

On the Cusp of a Cure

Is Asia Pacific Ready for the Precision Era?





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Executive summary

Over the next decade, the nature of disease treatments and the way medical therapies are delivered to patients will dramatically change as a result of technological breakthroughs in diagnostics, big data and artificial intelligence (AI). Cuttingedge scientific advances like genomic profiling are transforming our understanding of what causes disease and are enabling researchers to predict treatment suitability and outcomes more accurately for patients.

Cutting-edge scientific advances like aenomic profiling are transforming our understanding of what causes disease and are enabling researchers to predict treatment suitability and outcomes more accurately for patients.

As a result of these advances, we are entering a transformative period in medicine - the 'Precision Era', where the fundamental way in which patients are treated is being redefined. In the Precision Era, medicines will move away from being generically prescribed and administered small molecule treatments aimed at alleviating symptoms, which require regular medication to manage chronic conditions. Instead, treatments are becoming highly tailored to individual patients and provide patients with the potential for a curative solution, specific to their disease. We call this new wave of innovative disease treatments precision therapies.

Precision therapies are poised for rapid growth over the next decade, driven by technological

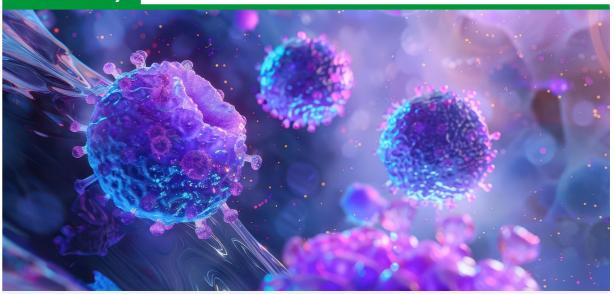
advancements. They are no longer a distant concept, but are already available for patients in many markets, with a significant pipeline of new precision therapies expected to launch within the next five years. In fact, looking at cell and gene therapies alone, there are nearly 4,000¹ therapies in development. Precision therapies are broader than just cell and gene therapies.

In this report, we include the following technologies as a representative sample of precision therapies:

- Cell therapies involve the addition or transplantation of modified human cells into a patient to treat a disease
- Gene therapies treat or prevent disease by correcting disease causing DNA mutations in patients
- Targeted antibody therapies, which allow the targeted treatment of a broad variety of diseases ranging from cancer to autoimmune conditions, often used in conjunction with innovative diagnostics such as comprehensive genomic profiling
- Drug-device therapies, which improve on traditional treatment and drug delivery because the drug is sent directly to tumorous cells, reducing dosage, side effects and damage to healthy cells, and
- **Diagnostic technologies** such as comprehensive genomic profiling which are used to identify specific patient populations for treatment by gene and targeted antibody therapies.



Case study



Precision therapies represent a breakthrough in cancer treatment for solid tumours such as lung cancer, the most common cancer in China. Lung cancer ranks first among malignancies in China in both incidence and mortality, with an overall 5-year survival rate of only about 20% for advanced-stage patients . From 2025 to 2035, an estimated 15Mn individuals in China are projected to be diagnosed with lung cancer.²

Patient Z, a 67-year-old retiree who had always enjoyed a quiet life with his family, was diagnosed with advanced lung cancer. The diagnosis came as a devastating blow - his tumour was already large, and liver metastases had developed. As his condition rapidly worsened, he spent sleepless nights wondering if he should even pursue treatment, given his advanced age and modest financial means. It was then that Z's doctor explained the possibility of participating in a targeted antibody therapy clinical trial, detailing the treatment plan and potential benefits. After much

Each of these technologies are considered part of the Precision Era because they provide enhanced health benefits to patients through a more tailored approach, represent a paradigm shift to how care has been provided previously, and are the focus of significant research and development (R&D) efforts and investment with a wave of new therapies expected to launch in the next five to ten years.

contemplation, Z decided to take a leap of faith and enrol in the trial. Two years later, Z's story became one of hope and renewal. The lung lesion that once threatened his life was completely gone, and the liver metastases had significantly shrunk. With tears of joy streaming down his face, Z expressed his heartfelt gratitude: "Thanks to my physician and this breakthrough therapy, I've been given a second chance at life. Every day now feels like a gift."

With the access to biomarker-driven antibody therapies and its inclusion into earlier treatment lines, the potential for life years gained could be life changing. Precision therapies are expected to bring new hope and transformative benefits to patients with various types of tumours. By technology type, targeted antibody & drug-device combo contributes the largest proportion of the years of life gained (c.7.3Mn), followed by cell therapy (c.1.7Mn) and gene therapy (c.0.2Mn) in comparison to the standard of care.

Through the rapid developments in these precision therapies, some experts have suggested that we may be on the "cusp of a cure" for diseases that have previously been considered incurable, such as many cancers and aenetic disorders.

Precision therapies hold enormous benefits for not just patients, but also their families, carers, healthcare systems and the broader economy.

¹ Australian Government Department of Health and Aged Care, 2024. Minister for Health and Aged Care press conference – 28 August 2024. [online] Available at: <u>https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/minister-for-health-and-aged-care-press</u>conference-28-august-2024

Oncology Society of Chinese Medical Association, 2024. Chinese Medical Association guideline for clinical diagnosis and treatment of lung cancer (2024 edition). [online] Available at: https://rs.yiigle.com/CN115399202004/1512963.htm

This report focuses on first-of-its-kind research outlining these wide-ranging benefits in detail. However, as with many innovations, capturing the full value of precision therapies will require coordinated changes across the broader healthcare ecosystem, including funding models, infrastructure, physician capabilities, patient care and journeys. This report also identifies the key barriers currently limiting adoption and impact and provides actionable recommendations to address them.

Our research and modelling included data from more than 1,000 clinical trials across the key technologies considered. The analysis shows that in addition to patient benefits, these medicines will also deliver a broad range of social and economic benefits. They are projected to reduce healthcare costs, strengthen R&D activity, improve healthcare infrastructure, and training for healthcare providers. All of which will in turn generate greater investment into the sector and productivity improvements. The broader economy will also benefit, with industry driving innovation and creating skilled jobs.

The analysis shows that in addition to patient benefits, these medicines will also deliver a broad range of social and economic benefits.

In addition to direct benefits, improving access to precision therapies will also drive multiplier effects indirectly. Multiplier effects describe how an initial injection of investment into an economy can lead to a larger increase in economic output and employment, as the initial impact ripples through different sectors and stimulates additional economic activity.

However, there are several barriers that restrict patient access to these innovative treatments and prevent the realisation of the multitude of benefits described above. Recognising the potential benefits of precision therapies, L.E.K. Consulting has taken a systematic approach to assessing the barriers to adoption and solutions that can address these barriers.³

Through in-depth consultation with independent experts in patient advocacy, industry, government and economic policy, we have assessed four key Asia-Pacific (APAC) markets - Australia, China, Japan and South Korea. For China, the specific findings of the studies can be seen on the next page.

As illustrated in the exhibit below, precision therapies offer enormous health and economic benefits to all Chinese and to the Chinese economy. Realising these benefits will require a coordinated effort across all stakeholders involved - industry, government, clinicians and the broader healthcare workforce, researchers and investors.

China

Benefits (10 year cumulative view)



10.5Mn patients

with improved treatments & outcomes, including access to precision therapies, supporting diagnostics and clinical trials

Over **¥200Bn** RMB

in avoided healthcare costs through curative treatments for previously untreatable diseases

¥1.45Tn RMB

invested across 'R&D, diagnostics and manufacturing support' for consistency across report development of new skills and expertise

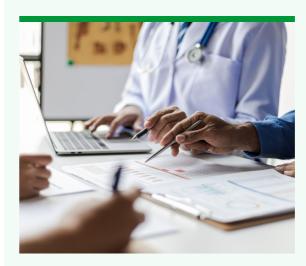
Potential of over **¥8Tn** RMB of investment

in economic activity and 850,000 jobs generated through multiplier effects of investment and patient benefits across the broader community

China

Solutions







³ Jackson, Stuart and Trakhtenberg, Ilya, 2025, Predictable Winners, Stanford University Press

Create a supporting environment which promotes innovation

- Strengthen regulatory approval frameworks
- Improve pricing, reimbursement and funding for precision therapies

Improve the infrastructure for precision therapies

• Boost investment in the infrastructure for precision therapies

Expand awareness and education on precision therapies

- Develop clinical guidelines and provide further education for healthcare providers and patients
- Support the formation and growth of patient advocacy groups

Regional perspectives

At a regional level, there is huge potential for economic investment in R&D, diagnostics and manufacturing as well as healthcare cost savings over the next 10 years. Importantly, millions of patients will benefit.

This first-of-its-kind research evaluates the whole system benefits of precision therapies in Asia Pacific, with a focus on Australia, China, Japan and Korea:

- Economic investment of around \$450Bn
 USD over the next 10 years across the four markets.
- Creation of almost 1.2Mn jobs.
- Additional indirect economic growth through a multiplier effect on adjacent industries as the initial growth ripples through more

sectors and stimulates economic activity culminating to **an estimated \$1.615Tn USD** growth.

Greater workforce participation from over
 24Mn patients and caregivers

As conservative projections of future patient numbers and treatment paradigms were used, the actual impact is likely to be much higher than forecasted in this report as further treatments are brought to market and innovative treatments are likely to be offered earlier in the patient pathway.

There is huge potential for economic investment in R&D, diagnostics and manufacturing as well as healthcare cost savings over the next 10 years.



Projected benefits of precision therapies (cumulative over 10 years)

	Australia	China	Japan	South Korea
Improved	250k patients	10.5Mn	1.5Mn	400k
outcomes		patients	patients	patients
Invested in R&D, Diagnostics and Manufacturing	Over \$50Bn AUD \$32Bn USD	Over ¥1.45Tn RMB \$200Bn USD	Over ¥17Tn JPY \$110Bn USD	Over ₩61Tn KRW \$44Bn USD
Avoided	\$2.6Bn	¥216Bn	¥860Bn	₩2.2Tn
healthcare	AUD	RMB	JPY	KRW
costs	\$1.7Bn USD	\$30Bn USD	\$5.7Bn USD	\$1.6Bn USD

Each of the four markets assessed in this report are not alone in facing challenges to enabling access to precision therapies. In fact, there are three common barriers that we have observed across the four APAC markets investigated as described below.

Common barriers

The first was the lack of a clear, fit-forpurpose regulatory and reimbursement pathways to properly evaluate these paradigm-shifting precision therapies

The impact of this being delayed access to therapies by patients, lower reimbursement for diagnostics and novel therapies resulting in higher out-of-pocket-costs and affordability constraints.

Low patient and healthcare provider awareness of these novel therapies and the benefits they offer to patients, their families and friends and society-at-large

The impact of this being potential misdiagnosis and delays, reluctance of treating physicians to prescribe patients novel therapies and difficulty in access to and navigation of the environment by patients.

3 Key healthcare infrastructure and investment to support patient access to these medicines

Such as improving access and number of clinical trials that local patients can participate in, access to information about novel therapies, access to molecular profiling (which includes both genomic and protein-based components) as the standard of care, leveraging genomic data for R&D and to build knowledge, and supporting innovation and R&D to continue progress of development in precision therapies.

The recommendations in this report need to be implemented with urgency if these four markets (Australia, China, Japan and South Korea) are to gain significantly from the multitude of benefits that precision therapies hold. Governments, industry, healthcare professionals and patient advocacy groups will need to all work together collaboratively to ensure the full potential of the precision therapies is realised.



Common solutions

Develop streamlined, fit-for-purpose regulatory and reimbursement pathways for the precision therapies that recognise wider value of these medicines to patients, their carers and families, and the broader society and economy

Including more timely access to diagnostics, curative therapies for patients, improved affordability either through pricing, reimbursement or insurance programs for both treatments and diagnostics.

Increase efforts to educate healthcare providers, patients and the broader public about precision therapies

Supporting healthcare providers with clinical guidelines and medical information on these innovative therapies and assisting them and advocacy groups in navigating the complex patients pathways.

Encourage cross-sectoral collaboration between the public sector and industry to foster innovation and promote access

Supporting industry to continue its investment into new therapies and diagnostic tools locally, to improve accessibility in-country and the development of local resources and talent.



1.0 Introduction

1.1 Evolution of medicines

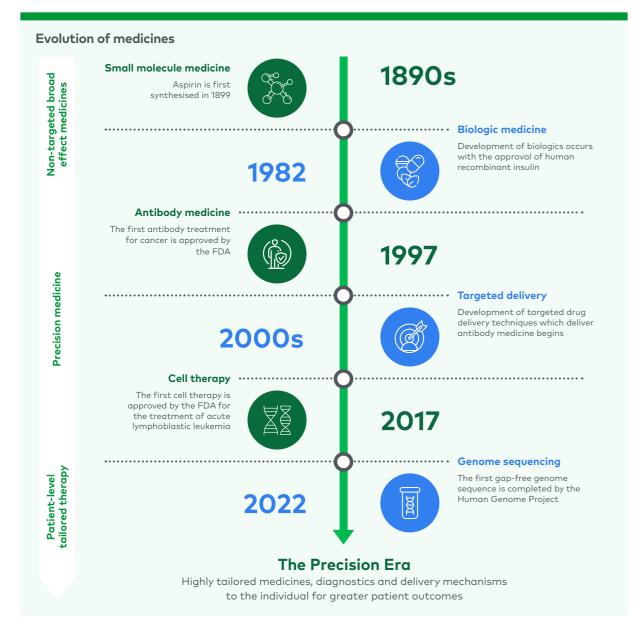
For much of the 20th century, medical innovation was focused on managing symptoms. While discoveries like penicillin were lifesaving, most innovations only extended life rather than provide cures. Over the last 30 to 40 years, medical advancements have accelerated, driven by advances in technology and our understanding of the human genome.

In the late 20th century, biologics — natural molecules in humans and animals — were developed to address disease symptoms more effectively.

At the turn of the century, immunotherapies, such as antibody therapies, emerged. These treatments harness the body's immune system to fight diseases. In the 21st century, targeted drug delivery techniques improved the effectiveness of antibody therapies, reducing side effects and offering patients more freedom from regular treatments.

Technological advancements over the last five years, including tools that identify and edit disease-causing mutations and the achievement of the first complete genome sequence, have marked a turning point in the acceleration of medicine and healthcare.

These breakthroughs are causing a revolution in the way patients are treated. In contrast to traditional treatments, novel cancer treatments are becoming more personalised through individual genomic information and data, and



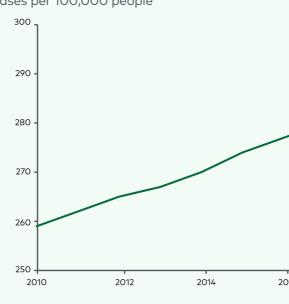
Technological advancements over the last five years have marked a turning point in the acceleration of medicine and healthcare.

offering the potential for a curative solution specific to a disease for diseases previously thought to be incurable. This enables clinicians to match patients with the most effective treatments, ushering in the Precision Era.³

In the context of an increasing burden of disease, this innovation is critical. Precision therapies are becoming the gold standard in personalized treatment and to date, have largely been aimed at treating cancer, which is one of the leading causes of death in APAC and globally.⁴ In 2024, over 20Mn people globally will be diagnosed with cancer and over 10Mn will die of the disease — reflecting a sharp and continuing rise in prevalence.⁵

Looking forward, treatments may no longer require ongoing medication or regular doses. Instead, highly individualized cell and gene therapies may be one-time treatments that can slow or stop disease progression — and even cure or prevent disease.

Global incidence of cancer (2011-21) Cases per 100,000 people



⁴Institute for Health Metrics and Evaluation (IHME), 2024. Global Burden of Disease (GBD) Data. [online] Available at: <u>https://www.healthdata.</u> org/research-analysis/gbd-data

⁵ Institute for Health Metrics and Evaluation (IHME), 2024. Global Burden of Disease (GBD) Results. [online] Available at: <u>https://vizhub.</u> healthdata.org/gbd-results/

⁶ Australian Government Department of Health and Aged Care, 2024. Minister for Health and Aged Care press conference – 28 August 2024. [online] Available at: <u>https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/minister-for-health-and-aged-care-press-conference-28-august-2024</u>

⁷ European Commission, 2024. Rare diseases. [online] Available at: <u>https://health.ec.europa.eu/rare-diseases-and-european-reference-networks/</u> rare-diseases_en

Over the next five to ten years, the pharmaceutical and biotechnology industries are expected to deliver a surge of precision therapies, especially in oncology, immunology, and neurology. In cell and gene therapies alone, nearly 4,000 therapies are currently being developed around the world.⁶

Beyond cancer, precision therapies can be used for rare, often poorly funded, genetic diseases. Though an individual rare disease may affect fewer than five in every 10,000 people, they collectively impact around 8% of the global population.⁷These diseases are often progressive and incurable, affecting patients' quality of life and life expectancy.

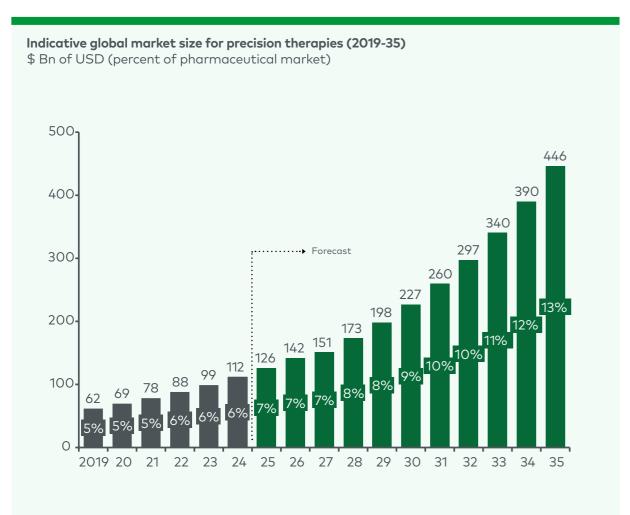
Precision therapies offer hope by significantly advancing the standard and options of care for these previously untreatable conditions.

Looking forward, treatments may no longer require ongoing medication. Instead, highly individualised cell and gene therapies may be one-time treatments that can slow disease progression – or even cure disease.

116	2018	2020	2022	

1.2 Drivers of growth in the precision era

Precision therapies are expected to grow at 14.5% annually to reach \$446Bn USD globally by 2035, outpacing broader medicine market growth of 6.6%.^{8,9}



⁸ Statista, 2024. Global spending on precision medicine treatments from 2020 to 2027. [online] Available at: https://www.statista.com/ statistics/1420946/spending-on-precision-medicine-treatments-globally/
^o IQVIA, 2024. The global use of medicines 2024: Outlook to 2028. [online] Available at: <u>https://www.iqvia.com/insights/the-iqvia-institute/</u> reports-and-publications/reports/the-global-use-of-medicines-2024-outlook-to-2028

Several factors are driving the rapid growth of precision therapies:











To keep pace with these advancements, healthcare systems will need to adapt to provide patients with access to these treatments.

• **Treating clinicians** will require training on when and how to prescribe these therapies, and nurses and other healthcare workers will need to learn how to support patients undergoing treatment.

Medical unmet need

- Numerous orphan diseases remain with identified genetic causes but complex or unclear pathophysiology
- Current standards of care in oncology using chemotherapy exhibit low response rates

Biomedical research

• Increasing R&D investment into biomarker discovery and development of precision therapies, driven by the promise of improved patient outcomes

Diagnostic advancements

- Advanced diagnostic techniques (e.g., nextgeneration sequencing, or NGS) facilitating biomarker-based testing
- Expanding precision diagnostic use cases (e.g., molecular testing in oncology evolving from limited late-stage therapy guidance to full integration from screening to posttreatment surveillance)

Big data and Al

• Availability of big data to inform medical discoveries and predict disease and treatment outcomes

Policy evolution

- Growing recognition of the need for improved test access to harness the benefits of precision therapies
- Expanding guideline inclusion enabling access to precision therapies for an increasing number of indications
- Regulatory bodies will need to develop new methods to assess the safety and efficacy of these treatments, as traditional models may not apply.
- **Policy bodies** will also need to collaborate with industry to create new reimbursement models that ensure patients can afford these life-changing treatments.

1.3 Definitions

Precision therapies can have several interpretations based on what therapies are included in scope. In its broadest definition, it can include first-generation biologic medicines that require a simple, single biomarker test to determine suitability for a given patient. These have been available for over the last decade.

This report focuses on a narrower set of therapies that are representative of precision therapies. These therapies are designed to deliver more tailored diagnosis and treatment – therapies that some experts believe are on the cusp of a cure in terms of their potential to treat and cure patients.

Precision therapies are designed to deliver more tailored diagnosis and treatment - therapies that some experts believe are on the cusp of a cure in terms of their potential to treat and cure patients.

Four novel technology types have been assessed for the purposes of this report – cell therapy, gene therapy, targeted antibody therapy, and drug-device combination therapies as outlined below. Companion diagnostics can be used in conjunction with these technologies and therapy types to identify more accurately those patients likely to benefit from treatment.

Technology types assessed for the purposes of this report



Cell therapy

Cell therapy that involve the genetic modification of a patient's own cells, utilising the regenerative and immune-activating properties of cells to treat disease



Gene therapy

Gene therapy treat or prevent disease by correcting disease-causing DNA mutations in patients



Targeted antibody therapy

Antibody therapy can target specific cells and utilise the body's immune response or deliver disease fighting agents to cause cancer cell death. When combined with genomic profiling, those patients who benefit materially can be identified based on their biomarkers, avoiding unnecessary treatment of patients who will not benefit



Drug device combination therapy

Drug device combination therapy offer an improved delivery mechanism for existing therapies for a range of diseases, using novel devices or techniques which deliver the therapy to the location of disease



Companion diagnostics

Precision Era can also be extended to diagnostic tools such as comprehensive genomic profiling (CGP) that are specifically required to identify populations for treatment by gene and antibody biomarker-driven therapies

1.3.1 Cell therapy

Cell therapy involves the addition or transplantation of modified human cells into a patient to treat a disease. These cells are generally modified outside of the patient and then re-introduced and may be derived from the patient or separate donor.

The cell therapy market is driven primarily by the development of chimeric antigen receptor T-cell (CAR-T) therapy which uses genetically







10 Sheykhhasan et al. Cancer Gene Therapy, 2024. CAR T therapies in multiple myeloma: unleashing the future. [online] Available at: https://www. nature.com/articles/s41417-024-00750-2

¹ Memorial Sloan Kettering Cancer Center, 2024. Off-the-shelf CAR cell therapy for multiple myeloma shows promise. [online] Available at: https://www.mskcc.org/news/shelf-car-cell-therapy-multiple-myeloma-shows-promise

- engineered immune cells from a patient to target and destroy tumour cells, in particular blood cancers, such as multiple myeloma and lymphoma.
- An emerging CAR-T technique is non-personalised or "off-the-shelf" therapies which use healthy donor cells instead of the patient's own cells. Approved donor cells are modified and able to treat multiple patients, overcoming the limitations of individual manufacturing of cell therapies for each patient.¹¹

1.3.2 Gene therapy

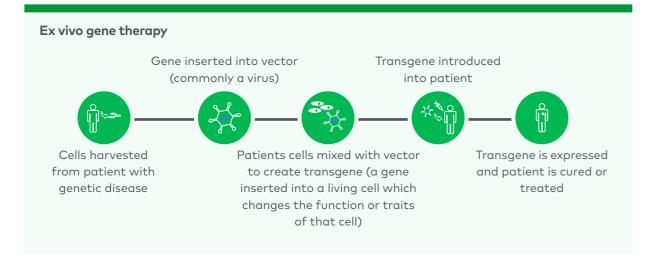
Most key functions in cells are carried by proteins, which carry out these functions based on the information provided by DNA. "Typos" or errors in our DNA can lead to a partial or complete loss of these cell functions. This is the origin of genetic disease.

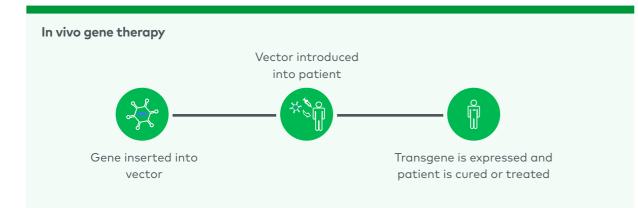
Gene therapy treats or prevents disease by correcting the DNA mutation using vectors, which are usually viruses that function as a 'vehicle' to

deliver therapeutic genetic material, such as a working gene, directly into a cell.¹²

Gene therapy involves modifying a patient's genes outside the body by mixing them with a vector before returning them to the patient or by delivering the genes with vectors directly into the patient's body.

Example diseases treated by gene therapies include inherited retinal diseases, spinal muscular atrophy, Duchenne muscular dystrophy and haemophilia.





¹² American Society of Gene & Cell Therapy (ASGCT), 2024. Vectors 101. [online] Available at: https://patienteducation.asgct.org/genetherapy-101/vectors-101

1.3.3 Antibody therapy

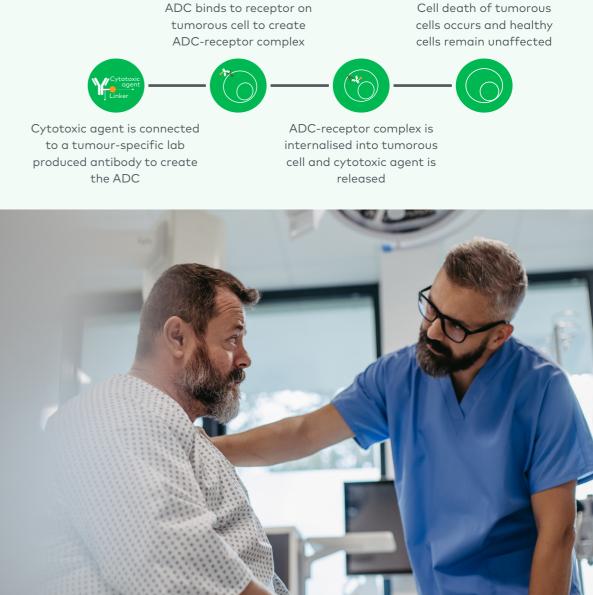
Antibody therapies allow the targeted treatment of a broad variety of diseases ranging from cancer to autoimmune conditions. Antibody therapies are commonly being used to treat a range of solid tumour cancers like lung, colorectal and melanoma.

In cancer treatment, antibody therapy involves the delivery of antibodies which identify and target specific tumour cells. In binding to the tumour cell, the antibody can then 'mark' these cells for destruction by the existing immune system.





to a tumour-specific lab



Antibody therapies can also release a particular drug upon the binding of an antibody to the targeted receptor. Such therapies are called Antibody-drug conjugate therapies (ADCs) and works by attaching antibodies to toxic substances. When the antibody binds to a tumour cell, the toxic substance is released and destroys the tumour cell.

More recent advancements in these therapies have seen the development of radioligand therapies, where radioactive isotopes are attached to molecules (called ligands) that specifically bind to tumour cells. Once attached, they deliver targeted radiation directly to the tumour sites.

1.3.4 Drug device combination therapies

Drug device combination therapies are used to treat patients for a range of diseases and conditions. Recent technology advancements for drug devices have seen innovation in how small-molecule drugs, such as chemotherapy is delivered for solid tumour cancers.

These technologies improve on traditional treatment and delivery because the drug is sent

directly to tumorous cells, reducing dosage, side effects and damage to healthy cells.

The implantable nature of many of these drug devices also reduces the length and frequency of drug administration.

These therapies are being used to treat a range of solid tumour cancers including bladder, carcinoma, prostate, breast and pancreatic cancer.

Example targeted drug delivery mechanisms

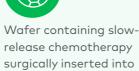




Chemotherapy delivered directly via catheter to bladder



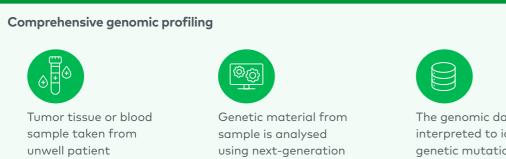
Encapsulated slow-release hormone implant delivered via injection to reduce tumor growth



1.3.5 Companion diagnostics

Companion diagnostics are tests that determine whether a particular therapy is suitable for a patient based on their unique genomic profile. For example, comprehensive genomic sequencing is a type of companion diagnostic that reveals genetic alterations and provides invaluable information to guide treatment options.

patient



sample is analysed using next-generation sequencing (NGS) technology The genomic data is interpreted to identify genetic mutations and that correlate with specific therapies, which can then be administered to the patient

1.4 Report development approach

In this paper, we outline the wide-ranging benefits of these medical innovations to patients, their carers and families, and the broader community. We also address the current barriers to accessing these treatments by providing recommendations across four key Asia Pacific healthcare markets — Australia, China, Japan, and South Korea that were reviewed as part of the study. These markets have been selected because they possess some of the largest and most established economies and health systems in the region.

The Executive Summary provides a regional overview and identifies the key themes across the four markets in the study. This is followed by an introduction to provide definitions on precision therapies, the technologies and therapies underpinning it and an overview of their mechanisms of action, which are the same across the four markets.

The remainder of the report is structured around the following three categories for China:

- **Benefits** in terms of economic contributions, cost saving, and life years gained by patients
- 2 Barriers that currently impact the access to and wider uptake of the precision therapies

Bare Commendations to progress the Precision Era specific to the needs of each country

1.4.1 Benefits framework

We have used a benefits framework (shown in the exhibit below) to assess the qualitative and quantitative benefits of precision therapies. These medicines have been shown to increase life expectancy and offer significant improvements in quality of life for patients. However, the benefits are much broader than patient benefits, and extend to health system benefits, uplift in economic activity, including multiplier effects. The benefits analysis was undertaken by L.E.K. Consulting, leveraging existing case studies and assessments, and a robust set of economic, and clinical data.

The benefits have been modelled conservatively based on the precision therapies and treatment paradigms available today for patients, leveraging existing clinical data.

The technologies and the applications of these to different disease states used in the benefits

modelling is not representative of the entire potential for the precision therapies today, the examples that have been used represent the largest and most applicable proven patient use cases that exist at the time of writing the report.

The actual benefits realised may be much greater over time as more such therapies become

The benefits have been modelled conservatively based on the therapies and treatment paradigms available today for patients in precision therapies leveraging existing clinical data.

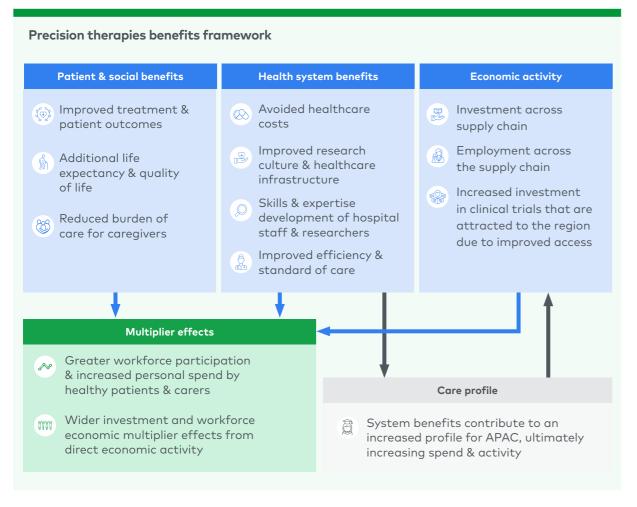
available earlier to patients in their treatment journey and deliver benefits to not only a larger number of patients, but also deliver even greater benefits to each patient through earlier treatment.

Additional detail on the calculation steps and values are provided in the Appendix.

Patient and social benefits have been determined by reviewing each technology type and selecting the most relevant disease category (e.g. blood cancers for cell therapy) for which a precision therapy exists. Research of published clinical trial and real-world results was then undertaken to determine the reported additional life expectancy compared to the existing standard of care and extrapolating this to the entire patient population that could be eligible for treatment in each country. It is expected this number will significantly increase as more treatments become available to treat other disease categories, and as existing treatments show results in earlier lines of use, e.g. used first line for treatment as opposed to after existing older therapies have been used without success.

Health system benefits take the improved life expectancy and what the cost would have been for each additional year of treatment under the standard of care and calculates the implied cost saving (or 'avoided healthcare cost'). Costs for standard of care are based on published data sets for each country.

Economic activity benefits are the financial investment and creation of new employment in the pharmaceutical, medical devices and diagnostic supply chain to support the development of local infrastructure required for



precision therapies, by local and foreign agencies. The quantification of the benefits is based on the observed investment and employment in the pharmaceutical sector from published datasets, adjusted for the proportion of precision therapies that are expected over the next ten years.

Multiplier effects are calculated based on two aspects:

- The recovered population's contribution back into society and the workplace — increased workforce participation and personal spend by healthy patients and their carers
- The broader ranging flow on benefits that are created from the "economic activity benefits" in the broader ecosystem — such as taxes paid on new jobs created to support precision therapies
- Secondary sources have been used to substantiate this opportunity size

In developing the analysis to determine the market potential, existing clinical trial data was used:

 The selection of clinical trials was based on the availability of data for the precision therapies aligned to the therapy areas outlined in the introduction (biomarker-based therapy/ gene/cell therapy)

- In total, this covered approx. 900-1,100 clinical trials across the 4 countries (Australia: 130-190, China: 500-620, Japan: 120-160, South Korea: 110-150 (noting there is some variation year to year)
- Selection of the included therapies was based on FDA approvals and their availability in each region

1.4.2 Barriers and recommendations

The barriers and recommendations were developed with the input of independent advisory committees established for each country. These advisory committees were made up of key opinion leaders and healthcare professionals, patients, and patient advocacy group representatives, as well as current and former industry representatives. A series of sessions were run in each country over a two to three-month period to gather information and distil this into the key messages.

We have taken this approach to ensure that the paper reflects the current requirements specific to each country and is actionable by government and industry groups.



2.1 Introduction

With a population exceeding 1.4Bn and one of the world's largest economies, China holds a prominent position as the second-largest pharmaceutical market globally. Substantial investments in healthcare infrastructure and technology have greatly enhanced accessibility and equity in healthcare delivery across the nation.13

While precision therapies have made great progress improving standards of care, current access is largely through clinical trials, with limited integration of access into the mainstream health sector.

China's healthcare system is characterized by a strong foundation of public providers, complemented by a growing private sector, encompassing over 1Mn healthcare and medical institutions nationwide. Through comprehensive reforms over the past few decades, the government has successfully implemented extensive universal health coverage, enabling more than 95% of the population to access to basic medical insurance, which covers a significant portion of medical costs.¹⁴

In 2015, the Precision Medicine Initiative was introduced, with the government committing ¥60Bn RMB (\$8.3Bn USD) by 2030 to advance R&D in this vital area.¹⁵ Following this, the "Healthy China 2030" strategic policy was launched in 2016, underscoring the strengthening of key technological breakthroughs such as precision medicine and advancing medical science and technology.

In 2024, the State Council approved the "Implementation Plan for Full-Chain Support of Innovative Drug Development," a significant

initiative aimed at driving advancements in innovative therapies. This comprehensive plan provides policy support across the entire drug development chain, from R&D and evaluation to approval, payment and financing.¹⁶ Additionally, local governments in cities such as Shanghai, Beijing and Hangzhou have already introduced policies to strengthen the biopharmaceutical sector, particularly in cell and gene therapy.¹⁷

In 2025, "Opinions of the General Office of the State Council on Comprehensively Deepening the Reform of Regulation of Drugs and Medical Devices to Promote the High-Quality Development of the Pharmaceutical Industry" was issued. The document proposed optimizing drug registration testing by reducing the single batch testing quantity from three times to two times the full test volume, thereby improving the accessibility of innovative medicines.¹⁸ In parallel, local governments such as Beijing have introduced corresponding supportive measures to further advance pharmaceutical innovation and development.19

Chinese pharmaceutical companies are increasingly prioritising the development of novel therapies. This progress is supported by robust manufacturing capabilities, a highly skilled biotech and data analytics workforce and recent improvements in the streamlined regulatory.

Despite this strong innovation ecosystem, China faces unique challenges in ensuring equitable access to precision therapies due to its large population and the wide disparity in distribution of healthcare resources and funding. To fully realise the potential for future innovation, a strong governance framework and efficient regulatory processes will be essential to support sustainable industry growth.

¹³ Fidelity, 2024. Growth medicine: China's burgeoning healthcare sector. [online] Available at: https://www.fidelity.com.au/insights/investmentarticles/growth-medicine-chinas-burgeoning-healthcare-sector/

¹⁴ Xinhua News Agency, 2024. Approx. 1.334 billion people! China's health insurance coverage remains stable above 95%. [online] Available at: https://www.gov.cn/lianbo/bumen/202404/content_6944652.htm ¹⁵ CPPCC Daily, 2015. Medical transformation under precision medicine. [online] Available at: <u>http://www.cppcc.people.com.cn/n/2015/0708/</u>

c34948-27268546.htm

6 CN-Healthcare, 2024. Major news! Executive meeting of the State Council passes the "Implementation Plan for Full-Chain Support of Innovative Drug Development". [online] Available at: https://mp.weixin.qq.com/s/v91xsxwFKCSo9AbCVqIEAA. ¹⁷ Shanghai Municipal People's Government, 2024. Several Opinions from the General Office of the Shanghai Municipal People's

ment on Supporting Full-Chain Innovation in the Biopharmaceutical Industry. [online] Available at: https://www.shanghai.gov.cn/ Govern nw12344/20240730/0fe29fc2246e4b478757dee3a01ccd08.html ¹⁸ General Office of the State Council, 2025. Opinions of the General Office of the State Council on Comprehensively Deepening the Reform

of Regulation of Drugs and Medical Devices to Promote the High-Quality Development of the Pharmaceutical Industry. [online] Available at: https://www.gov.cn/zhengce/content/202501/content_6996115.htm 17 Roiling Municipal Medical Journey Burgey 2025 Severe Marguere for Superstitution to the Unit of the Pharmaceutical Industry.

Beijing Municipal Medical Insurance Bureau, 2025. Several Measures for Supporting the High-Quality Development of Innovative Medicines in Beijing (2025). [online] Available at: https://yjj.beijing.gov.cn/yjj/zwgk20/zcwj91/743583391/index.html

2.2 Benefits of precision therapies

With an increasing burden of disease, unlocking access to precision therapies offers significant benefits across patient and social, economic and healthcare sectors. These benefits create ripple effects throughout the broader economy generating broader multiplier effects.

The benefits proposed below cover a range of factors that will impact patients, their communities, and the broader pharmaceutical, diagnostics and healthcare industries.

Patient and social benefits cover the improved quality of life of patients and their carers as a result of receiving precision therapies. Benefits to

Cumulative benefits of precision therapies (2025 - 35)



Patient & social benefits

- Improved treatment & patient outcomes for c.10.5M addressable patients
- · c.9.2M cumulative years of life gained across the addressable patient pool
- Reduced burden of care for 9.5-10.5M caregivers as a result of patients treated



Economic activity

- c. ¥1.45Tn RMB (\$200Bn USD) invested across the pharmaceutical value chain as well as c. ¥146Bn RMB (\$20Bn USD) in the diagnostics value chain
- Supporting up to c.142,000 highly skilled jobs in the pharmaceutical value chain with additional jobs in the diagnostics industry and health system
- Clinical trial activity generating ¥10-14.2Bn RMB (\$1.4-1.9Bn USD), providing patients with often free treatment access and upskilling the healthcare workforce

the healthcare systems deliver cost savings and increased capability in the system. Finally, the economic benefits and multiplier effects are in the form of investment dollars and additional value generation from increased direct investment in infrastructure and jobs across the pharmaceutical and diagnostic value chains.

Importantly, the benefits outlined and quantified below relate only to the subset of precision therapies investigated, i.e., the four technological areas which have been the focus of this report. The benefits, if applied to a broader definition of precision therapies, would be multiples larger.



Health system benefits

- c. ¥216Bn RMB (\$30Bn USD) in avoided healthcare costs from treatment of addressable patient pool
- Improved research culture & infrastructure in healthcare
- Hospital staff and researchers develop new skills and expertise
- Improved standard of care and higher efficiency



Multiplier effects

- Greater workforce participation, increased personal spend by c.10M healthy patients & 9.5-10M caregivers
- Economic multiplier effects from economic activity of 1-6x generating ¥1.5-8.7Tn RMB (\$200-1,200Bn USD) and supporting **142,000-850,000** jobs

2.2.1 Patient & social benefits

Precision therapies have the capacity to improve health outcomes for at least 10.5Mn patients in China between 2025 and 2035. These improvements are driven by several key factors: (1) increased efficacy and longer-lasting results, (2) the availability of treatments for previously untreatable diseases, and (3) enhanced safety through more targeted treatments. Collectively, these treatments could add an additional 9.2Mn years of life across the population over the next decade.

Precision therapies have the capacity to improve health outcomes for at least 10.5Mn patients in China between 2025 and 2035.

Further advancements are expected as the approved use for existing therapies expand, and they are used earlier in a patient's treatment journey. Currently, many of these therapies are administered as third or fourth-line treatments,

as they have not yet been widely tested as early stage interventions.²⁰ As more data is collected to demonstrate the efficacy of precision therapies in earlier stages, the life year gains per patient are expected to increase. Additionally, as innovation continues to broaden the range of diseases treated by these therapies, more patients will gain access to these life-changing treatments.²¹

Beyond the patients used in initial life year gain models, additional gains can be anticipated as prevalent populations gain access to these therapies once they are available in the market. For example, in 2025, approximately 2,400 people will be born with retinitis pigmentosa, a genetic eye disorder that impacts vision and fewer than 8% of these individuals will have the genetic mutations required for gene therapy treatment.^{22,} ^{23, 24} However, the overall population estimated to have this condition is estimated to be around 372,000 in China, with over 13,000 potentially eligible for gene therapy based on their age and the genetic profile. As these therapies are introduced, the short-term impacts are likely to be much greater than initially projected.²⁵

In addition to expending life expectancy, precision therapies bring substantial social benefits for patients, caregivers and the broader community.

By improving treatment efficacy, precision therapies can help alleviate the prolonged caregiving responsibilities often associated with serious illness. This in turn, reduces both the psychological and economic burdens on cancer patients and their caregivers. Given the severity of the diseases treated with precision

Precision therapies impact on patients' families and caregivers



Fewer side effects, shorter recovery periods following treatment and lower risk of disease recurrence



Enhanced physical, cognitive, emotional and social functioning

Additional patient life years

Incident addressable patients (2025-35) Additional life years per

patient with precision

therapies compared

to SoC

4.51

8.45

life years

Cell therapy

 \mathbb{B}

371.924 blood cancer

patients

Gene therapy

24,845

rare genetic disease patients

life years

Targeted antibody & drug device combination therapy



0.72 10.13Mn solid tumor life years cancer patients

7.28Mn life years across population

Total additional life

years from precision

therapies (2025-35)

1.68Mn

population

0.21Mn

population

life years across

life years across

²⁰ Cappell, K.M. and Kochenderfer, J.N., 2023. Long-term outcomes following CAR T cell therapy: what we know so far. Nature Reviews Clinical Oncology, 20, pp. 359-371. Available at: https://www.nature.com/articles/s41571-023-00754-1 ²¹ AstraZeneca, 2024. Next Generation Precision Medicine. [online] Available at: https://www.astrazeneca.com/r-d/precision-medicine.html ²² Cure Blindness Australia, 2024. Retinitis. [online] Available at: https://www.cureblindnessaustralia.org.au/retinitis 23 Wongchaisuwat, N., Amato, A., Lamborn, A. E., Yang, P., Everett, L., & Pennesi, M. E., 2023. Retinitis pigmentosa GTPase regulator-related retinopathy and gene therapy. Saudi journal of ophthalmology: official journal of the Saudi Ophthalmological Society, 37(4), 276–286. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10752277/

²⁴ Sun, Y., Li, J. K., He, W., Wang, Z. S., Bai, J. Y., Xu, L., Xing, B., Zhang, J. G., Wang, L., Li, W., & Chen, F., 2020. Genetic and clinical analysis in Chinese patients with retinitis pigmentosa caused by EYS mutations. Molecular genetics & genomic medicine, 8(3), e1117. Available at: https:// ²⁵ Hu D. N., 1987. Prevalence and mode of inheritance of major genetic eye diseases in China. Journal of medical genetics, 24(10), 584–588.

Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1050283/ 26 Bedaso, A., Dejenu, G., & Duko, B., 2022. Depression among caregivers of cancer patients: Updated systematic review and meta-analysis. Psychooncology, 31(11), 1809-1820. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9828427/

therapies, more than 90% of patients require caregiving support. The increased availability and effectiveness of these therapies could reduce the need for extensive caregiving for approximately 9.5 to 10.5Mn caregivers.²⁶

The increased availability and effectiveness of these therapies could reduce the need for extensive caregiving for approximately 9.5 to 10.5Mn caregivers.



Ability to experience life milestones and participate in the community



Relief from the psychological burden of living with an incurable or terminal disease

2.2.2 Health system benefits

Precision therapies can deliver four key benefits to the healthcare system as described in the following section. They can reduce the cost of healthcare, improve the culture of R&D, upskill the healthcare workforce and generate improvements in the standard of care.

2.2.2.1 Avoided healthcare cost

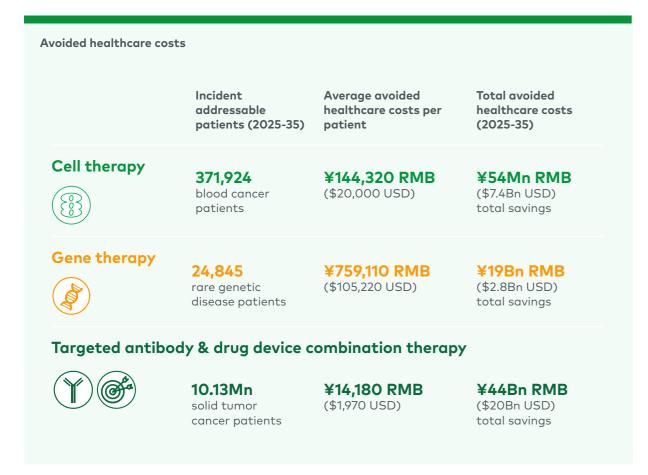
Precision therapies have the potential to generate substantial savings for China's healthcare system. Between 2025 and 2035, it is estimated that these treatments could save approximately ¥216Bn RMB (\$30Bn USD) in healthcare costs, benefiting a cumulative patient population of around 10.5Mn. To put this into context, these savings represent the total average healthcare expenditure for over 15Mn Chinese.

These cost savings are achieved through reduced hospital admissions, medication usage, specialist appointments and follow-up care, as precision therapies enables patients to remain free from disease progression for longer periods. Among the various technologies, gene therapies are expected to contribute the largest savings per patient, as they offer significant life expectancy gains, particularly for those with terminal orphan diseases. However, it is important to note that the long-term efficacy of these therapies is still being evaluated, given their recent introduction to market.

As precision therapies are increasingly used earlier in the treatment process, additional cost savings can be anticipated. This is due to greater efficiency as more patients are treated at an earlier stage, yielding better outcomes and avoiding the need for multiple rounds of less effective therapies.

2.2.2.2 Improved research culture and healthcare infrastructure

The rise of precision therapies has driven the significant investments in cutting-edge research infrastructure across China, including the development of advanced biobanks in that facilitate genomic research and industrial applications. In 2016, the Chinese government



strategically integrated precision medicine into its 13th Five-Year Plan, allocating significant financial resources to foster innovation and industrialization within the sector.²⁷

As part of these efforts, the Ministry of Science and Technology (MOST) launched the a key special research project on precision medicine under the National Key R&D Program.

Between 2016 and 2018, MOST allocated nearly ¥1.3Bn RMB to more than 100 initiatives, including large-scale population-based cohort studies.²⁸ One prominent example is the China Kadoorie Biobank, one of the world's largest prospective studies, housing nearly 5Mn biological samples along with extensive bioinformatics data. This biobank has enabled the identification of new biological pathways linking specific risk factors to various diseases, spurring the development of novel therapeutic approaches.^{29,30}

2.2.2.3 Enhanced skills and expertise for healthcare professionals

The advancement of precision therapies necessitates specialized training for healthcare professionals to ensure they have the necessary skills to deliver these innovative treatments. In China, numerous talent development programs, often backed by hospitals and pharmaceutical biotech associations, equip physicians with cutting-edge knowledge and practical clinical insights into precision therapies.³¹

Moreover, China conducts more than 750 industry-funded clinical trials in precision therapies each year, providing healthcare

²⁷ Xinhua News Agency, 2016. The 13th Five-Year Plan for Economic and Social Development of the People's Republic of China. [online] Available at: <u>https://www.gov.cn/xinwen/2016-03/17/content_5054992.htm</u>
 ²⁸ Nature Spotlight, 2017. From autism to chronic disease: Precision medicine in China. [online] Available at: <u>http://www.naturechina.com/articles/nature-spotlight-precision-medicine-2022</u>
 ²⁹ Chinese Academy of Medical Sciences, 2016. Building a large Chinese population cohort to promote the era of Next Generation Precision Medicine. Chinese Journal of Epidemiology, 37(9): 1319-1319. Available at: <u>http://html.rhhz.net/zhlxbx/20160926.htm</u>
 ²⁰ China Kadoorie Biobank, 2024. China Kadoorie Biobank. [online] Available at: <u>https://www.ckbiobank.org/</u>
 ²¹ The Paper, 2020. Precision medicine training program launched to support clinical talent development and reserve in precision medicine. [online] Available at: <u>https://www.thepaper.cn/newsDetail_forward_8063863</u>
 ²² Citeline, 2024. Clinical Intelligence. [online] Available at: <u>https://clinicalintelligence.citeline.com/</u>
 ²³ Gill, J., Fontrier, A.-M., Miracolo, A. & Kanavos, P., 2020. Access to personalised oncology in Europe. [pdf] Available at: <u>https://www.efpia.eu/media/580518/access-to-personalised-oncology-in-europe.pdf</u>
 ²⁴ Zhang S.,2019. Diagnosis and treatment of rare diseases in China. Clinical Focus, 34(3), 197-200. Available at: <u>https://huicui.hebmu.edu.cn/</u>CN/10.3969/j.issn.1004-583X.2019.03.001

³⁵ Rare Diseases Society Singapore (RDSS), 2024. Rare Facts. [online] Available at: <u>https://www.rdss.org.sg/rarefacts/</u>

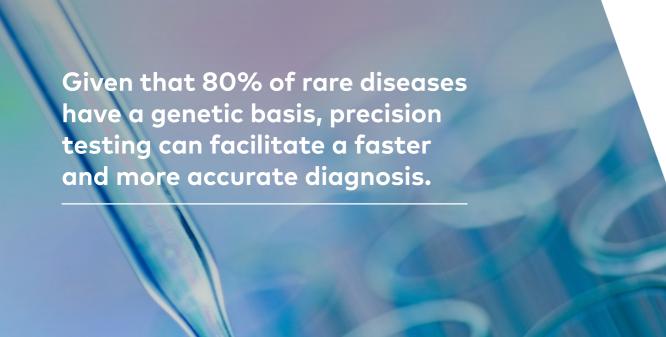
professionals with hands-on experience. This exposure enhances their ability to deliver comprehensive, precise care and make more informed treatment decisions, ultimately elevating the overall standard of care in precision therapies.³²

China conducts more than 750 industryfunded clinical trials in precision therapies each year, providing healthcare professionals with hands-on experience, enhancing their ability to deliver comprehensive, precise care and make more informed treatment decisions.

2.2.2.4 Improved standard of care and higher efficiency

Precision therapies enhance the efficiency of care delivery by reducing the length of treatment episodes. For example, a study by the London School of Economics found that cancer patients treated with precision therapies had an average hospital stay of three to four days, compared to the seven-day average for those undergoing chemotherapy.³³

China faces significant diagnostic challenges in rare diseases, with 58% of patients initially misdiagnosed.³⁴ Since 80% of rare diseases are caused by genetic mutations, precision therapies' genomic testing can improve the accuracy of diagnosis, enabling faster and more precise screening and treatment decision making.³⁵



2.2.3 Economic benefits

Improving access to precision therapies can help drive three key economic benefits - greater investment from local and foreign companies across the pharmaceutical value chain, growth in jobs, and increased investment in R&D particularly in clinical trials.

The pharmaceutical value chain could create up to approximately 142,000 highly skilled jobs across the pharmaceutical supply chain, representing a 7% increase in China's current pharmaceutical workforce.

Rapid pharmaceutical innovation in precision therapies is driving significant economic activity in China, generating new jobs and investment in the infrastructure required to develop, manufacture and distribute these therapies. Between 2025 and 2035, industry investments,

Pharmo

(1

aceutical value chain investment and job creation (2025-35)				
?&D	Manufacturing	Sales and distribution		
4664Bn RMB	¥273Bn RMB	¥512Bn RMB		
\$92Bn USD)	(\$38Bn USD)	(\$71Bn USD)		
hvested	Invested	Invested		
51,500	44,100	36,200		
lobs created	Jobs created	Jobs created		

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<sup>36</sup> FESCO, 2023. Overview of key trends in the pharmaceutical manufacturing industry in 2023. [online] Available at: <u>https://www.fesco.com.cn/</u>
newsDetails.html?id=105980
<sup>37</sup> Statista, 2024. In Vitro Diagnostics – Worldwide. [online] Available at: https://www.statista.com/outlook/hmo/medical-technology/in-vitro-
diagnostics
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both local and foreign are expected to reach around ¥1.5Bn RMB (\$200Bn USD) supporting the creation of approximately 142,000 highly skilled jobs across the pharmaceutical supply chain. This represents a 7% increase in China's current pharmaceutical workforce.³⁶

Additionally, an estimated \$146Bn RMB (\$20Bn USD) will be required for companion diagnostics to facilitate access to precision therapies.³⁷ Local R&D investment, increased by local clinical trial activity is expected to grow, contributing to market expansion, with investments ranging from ¥10 to ¥14.2Bn RMB (\$1.4 to \$1.9Bn USD) by 2035. This will not only benefit patients, who often gain free access to medicines through clinical trials but will also enhance the skill set of healthcare professionals in the field.

2.2.4 Multiplier effects

Precision therapies have a far-reaching impact on the Chinese economy, creating ripple effects that boost economic activity across various sectors.

2.2.4.1 Industry economic activity multiplier effects

The increase in industry economic activity and the benefits of precision therapies extend far beyond the pharmaceutical sector, creating ripple effects that amplify its overall impact on the economy. Direct investment in precision therapies could create multiplier benefits of one to six time, generating between ¥1.5Tn and ¥8.7Tn RMB (\$200Bn to \$1.2Tn USD) and supporting the creation of 142,000 to 850,000 jobs between 2025 and 2035.

These estimates are based on previous studies that examine the indirect economic multipliers associated with investments in the pharmaceutical industry.^{38, 39, 40, 41} These multipliers reflect increased wages from job creation, greater consumer spending and expanded tax revenue, as well as job growth in sectors that intersect with the precision therapy value chain.

Between 2025 and 2035, local and foreign industry investments are expected to reach around ¥1.5Bn RMB (\$200Bn USD).

2.2.4.2 Broader economic multiplier effects

Beyond these indirect economic gains, the recovery and improved health of approximately 10Mn patients treated with precision therapies will enable them to return to work sooner and remain in the workforce longer. This contributes to higher productivity and sustainable tax revenues over the next decade, while also increasing personal spending on goods and services.

Similarly, greater workforce participation, and increased personal spending by 9.5 to 10Mn caregivers are expected over the next ten years, as patience experience better health outcomes.

Precision therapies also offer potentially curative therapies to patients with previously untreatable conditions, allowing them to transition from chronic treatment to a state of cure. As a result, they will no longer rely on continuous healthcare benefits and social welfare, instead contributing financially to the healthcare system through their insurance premiums. This will help reduce the strain on social welfare systems.

The recovery and improved health of approximately 10Mn patients treated with precision therapies will enable them to return to work sooner and remain in the workforce longer.

The total economic benefits of enabling patients to rejoin the workforce could be even more significant than current estimates suggest, as these projections assume treatment for advanced-stage patients. If precision therapies are introduced earlier in the disease progression, it could further enhance patients' ability to return to work and contribute meaningfully to society.

2.3 Barriers to access

Precision therapies hold great promise for transforming healthcare by offering personalised treatment plans tailored to an individual's unique genetic makeup. However, despite its proven



Barrier to access

2.3.1 Complex regulatory approvals

Complex approval pathways

- The current regulatory process for drug-device combinations and companion diagnostics, is complicated by dual approval pathways and a lack of clear, unified guidelines. Different regulatory bodies, such as the Center for Drug Evaluation (CDE) and the Center for Medical Device Evaluation (CMDE), often work independently, leading to delays
- The absence of a cohesive framework for drug-device combination products, which have different regulatory requirements for each component, adds further complexity. This disjointed process increases administrative burden, and prolongs the time it takes to get the treatments to patients. Additionally, the limited number of studies on drugs and companion diagnostics or devices conducted with concurrent clinical trials remains an obstacle

³⁹ Or Clinical Research, 2017. The Economic Impact of the U.S. Biopharmaceutical Industry: 2015 National and State Estimates. [online] Available at: <u>http://orclinicalresearch.com/wp-content/uploads/2018/12/teconomy-partners-2017-study.pdf</u>

^a Australian Commission on Safety and Quality in Health Care, 2024. Economic evaluation of investigator-initiated clinical trials conducted by networks. [online] Available at: https://www.safetyandquality.gov.au/sites/default/files/migrated/Economic-evaluation-of-investigatorinitiated-clinical-trials-conducted-by-networks.pdf



effectiveness, several challenges will need to be addressed to unlock its full potential and ensure patient access. The key barriers are outlined below:

Stringent testing requirements for imported products

· Imported therapies, especially cuttingedge treatments such as gene therapy face significant hurdles due to testing requirements that are not well-suited to their unique characteristics. For example, regulations mandate that companies provide two times the standard amount of inspection samples, which can delay access for Chinese to these life-changing therapies, particularly given the limited patient populations and high costs involved

³⁸ Medicines Australia, 2020. Economic contribution of the innovative pharmaceutical industry in Australia. [online] Available at: <u>https://www.</u> nedicinesaustralia.com.au/wp-content/uploads/sites/65/2020/11/Economic-Contribution-In vative-Pharma-industry-Australia.p

⁴¹ Rare Cancers Australia, 2024. The true value of investing in cancer treatment. [online] Available at: https://www.rarecancers.org.au/news/483/ the-true-value-of-investing-in-cancer-treatment



Barrier to access 2.3.2 Affordability

Differences in coverage between provinces

• There is no national system for reimbursing companion diagnostics, meaning that access to these essential diagnostic tests varies by province, as well as potential reimbursement caps. While some regions, like Beijing and Fujian offer reimbursement for nextgeneration sequencing (NGS), most patients must pay out-of-pocket, limiting access to these advanced tests

Low reimbursement for precision therapies

- Reimbursement rates for precision therapies are low, and there are significant differences in coverage for diagnostics and therapies
- While some treatments for rare diseases are covered by the National Reimbursement Drug List (NRDL), higher-cost therapies such as cell therapies are often excluded. This is partly due to the policy's focus on a price-volume trade-off, prioritizing price reductions in exchange for a larger patient base. In general, the NRDL is typically negotiated with price ceilings that are intended for large patient populations, which means precision therapy targeted at smaller populations, which still have a low total budget even at higher treatment cost, are disadvantaged⁷⁷. This results in substantial financial burdens for patients, making it difficult for them to access these innovative treatments



Barrier to access 2.3.3 Inadequate data infrastructure

Underdeveloped data infrastructure

- China's data infrastructure for precision therapies remains in its early stages, marked by inadequate data capabilities such as limited cancer databases and insufficient large cohort studies for research and development, and there is a pressing need for substantial investment to enhance these data capabilities
- The lack of data sharing between institutions hinders research and patient care, making it harder to deliver effective treatments and slowing local research and development

2.3.4 Low awareness of precision therapies among stakeholders

Low and limited access to professional education on precision therapies among healthcare professionals

- While the general term of precision therapies is familiar, the actual usage, the treatments available, and how to apply them may not be top of mind for physicians
- Many healthcare providers lack adequate professional training on precision therapies, leading to missed opportunities for accurate diagnosis and access to life-saving treatments.
- · Physicians often rely primarily on costeffective therapies, limiting patient access to newer options that may have better clinical outcomes. Addressing this gap in knowledge is crucial for ensuring that more patients can benefit from precision therapies, particularly for rare diseases

Low patient awareness

• Many patients are unaware of precision therapies and its potential to improve their health outcomes. This lack of public understanding limits their ability to advocate for these therapies in treatment plans. Additionally, patient skepticism about the safety and efficacy of some precision therapies, especially following incidents like the 2016 Wei Zexi case, has further complicated patient willingness to pursue potentially life-saving precision therapies. Bridging these awareness gaps is essential to empowering patients and building a supportive environment for the adoption of advanced and new therapies



2.4 Recommendations

Unlocking the full potential of precision therapies requires well-designed government policies and cooperation among all stakeholders. The government plays a key role in driving partnerships, supporting innovation, and ensuring access through its regulatory frameworks and financial support. This paper outlines three key policy recommendations:

1 Create a supporting environment which promotes innovation 2 Improve the infrastructure for precision therapies



Recommendation 2.4.1 Create a regulatory environment which promotes innovation

1a. Strengthen regulatory approval frameworks

- Advance research on new therapies, medical devices, and diagnostics, while improving the approval and evaluation systems for medical innovations
- Establish a single, streamlined regulatory registration pathway for approving drug device combination therapies and companion diagnostics, either through the current drug approval process or by creating a dedicated working group
- Simplify import inspection requirements for innovative and urgently needed biologic treatments to speed up the registration process and make these therapies available to patients sooner



3 Expand awareness and education on precision therapies

1b. Improve pricing, reimbursement and funding for precision therapies

- Enhance the National Reimbursement Drug List (NRDL) negotiation framework to more explicitly include considerations such as equity, disease severity, quality of life improvements, life expectancy gains and drug costs
- Introduce multi-year evaluations to support the inclusion of high-efficacy and irreplaceable advanced therapeutic options
- Encourage to establish standardized medical device and diagnostics lists to facilitate the provincial procurement process and reimbursement standards for medical device
- Develop value assessment frameworks for medical devices and for diagnostics that fully evaluates benefits
- Explore diversified medical payment methods for precision therapies such as payfor-performance schemes
- Highlight the role of commercial insurance as a complementary payment method, exploring options such as expanded city commercial insurance, encouragements for individuals, employers and/or other groups to purchase private health insurance



Recommendation 2.4.2 Improve the infrastructure for precision therapies

2a. Boost investment in the infrastructure for precision therapies

· Provide strategic incentives to boost investment in critical infrastructure of precision therapies, such as gene banks, biobanks, cancer databases, large population cohort resources, and Alpowered data analysis platforms. Align these incentives with a clear legal framework to ensure the smooth integration of innovative treatments into healthcare systems, promoting both scientific progress and the highest standards of patient care



Recommendation

2.4.3 Expand awareness and education on precision therapies

3a. Develop clinical guidelines and provide further education for healthcare providers and patients

- Develop clear clinical guidelines and expert consensus on the role of precision therapies in treatment pathways. These guidelines will help healthcare providers understand when and how to use precision therapies in patient treatment plans
- Provide healthcare providers with comprehensive and accurate medical information on precision therapies through workshops, seminars, and online learning modules. This will ensure they are well-equipped to incorporate precision therapies into their clinical practice and stay updated on new developments
- Encourage academic medical associations to develop patient-friendly and understandable disease consensus and guidelines, and promote through community organizations, volunteers, and pharmaceutical companies to help patients better understand their conditions. Additionally, increase public media efforts in disease education and awareness to provide patients and the general public with a deeper understanding of diseases

3b. Support the formation and growth of patient advocacy groups

• Encourage the development of patient advocacy groups to raise public awareness about precision therapies. These groups can play a vital role in educating patients, fostering dialogue, and advocating for policies that improve access to these treatments. By connecting individuals with shared experiences, advocacy groups can empower patients, influence public perception and support the wider adoption of precision therapies

3.0 Appendix

Appendix details the approach to quantitative benefits modelling. A range of government data sets, industry data sets, public reports, market reports, and company financial statements have been used as inputs in this modelling. We describe generally how these sources have been used and detail these sources in the bibliography. Advisory committees have reviewed the model methodologies and observed the outputs but were not involved in validating any outputs.

3.1 Modelling methodology



Total annual years of life gained was considered for each of the four key technology types — cell therapy, gene therapy, and targeted antibody and drug-device combinations (the last two were considered together)

For cell therapies, targeted antibody and drua-device combinations

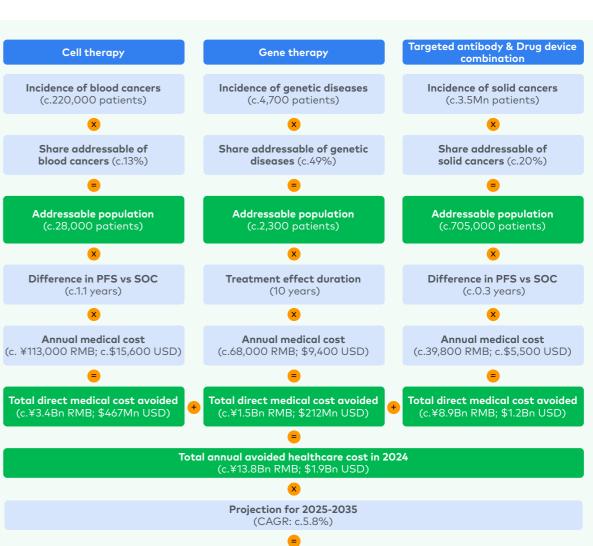
• First, the total addressable patient population was estimated by multiplying the incidence population of cancer patients (blood cancers for cell therapies and solid cancers for targeted antibody and drug device combination therapies using the Global Disease Burden database) by the share of those patients addressable by each technology type (estimated using a range of peer-reviewed global studies)

For gene therapies

• The total addressable patient population was estimated by multiplying the incident population of patients with genetic

diseases (estimated using peer-reviewed global studies) by the share of patients addressable by gene therapies (based on clinical trial data)

- The annual years of life gained for each therapy is estimated by multiplying the addressable population of targeted therapies by the incremental years of life gained over the SoC per patient
- The incremental years of life gained was sourced from peer-reviewed papers and other HTA reports (e.g., Canadian Agency for Drugs and Technologies in Health (CADTH) assessment report). Currently, many of these treatments for cancer are being used as 3rd or 4th line therapy as they have not yet been tested as an early line therapy. If proven successful for earlier line therapy, years of life gained could be significantly higher



Cumulative total avoided healthcare cost 2025-2035 (c. ¥216Bn RMB; \$30Bn USD with c.10.5Mn addressable population)

Total avoided healthcare cost in precision therapies was estimated by considering the total annual direct medical cost avoided for cell therapy, gene therapy, and targeted antibody and drug-device combinations. This includes all direct treatment costs, including medicines, hospitalisation etc.

3.1.2 Avoided healthcare cost

For cell therapies, targeted antibody and drug-device combinations

• First, the total addressable patient population was estimated by multiplying the incidence population of cancer patients (blood cancers for cell therapies and solid cancers for targeted antibody and drug device combination therapies using the Global Disease Burden database) by the share of those patients addressable by each technology type

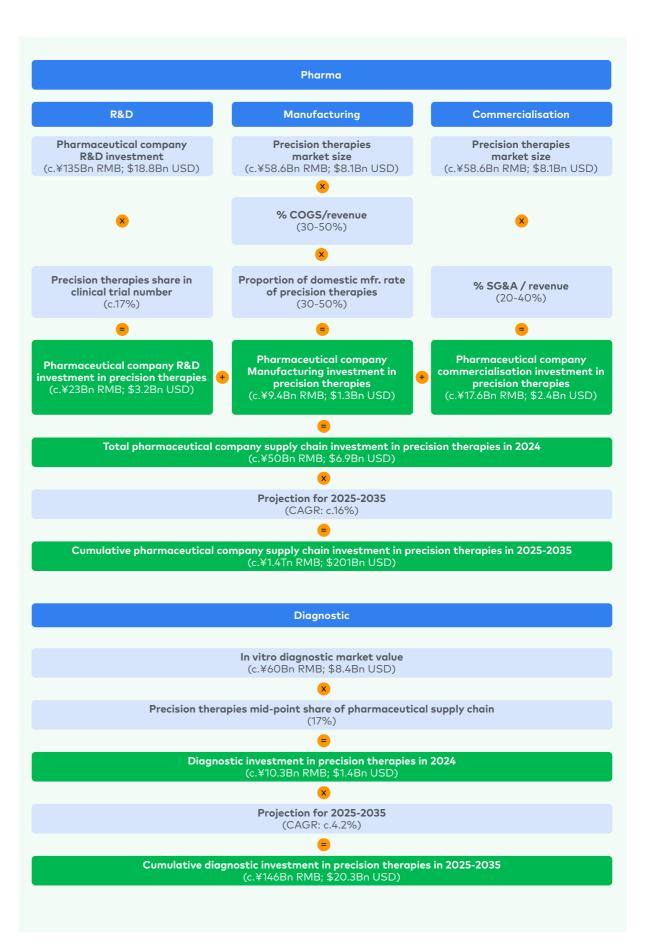
(estimated using a range of peer-reviewed global studies)

Then we calculated the avoided healthcare cost per patient by multiplying the incremental length of Progression-Free Survival (PFS) per patient realised by precision therapies compared to Standard of Care (SoC) with the average cost of SoC per patient. Both these inputs were derived from peer-reviewed global studies such as clinical trials, government reports and national health expenditure data. Currently, many of these treatments are being used as 3rd or 4th line therapy as they have not yet been tested as an early line therapy. If proven successful for earlier line therapy, Difference in PFS between 'precision therapies and SOC per patient would likely be even greater

3.1.3 Industry economic investment

For gene therapies

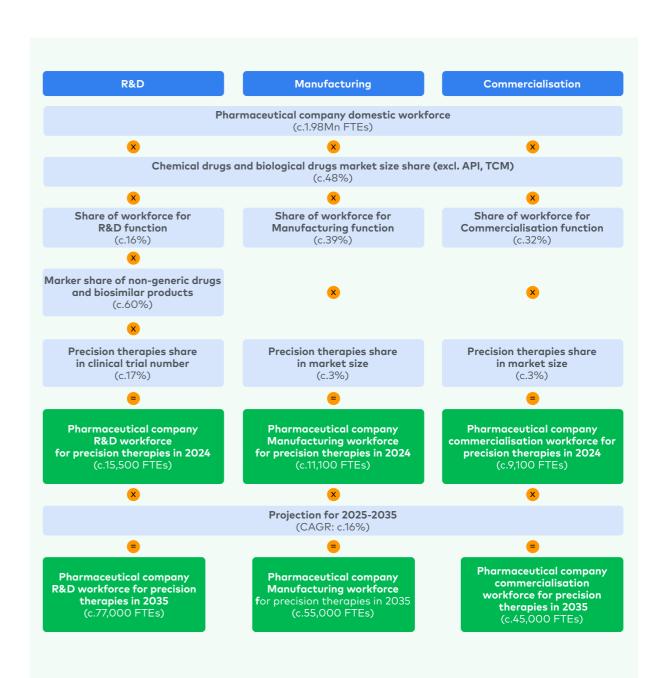
• The total addressable patient population was estimated by multiplying the incident population of patients with genetic diseases (estimated using peer-reviewed global studies) by the share of patients addressable by gene therapies (based on clinical trial data) Then we calculated the avoided healthcare cost per patient by estimating the treatment effect duration (given the lack of long-term efficacy data for gene therapies) multiplied by average cost of SoC per patient (estimated using a range of peer-reviewed studies and national health expenditure data)



3.1.4 FTE

- Total economic investment in precision therapies was estimated by considering the investments in R&D, manufacturing, commercialisation (e.g., sales & marketing, market access, etc.) in 2024
- R&D investment was estimated by multiplying total pharmaceutical company investment in R&D in 2024 by the proportion of that investment spent on precision therapies (share of total clinical trials categorised as precision therapies from 2020-23 used as a proxy based on Pharmaprojects data)
- Manufacturing investment was estimated by multiplying total market size of precision therapies in 2024 by an estimated proportion of manufacturing spending (estimated through benchmarking % COGS of listed pharmaceutical companies with a focus on precision therapies in China using financial reports) and an estimated proportion of internal manufacturing rate of precision therapies (estimated though benchmarking domestic manufacturing rate of monoclonal antibodies based on DXY database)

- Commercialisation investment was estimated by multiplying the total market size for precision therapies in 2024 by an estimated proportion of SG&A spend (estimated through benchmarking listed pharmaceutical companies with a focus on precision therapies and oncology in China)
- Diagnostics supply chain investment was estimated based on the total in-vitro market value (based on market reports) and applying the proportionate weighted average share of precision therapies as applied to the pharmaceutical supply chain
- The total annual investment values include investments in the supply chain as well as FTE



- The total number of jobs supported in precision therapies was estimated by considering jobs supported in R&D, manufacturing, and commercialisation
- Jobs supported in R&D were estimated by multiplying the total number of employees in the pharmaceutical company in China in R&D functions in 2024 (estimated by multiplying the total targeted pharmaceutical industry workforce by

share of R&D functions of 300 listed pharmaceutical companies in China in 2017 as proxy) and the share of non-generic drug and biosimilar products market size share (based on market report) and the proportion of jobs supported in precision therapies (which was estimated by the share of total clinical trials categorised as precision therapies from 2020-23 as a proxy based on Pharmaprojects data)

References

- Jobs supported in manufacturing were estimated by multiplying the total number of employees in the pharmaceutical company in China in manufacturing in 2024 (estimated by multiplying the total targeted pharmaceutical industry workforce by share of manufacturing of 300 listed pharmaceutical companies in China in 2017 as proxy) by the proportion of the overall pharmaceutical market size attributable to precision therapies (estimated through benchmarking the share of precision therapies in China as a proxy)
- Jobs supported in commercialisation were estimated by multiplying the total number of employees in the targeted pharmaceutical company in China in commercialisation in 2024 (estimated by multiplying the total targeted pharmaceutical industry workforce by share of commercialisation of 300 listed pharmaceutical companies in China in 2017 as proxy), and the proportion of the overall pharmaceutical market size attributable to precision therapies (estimated through benchmarking the share of precision therapies in China as a proxy)

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Helen Chen is Global Sector Co-Head for Healthcare and a Greater China Managing Partner of L.E.K. Consulting based in Shanghai. She is also a Director of the firm's Asia-Pacific Life Sciences Centre of Excellence. Helen was named one of Consulting magazine's Global Leaders in Consulting in 2019.

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