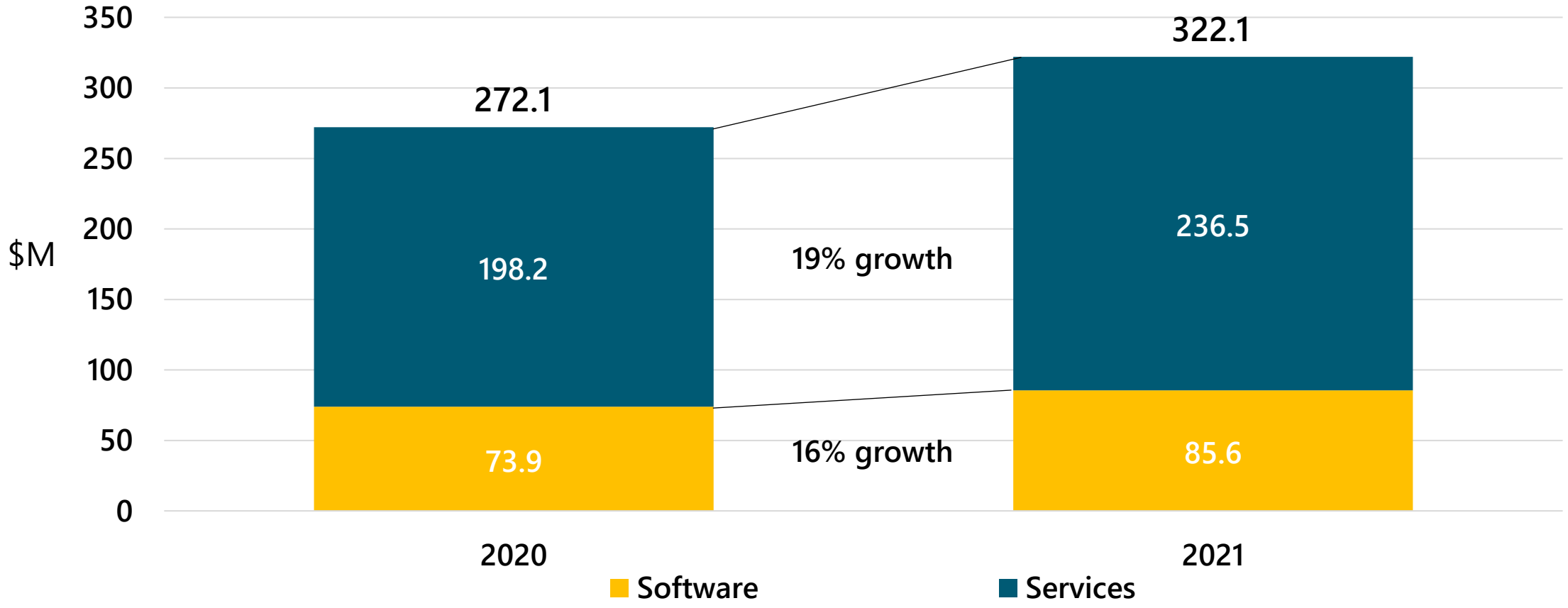
Bookings growth drives strong visibility

TTM Bookings (through October 31, 2021)



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Acquisition of Pinnacle 21, a leader in data standardization software

- Closed acquisition on 10/1 for purchase price of $310M with approximately $250M in cash consideration and 2,239,717 shares of Certara restricted common stock
- Estimated 2021 pro forma revenue of $23-24M, contributing $6M in 4Q21
- Accretive to revenue and adjusted EBITDA
- 57 employees and ~70% are software developers and data standards experts
- Pinnacle 21 Enterprise Software
  - >130 customers, including **22 of top 25** leading biopharma companies
  - Average annual customer subscription value **>$100k** in 2020 and growing
  - **94%** aggregate renewal rate in 2020

$300M
Total Addressable Market(1) for CDISC Compliance Software

12%–15% CAGR
(2022–2026)

Expecting 2022 Pinnacle 21 revenue of $28-31M
and adjusted EBITDA of $12 - 13M (~43% EBITDA margin)

1.Internal estimate based off of commissioned market research
We have not reconciled the adjusted EBITDA and adjusted EIBTDA margin above to the most directly comparable GAAP measures because this cannot be done without unreasonable effort due to the variability and low visibility with respect to costs related to acquisitions, financings, and employee stock compensation programs, which are potential adjustments to future earnings. We expect the variability of these items to have a potentially unpredictable, and a potentially significant, impact on our future GAAP financial results.

FASB final guidance no longer requires purchase accounting adjustment

- Subsequent to our third quarter earnings release, the FASB issued final guidance that requires companies to apply ASC 606 to recognize and measure contract assets and liabilities from contracts with customers acquired in a business combination. This creates an exception to the general recognition and measurement principle in ASC 805.
- As a result, companies will recognize contract assets and contract liabilities at amounts consistent with those recorded by the acquiree immediately before the acquisition date.
- The standard is effective for fiscal years beginning after December 15, 2022; however, Certara will early adopt the standard for fiscal year 2021.

No deferred revenue valuation adjustment will be required, and Certara will not be providing guidance or report an Adjusted Revenue metric

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2022 Outlook

Certara Initiates 2022 Guidance

Revenue
$350-$370M

Adjusted EBITDA(1)
$127-$135M

Adjusted Diluted EPS(1)(2)
$0.48-$0.53

20-25%
YoY growth

36-37%
EBITDA Margin

This financial guidance was provided as of December 15, 2021, and its inclusion in this presentation should not be construed as continued affirmation of such guidance beyond that date.

(1) We have not reconciled the adjusted EBITDA and adjusted diluted EPS forward-looking guidance above to the most directly comparable GAAP measures because this cannot be done without unreasonable effort due to the variability and low visibility with respect to costs related to acquisitions, financings, and employee stock compensation programs, which are potential adjustments to future earnings. We expect the variability of these items to have a potentially unpredictable, and a potentially significant, impact on our future GAAP financial results.

(2) The company is planning to revise the calculation of adjusted eps to exclude amortization expense related to M&A. Amortization related to P21 estimated based on preliminary purchase accounting valuation to be updated before year end.

(3) Pinnacle21 Goodwill Amortization which will provide a cash tax benefit of approximately $500K per year

Key Assumptions 2022 Guidance

- Revenue growth excluding Pinnacle 21 expected to be **12-17%**
- Fully diluted shares expected to be in the range of **156-158M**
- GAAP tax rate expected to be in the range of **40-45%**
- Cash tax rate expected to be **20-25%**(3)

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Concluding Remarks

William Feehery
Chief Executive Officer

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Full Certara toolkit to advance a drug program

Software			
• D360 • Simcyp QSP	• Simcyp Simulator • Phoenix Software • Secondary Intelligence	• Pinnacle 21 • Integral CODEx • GlobalSubmit eCTD • Synchrogenix Writer	• BaseCase Software
Technology-driven Services			
• Simcyp consulting	• Drug development & regulatory strategy • IND submission • Toxicology	• Clinical pharmacology • Pharmacometrics • Model-based meta-analysis • Regulatory writing • Regulatory submissions	• Market access • Real world evidence • Pharmacovigilance

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Certara investment highlights

- Attractive end markets growing in mid-teens driven by R&D efficiency demand and global adoption
- Technology leader with highly predictable business model with 90%+ renewal rates
- Deeply embedded scientific solutions at the core of R&D with 1,650+ customers
- Significant opportunities to expand within customer base and add new customers worldwide
- Proven track record of innovation and 15 successful strategic acquisitions
- Long track record of growth and profitability with EBITDA margins in mid- to high- 30's and strong free cash flow

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CERTARA®

accelerating medicines

Investor Day 2021

Appendix

Reconciliation of Net Income (Loss) to Adjusted EBITDA

(in thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Net income (loss)[a]	$ (1,762)	$ 1,227	$ (3,567)	$ 5,050
Interest expense[a]	3,289	5,929	13,549	19,810
Interest income[a]	(84)	(12)	(255)	(36)
(Benefit) provision for income taxes[a]	(1,631)	350	349	4,696
Depreciation and amortization expense[a]	533	614	1,687	1,836
Intangible asset amortization[a]	10,209	9,956	30,436	29,804
Currency gain (loss) [a]	(545)	37	(189)	(190)
Equity-based compensation expense[b]	8,165	1,181	20,846	2,286
Acquisition-related expenses[c]	7,561	216	9,713	1,165
Integration expense[d]	—	57	—	57
Transaction related expenses[e]	154	487	1,776	487
Severance expense[f]	—	150	—	361
Reorganization expense[g]	—	83	—	190
Loss on disposal of fixed assets[h]	22	9	304	9
Executive recruiting expense[i]	86	188	413	188
First-year Sarbanes-Oxley implementation costs[j]	129	—	469	—
Adjusted EBITDA	$ 26,126	$ 20,472	$ 75,531	$ 65,713

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Reconciliation of Net Income (Loss) to Adjusted Net Income (Loss)

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net income (loss)[a]	$ (1,762)	$ 1,227	$ (3,567)	$ 5,050
Currency gain (loss) [a]	(545)	37	(189)	(190)
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Reorganization expense[g]	—	83	—	190
Loss on disposal of fixed assets[h]	22	9	304	9
Executive recruiting expense[i]	86	188	413	188
First-year Sarbanes-Oxley implementation costs [j]	129	—	469	—
Income tax expense impact of adjustments[k]	(3,036)	(335)	(5,382)	(600)
Adjusted net income	$ 10,774	$ 3,300	$ 24,383	$ 9,003

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Reconciliation of Diluted Earnings Per Share to Adjusted Diluted Earnings Per Share

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Diluted earnings per share[a]	$ (0.01)	$ 0.01	$ (0.02)	$ 0.04
Currency gain (loss) [a]	—	—	—	—
Equity-based compensation expense[b]	0.05	0.01	0.13	0.02
Acquisition-related expenses[c]	0.05	—	0.06	—
Integration expense[d]	—	—	—	—
Transaction related expenses[e]	—	—	0.02	—
Severance expense[f]	—	—	—	—
Reorganization expense[g]	—	—	—	—
Loss on disposal of fixed assets[h]	—	—	—	—
Executive recruiting expense[i]	—	—	—	—
First-year Sarbanes-Oxley implementation costs[j]	—	—	—	—
Income tax expense impact of adjustments[k]	(0.02)	—	(0.03)	—
Adjusted diluted earnings per share	$ 0.07	$ 0.02	$ 0.16	$ 0.06
Diluted weighted average common shares outstanding	149,016,609	132,407,786	147,894,227	132,407,786
Effect of potentially dilutive shares outstanding [l]	4,303,765	—	4,584,295	—
Adjusted diluted weighted average common shares outstanding	153,320,374	132,407,786	152,478,522	132,407,786

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Notes to Reconciliations

(a) Represents amounts as determined under GAAP.

(b) Represents expense related to equity-based compensation. Equity-based compensation has been, and will continue to be for the foreseeable future, a recurring expense in our business and an important part of our compensation strategy.

(c) Represents costs associated with mergers and acquisitions and any retention bonuses pursuant to the acquisitions.

(d) Represents integration costs related to post-acquisition integration activities.

(e) Represents costs associated with directly expensed costs from the secondary offerings and debt modification.

(f) Represents charges for severance provided to former executives and non-executives.

(g) Represents expense related to reorganization, including legal entity reorganization.

(h) Represents the gain/loss related to disposal of fixed assets.

(i) Represents recruiting and relocation expenses related to hiring senior executives.

(j) Represents the first year Sarbanes-Oxley costs for accounting and consulting fees related to the Company's preparation to comply with Section 404 of the Sarbanes-Oxley Act in 2021.

(k) Represents the income tax effect of the non-GAAP adjustments calculated using the applicable statutory rate by jurisdiction.

(l) Represents potentially dilutive shares that were excluded from the Company's GAAP diluted weighted average shares outstanding because the Company had a reported net loss and therefore including these shares would have been anti-dilutive.

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