LEK™

South Korea

# On the Cusp of a Cure

## Is Asia Pacific Ready for the Precision Era?

LEK™

# On the Cusp of a Cure

## Is Asia Pacific Ready for the Precision Era?

# Acknowledgements

L.E.K. Consulting would like to acknowledge the contributions of all the Advisory Committee members who have provided critical insights into the development of this report. Specifically, their contributions have guided the assessment of barriers facing the adoption of precision therapies and recommendations to addressing these barriers.

| Name | Position | Organisation |
|---|---|---|
| **Australia** | | |
| David Thomas | Chief Scientific Officer | Omico |
| Jaala Pulford | Chair of the Board | MTPConnect |
| Christine Cockburn | CEO | Rare Cancers Australia |
| **China** | | |
| Baorong Yu | Professor and market access key opinion leader | University of International Business and Economics |
| Andy Mok | Head of China | Guardant Health |
| Kevin Huang | Founder and President | China Organization for Rare Disorders (CORD) |
| Zhou Caicun | Professor and lung cancer key opinion leader | School of Medicine, Tongji University |
| **Japan** | | |
| Teruyuki Katori | Representative Director<br>Specially Appointed Professor | Future Institute Wolong, General Incorporated Association<br>Graduate School of Social Sciences, University of Hyogo |
| Daisuke Sato | Professor | Fujita Health university |
| Manabu Muto | Professor | Kyoto University Graduate School of Medicine |
| Masahiro Miyake | Professor | Kyoto University Hospital |
| Naomi Sakurai | Founder and CEO | Cancer Solutions |
| Keisuke Shimizu | Leader | Lung cancer HER2 "HER HER" |
| **South Korea** | | |
| Paul Lee | Former GM | Gilead Sciences Korea |
| Jin-Ah Kim | Advocate for rare diseases | Seoul National University Hospital, Department of Genomic Medicine, Rare Disease Centers |
| Prof Jeonghoon Ahn | Professor of Health Convergence | Ewha University |

This report was sponsored by Johnson & Johnson. The research and writing of this report was conducted independently and reflects the unbiased analysis and conclusions of the authors.

## Disclaimer

# Contents

# 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). Cutting-edge 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 genomic profiling are transforming our understanding of what causes disease and are enabling researchers to predict treatment suitability and outcomes more accurately for patients.**

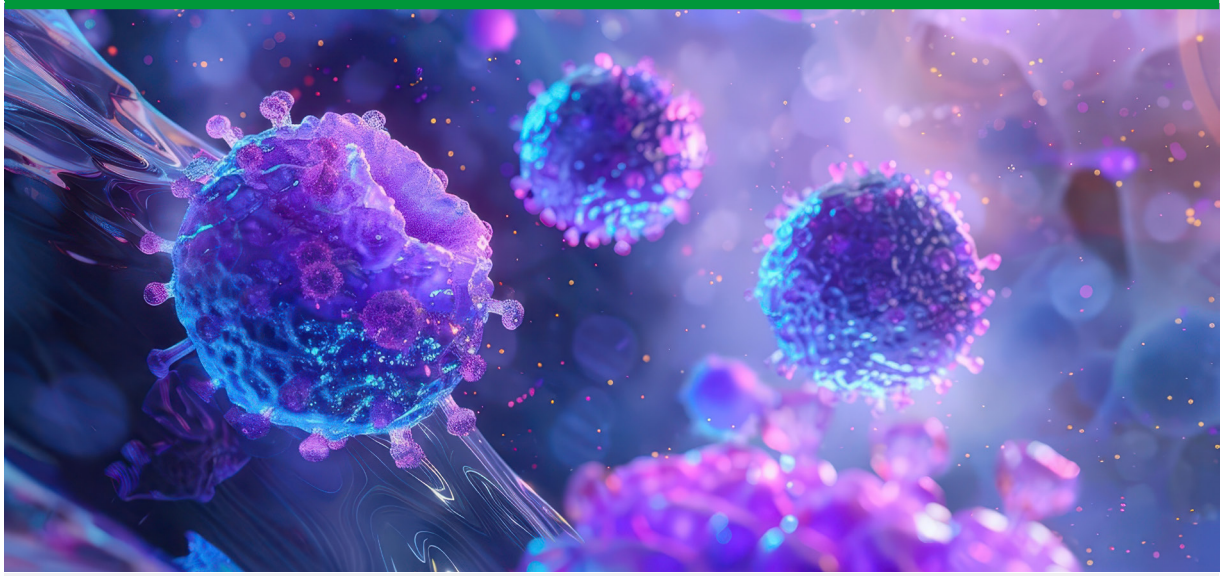
As a result of these advances, we are entering a transformative period in medicine — the 'Precision Era', where the fundamental way in which patients are treated is being redefined. In the Precision Era, medicines will move away from being generically prescribed and administered, small molecule treatments 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 4,000[1] 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



CAR-T cell therapy represents a groundbreaking advancement in cancer treatment, for blood cancers like diffuse large B-cell lymphoma (DLBCL), the most common form of non-Hodgkin lymphoma. While the five-year relative survival of DLBCL is 70%, approximately 30%-40% of patients will progress to relapsed/refractory disease.[2,3] The current care regime for DLBCL involves treatment with chemotherapy and radiotherapy, but one in three DLBCL patients will not respond or will relapse following first-line treatment.[4]

For Jin, who was diagnosed with DLBCL in his mid-thirties, CAR-T cell therapy provided a lifeline from this disease. While initial chemotherapy treatment showed progress in reducing his tumour size, by six rounds of chemotherapy, and an additional round of radiotherapy, the cancer was growing aggressively. It was at this point that his doctors recommended CAR-T therapy. Less than two months after his treatment, Jin's tumour disappeared. Jin has now been cancer free for over a year. He is now able to drop his kids off at school, has returned to work and has started coaching his daughter's soccer team.

Over 9,000 South Koreans will receive a diagnosis of relapsed/refractory (stage 4) DLBCL between 2025 and 2035. With access to CAR-T therapy, and inclusion in earlier line therapy, the clinical benefits of this treatment will be life changing.

Each of these technologies is 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.

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 genetic 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: https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/minister-for-health-and-aged-care-press-conference-28-august-2024

[2] Crump, M. et al., 2017. Outcomes in refractory diffuse large B-cell lymphoma: Results from the international SCHOLAR-1 study. Blood, 130(16), 1800–1808. Available at: https://ashpublications.org/blood/article/130/16/1800/36474/Outcomes-in-refractory-diffuse-large-B-cell

[3] Kesireddy, M., Lunning, M.A., 2022. Relapsed or refractory diffuse large B-cell lymphoma: "Dazed and confused". Oncology, 36(6), pp. 366-375. Available at: https://www.cancernetwork.com/view/journal-relapsed-or-refractory-diffuse-large-b-cell-lymphoma-dazed-and-confused

[4] Rare Cancers Australia, 2024. Belinda Trial: CAR-T Therapy Delivered Earlier for Relapsed/Refractory Aggressive Non-Hodgkin Lymphoma Patients. [online] Available at: https://www.rarecancers.org.au/news/346/belinda-trial-car-t-therapy-delivered-earlier-for-relapsedrefractory-aggressive-non-hodgkin-lymphoma-patients

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.

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

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.

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.[5]

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 South Korea, 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 South Koreans and to the South Korean economy. Realising these benefits will require a coordinated effort across all stakeholders involved — industry, government, clinicians and the broader healthcare workforce, researchers and investors. If such coordinated action is not taken, South Korea risks ever-increasing healthcare expenditure that compromises social equity and justice and delivers sub-optimal health outcomes for South Koreans.

## South Korea

**Benefits (10 year cumulative view)**

**400k patients**
with improved treatments & outcomes, including access to precision therapies, supporting diagnostics and clinical trials

**Over**
**₩2.2Tn KRW**
in avoided healthcare costs through curative treatments for previously untreatable diseases

**₩60Tn KRW**
invested across R&D, diagnostics and manufacturing supporting development of new skills and expertise

**Potential of**
**₩360Tn KRW**
in economic activity and 120,000 jobs generated through multiplier effects of investment and patient benefits across the broader community

# South Korea

## Solutions

### Build a framework that integrates the public sector and industry to foster innovation and expand access to precision therapies

- Increase PAG participation in pricing and reimbursement negotiations
- Revise the HTA evaluation framework to account for benefits beyond QALY gains including patient well-being, workforce participation and reduced social welfare costs
- Strengthen reimbursement and pricing frameworks to better accommodate innovative treatments, including a single reimbursement and pricing pathway for drug-device combination therapies and companion diagnostics
- Expand National Health Insurance coverage for diagnostic testing to improve access to precision therapies
- Expand pay-for-performance schemes across a broader range of medical conditions

### Strengthen data privacy laws and establish effective genomic data infrastructure to enhance R&D in precision therapies

- Improve genomic data access laws to encourage R&D while ensuring patient privacy to increase patient willingness to share their data
- Standardise genomic data collection across healthcare institutions to streamline analysis and reduce manual efforts

### Increase education and understanding of precision therapies among healthcare professionals, patients, the public and government officials

- Design and implement practical training modules to educate physicians about precision therapies, in collaboration with relevant physician organisations and key opinion leaders, to promote wider use by healthcare providers
- Raise public health literacy on genomics through health education campaigns
- Make healthcare pathway and clinical trial information more accessible to patients in language that is easily understood by the public

[5] Jackson, Stuart and Trakhtenberg, Ilya, 2025, Predictable Winners, Stanford University Press

# 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 ten 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 ten 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 outcomes** | **250k** patients | **10.5Mn** patients | **1.5Mn** patients | **400k** 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 healthcare costs** | **$2.6Bn** AUD | **¥216Bn** RMB | **¥860Bn** JPY | **₩2.2Tn** KRW |

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 | Common solutions |
|---|---|---|
| 1 | **The first was the lack of a clear, fit-for-purpose regulatory and reimbursement pathways to properly evaluate these paradigm-shifting precision therapies**<br>The impact of this being delayed access to therapies by patients and lower reimbursement for diagnostics and novel therapies, resulting in higher out-of-pocket costs and affordability constraints | **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**<br>Including more timely access to diagnostics, curative therapies for patients, improved affordability either through pricing, reimbursement or insurance programs for both treatments and diagnostics |
| 2 | **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**<br>The impact of this being potential misdiagnosis and delays, reluctance of treating physicians to prescribe patients novel therapies and difficulty in access and navigation of the environment by patients | **Increase efforts to educate healthcare providers, patients and the broader public about precision therapies**<br>Supporting healthcare providers with clinical guidelines and medical information on these innovative therapies and assisting them and advocacy groups in navigating the complex patient pathways |
| 3 | **Key healthcare infrastructure and investment to support patient access to these medicines**<br>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 | **Encourage cross-sectoral collaboration between the public sector and healthcare industry to foster innovation and promote access**<br>Supporting industry to continue its investment into new therapies and diagnostic tools locally, to improve in-country accessibility and the development of local resources and talent |

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, the healthcare industry, its professionals and patient advocacy groups must all work together collaboratively to ensure the full potential of the precision therapies is realised.

# 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 providing cures. Over the last 30 to 40 years, medical advancements have accelerated, driven by advances in technology and our understanding of the human genome.

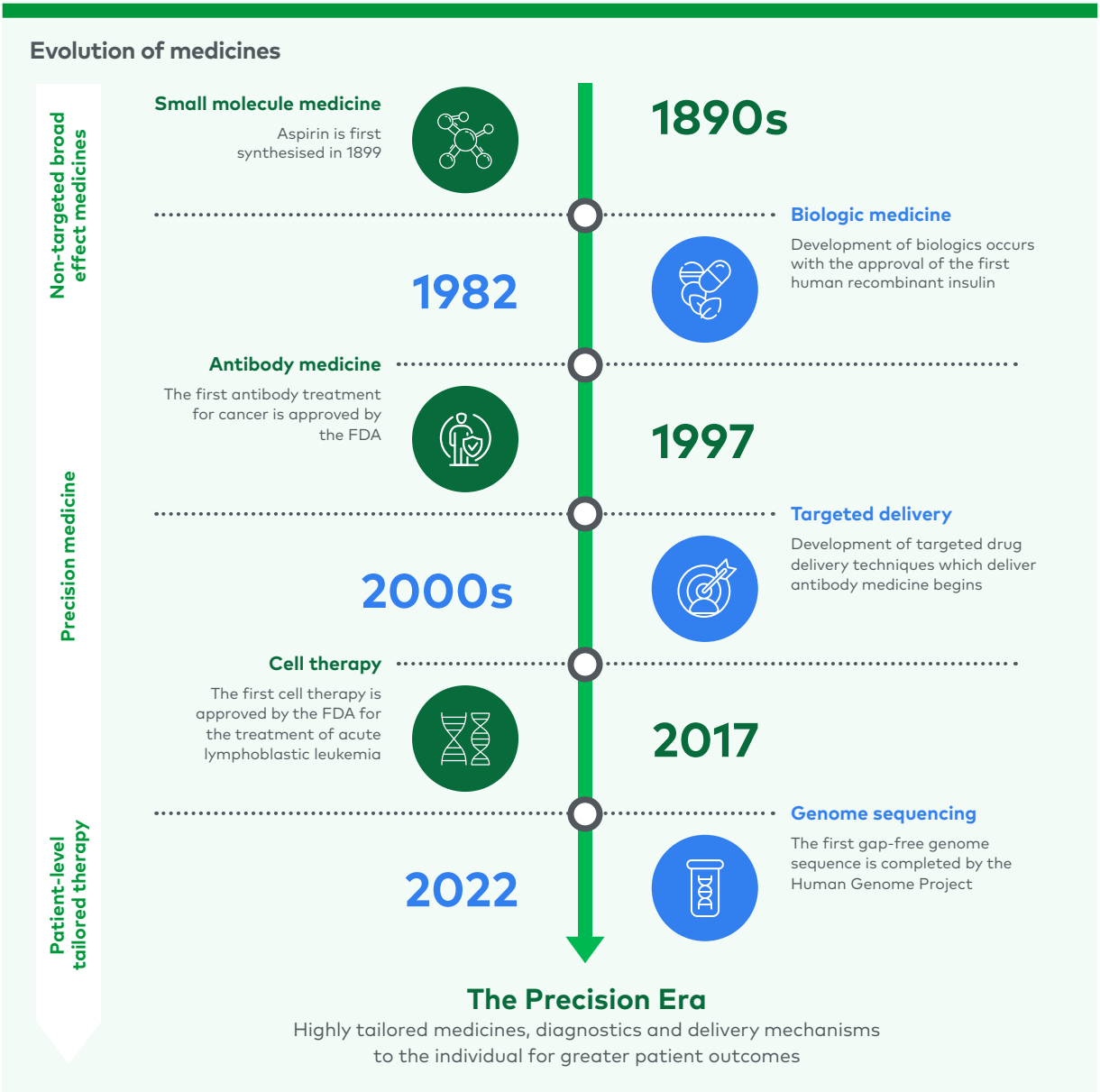
In the late 20th century, biologics — natural molecules in humans and animals — were developed to address disease symptoms more effectively.

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



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.[6]

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

In the context of an increasing burden of disease, this innovation is critical. Precision therapies are becoming the gold standard in personalised treatment and to date, has largely been aimed at treating cancer — one of the leading causes of death in APAC and globally.[7] 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.[8]

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

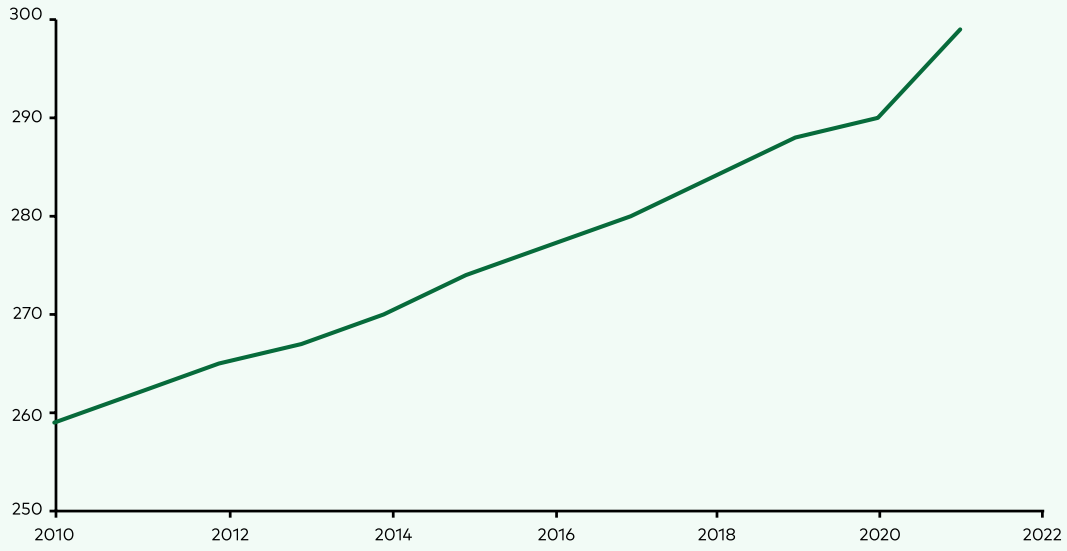
Over the next five to ten years, the pharmaceutical and biotechnology industries are expected to deliver a surge of precision therapies, especially in oncology, immunology, and neurology. In cell and gene therapies alone, nearly 4,000 therapies are currently being developed around the world.[9]

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.[10] These 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 or regular doses. Instead, highly individualised 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

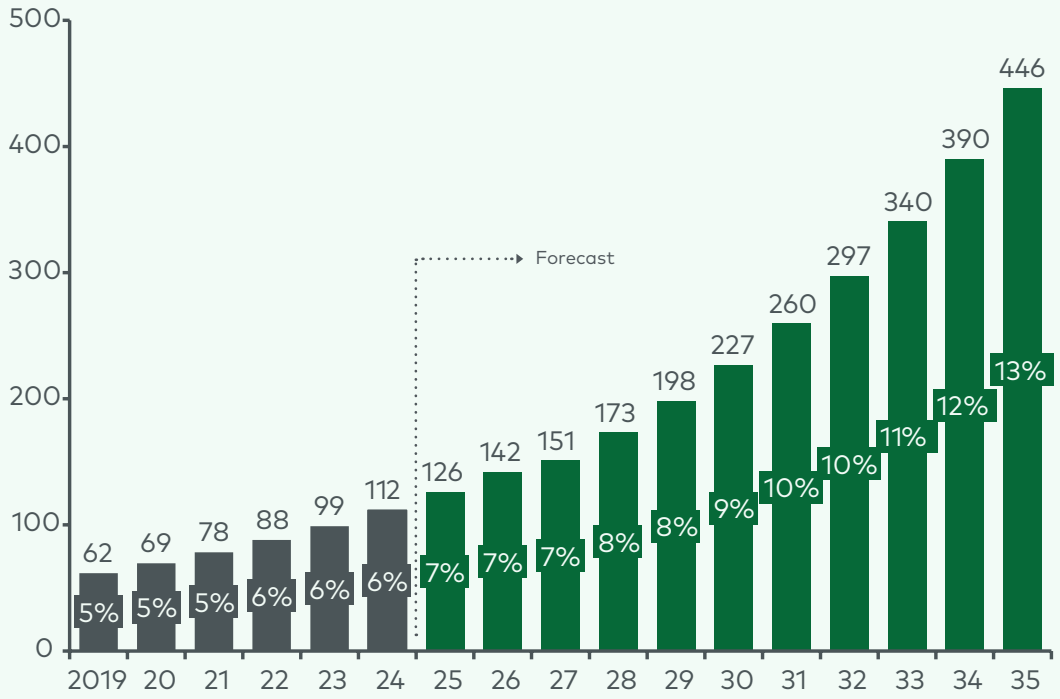



[6] National Institutes of Health (NIH), 2022. Researchers generate the first complete, gapless sequence of a human genome. [online] Available at: https://www.nih.gov/news-events/news-releases/researchers-generate-first-complete-gapless-sequence-human-genome
[7] Institute for Health Metrics and Evaluation (IHME), 2024. Global Burden of Disease (GBD) Data. [online] Available at: https://www.healthdata.org/research-analysis/gbd-data
[8] Institute for Health Metrics and Evaluation (IHME), 2024. Global Burden of Disease (GBD) Results. [online] Available at: https://vizhub.healthdata.org/gbd-results/
[9] Australian Government Department of Health and Aged Care, 2024. Minister for Health and Aged Care press conference — 28 August 2024. [online] Available at: https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/minister-for-health-and-aged-care-press-conference-28-august-2024
[10] European Commission, 2024. Rare diseases. [online] Available at: https://health.ec.europa.eu/rare-diseases-and-european-reference-networks/rare-diseases_en

# 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%.[11, 12]

**Indicative global market size for precision therapies (2019-35)**
$ Bn of USD (percent of pharmaceutical market)




[11] 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/
[12] IQVIA, 2024. The global use of medicines 2024: Outlook to 2028. [online] Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-global-use-of-medicines-2024-outlook-to-2028

## Several factors are driving the rapid growth of precision therapies

**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 precision therapies development, driven by the promise of improved patient outcomes

**Diagnostic advancements**

- Advanced diagnostic techniques (e.g., next-generation 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 post-treatment surveillance)

**Big data and AI**

- 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

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.
- **Regulatory bodies** must 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 more accurately identify patients most likely to benefit from treatment.

**Technology types assessed for the purposes of this report** [13]

**Cell therapy**

Cell therapies 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 therapies treat or prevent disease by correcting disease-causing DNA mutations in patients

**Targeted antibody therapy**

Antibody therapies 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 therapies 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 therapies 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

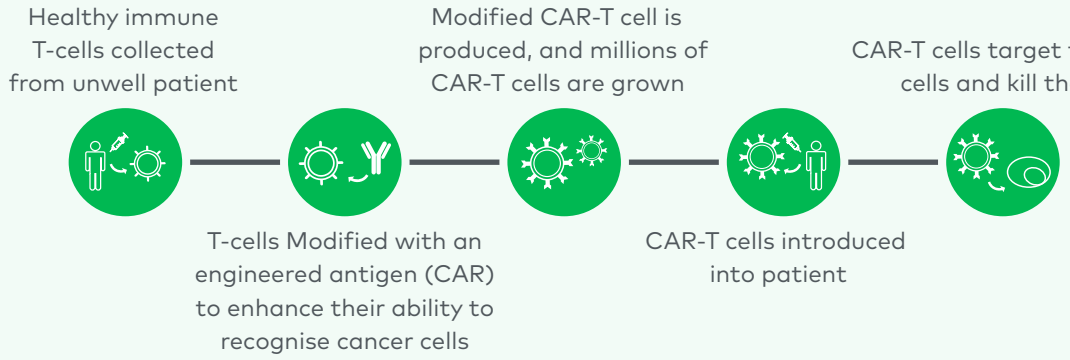
## 1.3.1 Cell therapy

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 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.[14]

**CAR-T technology for cancer cell elimination** [13]




[13] Sheykhhasan M., 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
[14] 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

## 1.3.2 Gene therapy

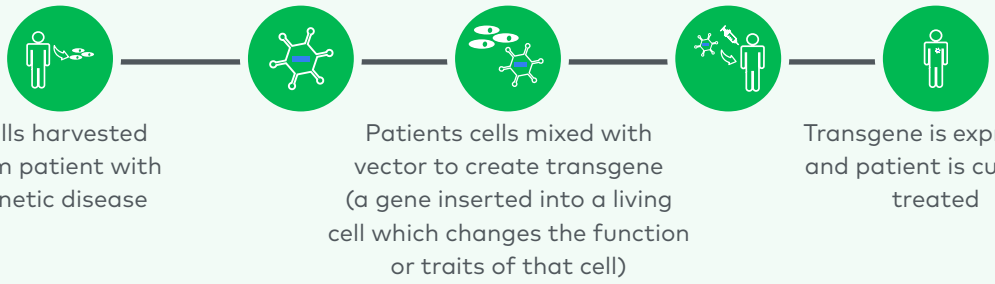
Most key functions in cells are carried by proteins, which carry out these functions based on the information provided by DNA. "Typos" or errors in our DNA can lead to a partial or complete loss of these cell functions. This is the origin of genetic disease.

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.[15]

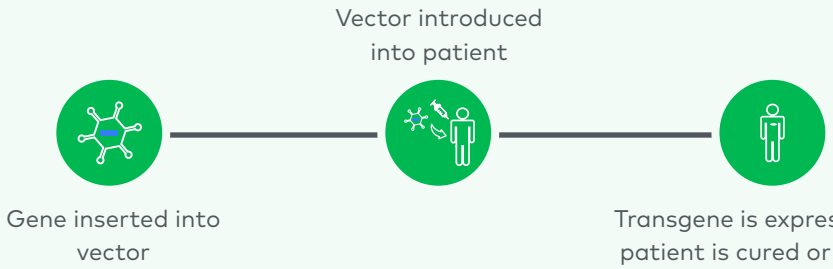
Gene therapy involves modifying a patient's genes outside the body by mixing them with a vector before returning them to the patient or by delivering the genes with vectors directly into the patient's body.

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

**Ex vivo gene therapy**




**In vivo gene therapy**




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

## 1.3.3 Antibody therapy

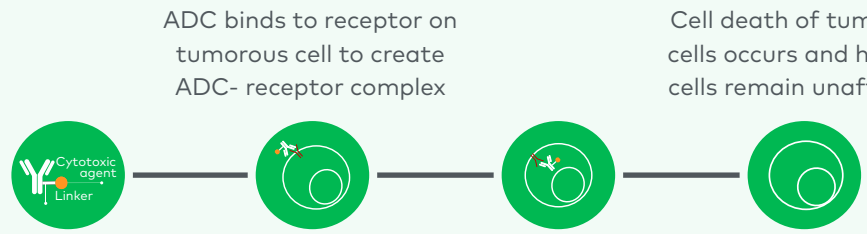
Antibody therapies allow the targeted treatment of a broad variety of diseases ranging from cancer to autoimmune conditions. Antibody therapies are commonly being used to treat a range of solid tumour cancers like lung, colorectal and melanoma.

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.

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 work 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.

**Antibody-drug conjugate therapy**




## 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, are 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 tumour growth

Wafer containing slow-release chemotherapy surgically inserted into patient

## 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.

**Comprehensive genomic profiling**

Tumour tissue or blood sample taken from unwell patient

Genetic material from sample is analysed using next-generation sequencing (NGS) technology

The genomic data is interpreted to identify genetic mutations 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 South Korea:

1. **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 precision therapies
3. **Recommendations** to progress precision therapies 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 therapies and treatment paradigms available today for patients in precision therapies, 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 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 benefits have been modelled conservatively based on the therapies and treatment paradigms available today for patients in precision therapies, leveraging existing clinical data.**

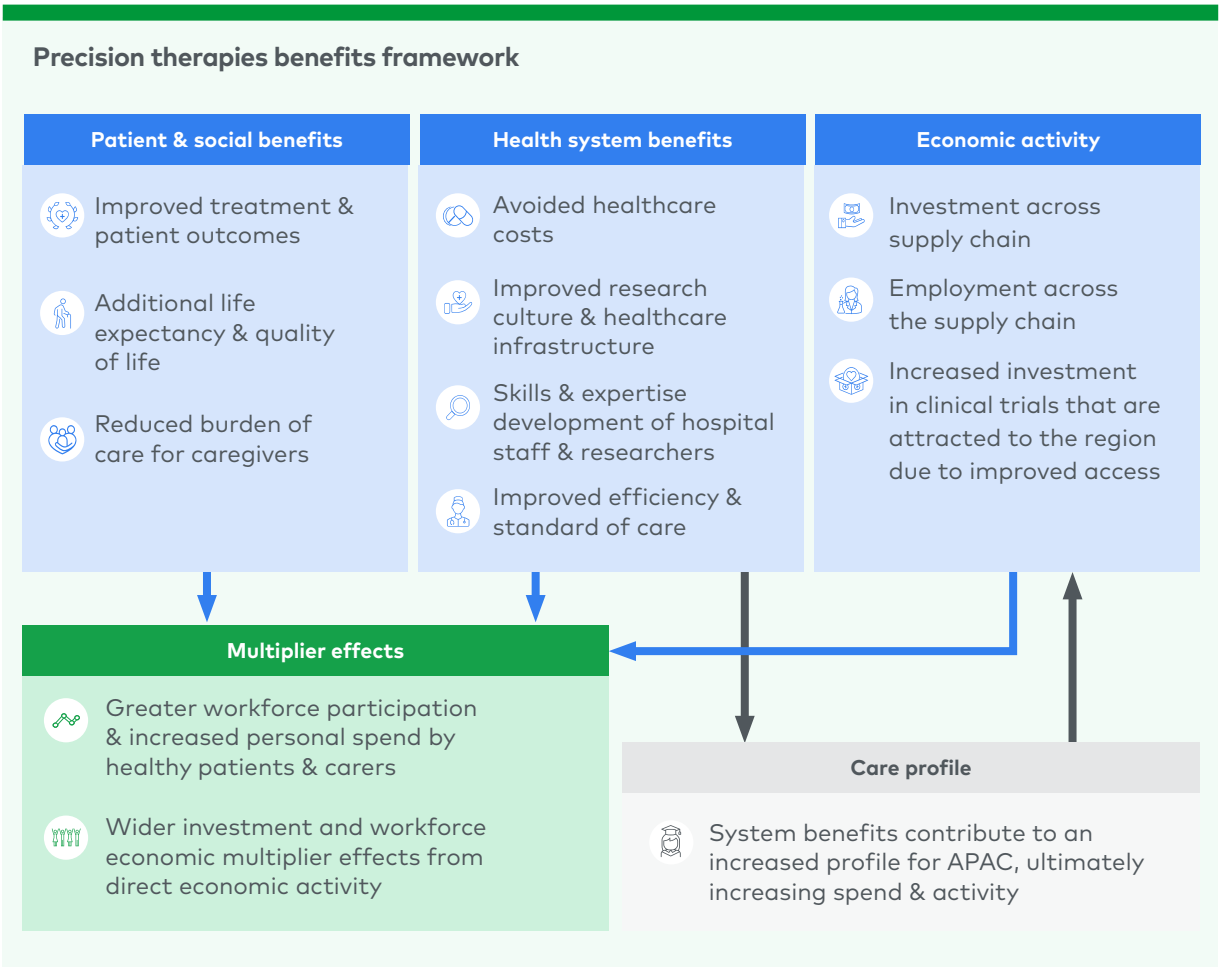
The actual benefits realised may be much greater over time as more such therapies become available earlier to patients in their treatment journey and deliver benefits to not only a larger number of patients, but also deliver even greater benefits to each patient through earlier treatment.

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** 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 therapies that are expected to be precision therapies related 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 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, healthcare professionals, patients, patient advocacy group representatives, current and former industry representatives, and in some countries, previous government ministers. 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.

# 2.0 South Korea

# 2.1 Introduction

South Korea has a strong pharmaceutical industry and is recognised as a leading location for clinical trials in the APAC region and globally. In the pursuit of innovation and expanding access to precision therapies, South Korea is well positioned to become a regional leader in the growth of this market.

**South Korea has a strong pharmaceutical industry and is recognised as a leading location for clinical trials across APAC. Together with its pursuit of expanding access to precision therapies, South Korea is well positioned to become a regional leader.**

The South Korean government has demonstrated its commitment to this industry. In 2016, 'Personalised medicine' was designated as a national strategic project and there has been strong government investment through the Korea Drug Development Fund (KDDF) to support innovation by Korean-based companies. This planning and investment is essential to advancing an industry which is fundamentally transforming health care.

Through the National Health Insurance Service (National Health Insurance), South Korea provides high-quality healthcare to all citizens. However, while the low pricing of medicines under National Health Insurance ensures widespread access, it makes it difficult for pharmaceutical companies to recover the costs of developing individualised and novel medicines. This can discourage companies from introducing new treatments to the South Korean market.

In the area of rare diseases, South Korea faces additional challenges, particularly due to the stigma associated with rare and genetic disease diagnoses.[16] As a result, access to effective care and treatment remains a significant issue for those living with rare genetic conditions. A 2020 report revealed that over 70% of patients with a rare disease in South Korea did not have access to the best evidence-based care.[17]

Furthermore, healthcare budgets are often seen as an expenditure, rather than an investment in people's health, limiting the potential for long-term benefits in healthcare innovation.

**In the area of rare diseases, South Korea faces additional challenges, particularly due to the stigma associated with rare and genetic disease diagnoses.[16] As a result, access to effective care and treatment remains a significant issue for those living with rare genetic conditions.**

[16] Baynam, G., Gomez, R. and Jain, R., 2024. Stigma associated with genetic testing for rare diseases-causes and recommendations. Frontiers in Genetics, 15, p.1335768. Available at: https://doi.org/10.3389/fgene.2024.1335768
[17] The Economist, 2020. Suffering in silence: Assessing rare disease awareness and management in South Korea. [online] Available at: https://www.cslbehring.co.jp/-/media/shared/economist-white-paper/eng_snapshot_a4_digital-south-korea-final.pdf

# 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 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 latest generation of precision therapies, 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.

**Cumulative benefits of precision therapies** (2025-35)

**Patient & social benefits**

- Improved **treatment & patient outcomes** for **c.389,000 addressable patients**
- **c.325,000 cumulative years of life gained** across the addressable patient pool
- **Reduced burden of care for c.350,000-389,000 caregivers** as a result of patients treated

**Health system benefits**

- **c.₩2.2Tn KRW ($1.6Bn 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**

**Economic activity**

- **c.₩61Tn KRW ($45Bn USD) invested** across the **pharmaceutical value chain** as well as **c.₩16T KRW ($12Bn USD)** in the **diagnostics value chain**
- Supporting up to **c.20,000 highly skilled jobs** in the **pharmaceutical value chain** with additional jobs in the **diagnostics industry and health system**
- **Clinical trial activity generating ₩11-16Tn KRW** ($0.8-1.2Bn USD), providing patients with often **free treatment access** and **upskilling the healthcare workforce**

**Multiplier effects**

- Greater **workforce participation, increased personal spend** by **c.389,000 healthy patients & c.350,000-389,000 caregivers**
- **Economic multiplier effects** from economic activity of 1-6x generating **₩61-366Tn KRW ($45-271Bn USD)** and supporting **20,000-120,000 jobs**

## 2.2.1 Patient & social benefits

Precision therapies have the potential to significantly improve health outcomes for at least 390,000 Koreans between 2025 and 2035. These improvements will come from several factors:

1. More effective and longer-lasting treatments,
2. Availability of therapies for diseases that were previously untreatable, and
3. Safer treatments that are more precisely targeted to individual patients.

Over the next ten years, these therapies could add at least 325,000 additional years of life for the eligible patient population.

**Precision therapies have the potential to significantly improve health outcomes for at least 390,000 Koreans between 2025 and 2035.**

Further benefits are expected as existing therapies are expanded and used earlier in patients' treatment journeys. 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. 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.[18] Additionally, as innovation continues and new therapies are developed for a wider range of diseases, more patients will have access to these life-changing treatments.[19]

For example, CAR-T therapies are currently used for patients with refractory or relapsed blood cancer who have received at least three prior treatments. However, research has shown that using CAR-T therapy earlier leads to better survival rates. If made available earlier, a larger group of patients could benefit from these treatments.[20]

**Additional patient life years**

| | Incident addressable patients (2025-35) | Additional life years per patient with precision therapies compared to SoC | Total additional life years from precision therapies (2025-35) |
|---|---|---|---|
| **Cell therapy** | **14,946** blood cancer patients | **3.4** life years | **51,007** life years across population |
| **Gene therapy** | **702** rare genetic disease patients | **7.87** life years | **5,520** life years across population |
| **Targeted antibody & drug device combination therapy** | **373,472** solid tumour cancer patients | **0.72** life years | **268,450** life years across population |

Additionally, life expectancy increases can be expected as these therapies reach a broader population. For example, in 2025, more than 40 people will be born with retinitis pigmentosa, a degenerative eye disease that leads to vision loss. Less than 8% of these people will have the necessary genetic mutations to qualify for gene therapy.[21, 22, 23] However, the overall number of South Koreans living with retinitis pigmentosa is estimated at 8,000, with about 300 potentially eligible for gene therapy treatment to halt or slow the disease's progression.[24]

This means the short-term impact of these therapies, once available will likely be much greater.[25]

Beyond extending life expectancy, precision therapies offer significant social benefits to patients, caregivers and the wider community.

**With broader access to these therapies, caregiving responsibilities for between 350,000 to 389,000 South Koreans could be significantly reduced.**

Precision therapies can also reduce the need for long-term caregiving by approximately 350,000 to 389,000 caregivers. By improving treatment outcomes, it relieves caregivers of their extended responsibilities and eases both the psychological and economic burdens faced by cancer patients and their caregivers.

**Precision therapies impact on patients' families and caregivers**

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

Ability to experience life milestones and participate in the community

Enhanced physical, cognitive, emotional and social functioning

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

[18] 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
[19] AstraZeneca, 2024. Precision Medicine. [online] Available at: https://www.astrazeneca.com/r-d/precision-medicine.html
[20] OncLive, 2024. Quadruplet therapy and early-line CAR T-cell therapy approvals mark shifting standards in multiple myeloma. [online] Available at: https://www.onclive.com/view/quadruplet-therapy-and-early-line-car-t-cell-therapy-approvals-mark-shifting-standards-in-multiple-myeloma
[21] Rim, T.H., Park, H.W., Kim, D.W. and Chung, E.J., 2017. Four-year nationwide incidence of retinitis pigmentosa in South Korea: a population-based retrospective study from 2011 to 2014. BMJ Open, 7(5), p.e015531. Available at: https://doi.org/10.1136/bmjopen-2016-015531
[22] 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/
[23] MiVision, 2022. Landmark Government Funding for Luxturna IRD Treatment. [online] Available at: https://mivision.com.au/2022/03/landmark-government-funding-for-luxturna-ird-treatment/
[24] Rim, T.H., Park, H.W., Kim, D.W. and Chung, E.J., 2017. Four-year nationwide incidence of retinitis pigmentosa in South Korea: a population-based retrospective study from 2011 to 2014. BMJ Open, 7(5), p.e015531. Available at: https://doi.org/10.1136/bmjopen-2016-015531
[25] Retina Australia, 2024. Retinitis Pigmentosa (RP). [online] Available at: https://retinaaustralia.com.au/resources/retinitis-pigmentosa-rp/

## 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 could lead to significant savings for South Korea's healthcare system. These savings come from reducing hospital admissions, specialist visits and follow-up treatments for patients using these innovative therapies. For genetic diseases, gene therapy can help patients recover or greatly improve their health, reducing overall medical costs.

It is estimated that precision therapies could save ₩2.2Tn KRW ($1.6Bn USD) in healthcare costs between 2025 and 2035, benefiting around 389,000 patients.

**Between 2025-25 the healthcare system could save around 2.2Tn KRW, enough to treat 389,000 patients.**

For example, treating 15,000 blood cancer patients with cell therapies could save around ₩339Bn KRW ($251Mn USD) in healthcare costs during this period. These savings could be even higher if such treatments are approved for earlier use.

**Avoided healthcare costs**

| | Incident addressable patients (2025-35) | Average avoided healthcare costs per patient | Total avoided healthcare costs (2025-35) |
|---|---|---|---|
| **Cell therapy** | **14,946** blood cancer patients | **₩22.65Mn KRW** ($17,000 USD) | **₩338.591Bn KRW** ($251Mn USD) total savings |
| **Gene therapy** | **702** rare genetic disease patients | **₩422.16Mn KRW** ($313,000 USD) | **₩296.14Bn KRW** ($219Mn USD) total savings |
| **Targeted antibody &drug device combination therapy** | **373,472** solid tumour cancer patients | **₩4.07Mn KRW** ($3,000 USD) | **₩1.52Tn KRW** ($1.1Bn USD) total savings |

#### 2.2.2.2 Improved research culture and healthcare infrastructure

Investing in precision therapies fosters a research culture that encourages the development of cutting-edge research facilities such as genomic databases and biobanks. These resources are crucial for high-quality research and translating discoveries into clinical practice.

Initiatives like the Korea Biobank Project, led by the National Biobank of Korea, collect and manage bioresources to study disease patterns and develop targeted therapies, playing a key role in supporting healthcare innovation.

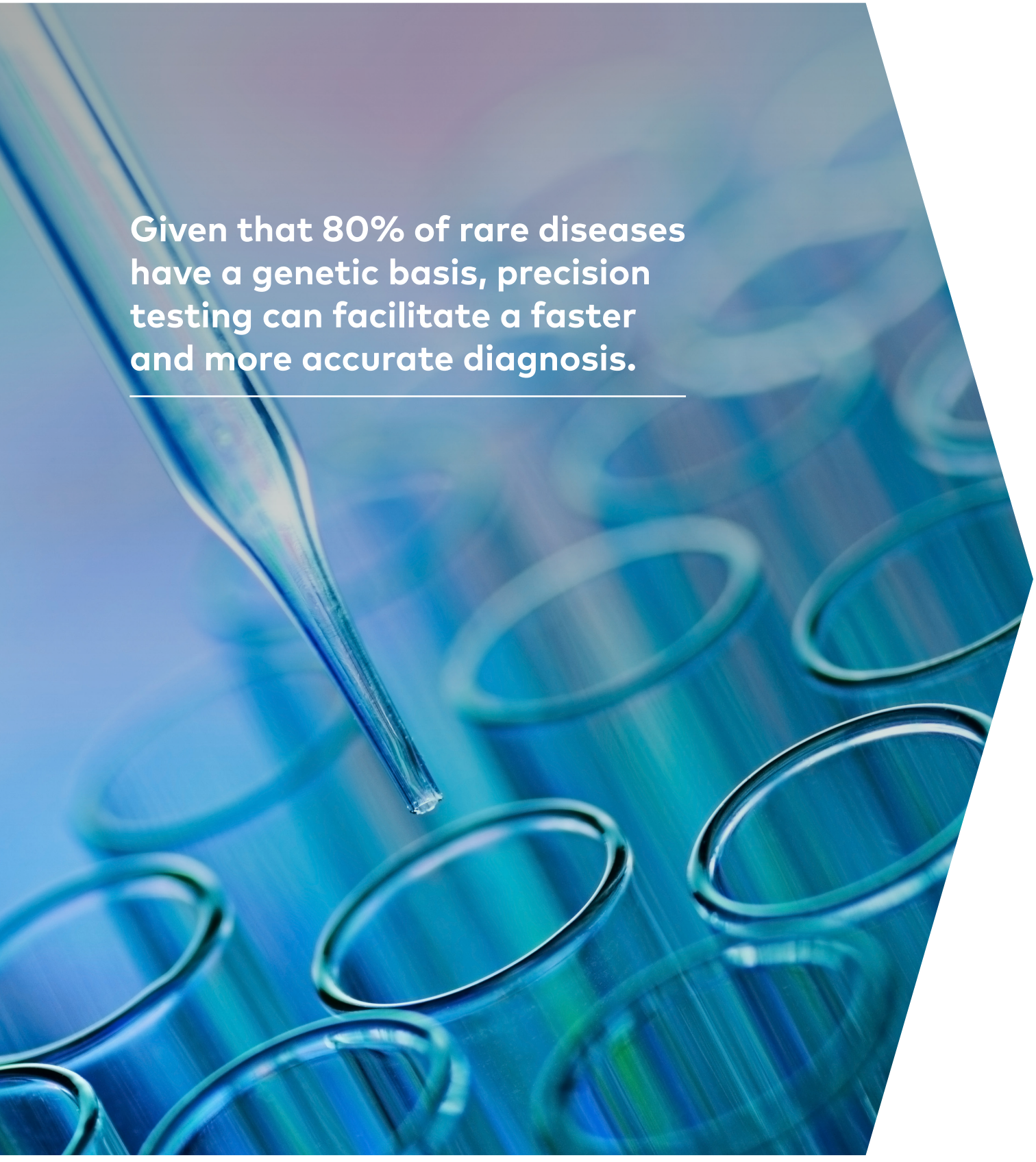
#### 2.2.2.3 Enhanced skills and expertise for healthcare providers

The growing use of precision therapies in South Korea requires specialised training for healthcare professionals, enhancing their skills and expertise. Programs like the Korea Precision Medicine Initiative and Korea Biobank Project offer training that equips researchers and clinicians with to use genomic data effectively. Multidisciplinary teams, including molecular tumour boards, also help healthcare providers improve their decision-making, ensuring patients receive the best possible care.

#### 2.2.2.4 Improved standard of care and efficiency

Precision therapies improve healthcare delivery by shortening the length of treatment. For example, a study from the London School of Economics showed that cancer patients treated with precision oncology drugs had an average hospital stay of just three to four days, compared to the seven-day average for patients receiving chemotherapy.

The Korea Precision Medicine Initiative and the Korean Genome Analysis Project demonstrate South Korea's progress in using genetic data to create precise treatment plans, reducing trial-and-error in therapies and delivering faster, more accurate care for patients. This ultimately improves the efficiency and effectiveness of the healthcare system.



**Given that 80% of rare diseases have a genetic basis, precision testing can facilitate a faster and more accurate diagnosis.**

## 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.

Pharmaceutical innovation in precision therapies is driving significant economic growth in South Korea, creating jobs and attracting investment in infrastructure for the development, manufacturing and distribution of therapies.

Significant industry investment (both local and foreign) of about ₩61Tn KRW ($45Bn USD) is expected over the next 10 years to support R&D, manufacturing, sales and distribution of precision therapies.

This investment will likely be distributed across the multiple areas of the sector, with an estimated ₩50Tn KRW ($37Bn USD) for R&D, ₩3.2Tn KRW ($2.4Bn USD) for manufacturing, and ₩8Tn KRW ($5.9Bn USD) for commercialisation.

- **Illustrative example:** local CAR-T manufacturing company, Curocell has received over c. ₩61Bn KRW ($45Mn USD) in investment to develop and manufacture CAR-T therapies and has partnered with an MNC to scale up manufacturing capabilities

Additional investment in companion diagnostics of around ₩16Tn KRW ($12Bn USD) will also be needed to facilitate access to precision therapies.

These investments could create around 20,000 highly skilled jobs over the next ten years in the pharmaceutical sector. This is based on 11,900 in R&D, 4,900 in manufacturing, and 3,400 jobs required for commercialisation.

**These investments could create around 20,000 highly skilled jobs over the next ten years in the pharmaceutical sector.**

Growth in local clinical trial activity is estimated to reach ₩11 to ₩16Tn KRW ($0.8 to $1.2Bn USD) by 2035. These investments will also benefit patients through often free access to medicines and benefit the health sector through upskilling of the healthcare workforce.

**Pharmaceutical value chain investment and job creation (2025-35)**

## 2.2.4 Multiplier effects

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

### 2.2.4.1 Industry economic activity multiplier effects

Beyond improving health outcomes, precision therapies will also create broader social and economic benefits.

- About 389,000 patients who recover or experience improved health due to precision therapy treatments will be able to return to work sooner and remain in the workforce longer, boosting productivity and contributing to sustainable tax revenue over the next ten years. These patients will also contribute to the wider economy through increased personal spending on goods and services.
- Additionally, around 350,000 to 389,000 caregivers will be able to participate more actively in the workforce over the next ten years, further increasing economic activity.

**About 389,000 patients who recover or experience improved health due to precision therapy treatments will be able to return to work sooner and remain in the workforce longer.**

- Precision therapies offer potentially curative therapies for previously untreatable conditions, reducing the need for patients to rely on healthcare benefits and social welfare. As these patients transition to a state of cure rather than chronic treatment, they can contribute financially to the healthcare system through insurance premiums, easing the burden on public welfare systems.

### 2.2.4.2 Broader economic multiplier effects

Precision therapies investment could reverberate throughout the economy, increasing its direct economic impact.

**Multiplier benefits could generate ₩61 to ₩366Tn KRW and support between 20,000 – 120,000 jobs between 2025 and 2035.**

Previous studies estimate that direct economic investment in precision therapies could generate multiplier benefits of between one to six times its initial value, potentially leading up to ₩61 to ₩366Tn KRW ($45 to $271Bn USD) in economic activity and supporting 20,000 to 120,000 jobs between 2025 and 2035.

# 2.3 Barriers to access

Despite its potential, several barriers limit patient access to precision therapies in South Korea. Key barriers identified include:

**Barrier to access**

## 2.3.1 Market access, pricing and reimbursement

### Barriers

- HIRA's capacity to review the growing volume of scientific data is insufficient to support cost-effectiveness reviews
- Low prices for innovative medicines discourage pharmaceutical companies from introducing them to the market[26]
- Current Health Technology Assessment (HTA) frameworks take a narrow view of patient benefits, focusing primarily on clinical outcomes rather than broader social benefits
- The high cost-effectiveness benchmarks and complex reimbursement processes further limit access to precision therapies
- There is limited involvement of patient advocacy groups in the reimbursement process[27]
- Diagnostic test coverage is restricted to a small range of cancer types
- Complex approval pathways for co-dependent technologies and drug device combination therapies create additional hurdles

### Impacts

- Delayed access to therapies for patients
- Pharmaceutical companies are discouraged from introducing new drugs to the market
- Low reimbursement rates (lower amount covered per drug) for therapies and diagnostics increase out of pocket patient costs for patients and reduce the adoption of precision therapies
- Additional administrative challenges make it difficult for pharmaceutical sponsors to bring companion diagnostics to the market

### Other details

- South Korea's pricing and reimbursement environment presents the most critical barrier to precision therapies access for Koreans
- The complexity and acceleration in innovation of medicines mean existing reimbursement, pricing and access frameworks are no longer fit for purpose
- Current HTA frameworks apply a narrow view of patient benefits, capturing only clinical benefits under Quality Adjusted Life Year (QALY) gains to represent the cost effectiveness of medicines. This neglects the breadth of social outcomes of innovative medicines
- Cost effectiveness benchmarks also disadvantage precision therapies due to high thresholds for cost effectiveness of therapies, which require new drugs to be more cost effective than existing comparators[28]

Barrier to access

## 2.3.2 Data laws and infrastructure

### Barriers

- Inadequate infrastructure to support the use of genomic data for R&D
- Limited interoperability of data across healthcare institutions to support complex care delivery and monitor health outcomes[29, 30]
- Legal restrictions on using genomic data for R&D

### Impacts

- Restricts local R&D investment in precision therapies, especially by foreign companies, which in turn reduces innovation that drives improved patient outcomes
- Limits patients' access to comprehensive care, particularly for those needing treatment across multiple health facilities
- Reduces the capacity of Korea to evaluate and improve their healthcare system[31]

### Other details

- While less significant to patient access, issues relating to data laws and infrastructure are limiting local innovation in R&D. Current legal restrictions on the utilisation of genomic data for R&D by international companies limit their ability to invest in local R&D activities. The limited interoperability of data across healthcare institutions also presents challenges to local companies operating in this space due to the manual effort required to collate and analyse genomic data

Barrier to access

## 2.3.3 Low awareness of precision therapies among the stakeholders

### Barriers

- Limited health literacy among the public, including low awareness of genomics and precision therapies
- Social stigma related to rare and genetic disease diagnoses[32]
- Lack of public and patient advocacy for government policies that facilitate investment and access to precision therapies
- Low understanding among policymakers of healthcare innovations, leading to insufficient priority of relevant policies.
- Limited healthcare provider awareness and access to precision therapies education

### Impacts

- Reduced willingness of physicians to prescribe new treatments
- Limits patients' ability to make informed decision about their care
- Reduces patients' ability to advocate for improved reimbursement and pricing policies to increase access.
- Hinders the integration of education, access and innovation into healthcare policies[33]

26, 27, 28, 29, 30, 31, 32, 33

[26] Assistant Secretary for Planning and Evaluation (ASPE), 2024. International Prescription Drug Price Comparisons: Estimates Using 2022 Data [online] Available at: https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf
[27] Single, A., Cabrera, A. and Fifer, S. et al., 2021. Patient advocacy group involvement in health technology assessments: an observational study. Research Involvement and Engagement, 7, p.83. Available at: https://doi.org/10.1186/s40900-021-00327-5
[28] Lee, D.Y., Cho, S.H., Lee, D.H., Kang, S.J. and Lee, J.H., 2024. Variables affecting new drug prices in South Korea's pricing system. Frontiers in Pharmacology, 15, p.1370915. Available at: https://doi.org/10.3389/fphar.2024.1370915
[29] Kwon, A., Lee, H.Y., Shin, S.Y., Yang, K., Sung, Y., Lee, K., Byeon, N.S., Lim, T.H. and Lee, J.H., 2024. Current Health Data Standardisation Project and Future Directions to Ensure Interoperability in Korea. Healthcare Informatics Research, 30(2), pp.93-102. Available at: https://doi.org/10.4258/hir.2024.30.2.93
[30] OECD, 2024. Towards an Integrated Health Information System in Korea. [online] Available at: https://www.oecd.org/en/publications/towards-an-integrated-health-information-system-in-korea_c4e6c88d-en/full-report/component-4.html#chapter-d1e202
[31] OECD, 2024. Towards an Integrated Health Information System in Korea. [online] Available at: https://www.oecd.org/en/publications/towards-an-integrated-health-information-system-in-korea_c4e6c88d-en/full-report/component-4.html#chapter-d1e202
[32] Lymphoma Coalition, 2023. Health Literacy in Asia-Pacific. [pdf] Available at: https://lymphomacoalition.org/wp-content/uploads/2023_Report_Health_Literacy_In_Asia_Pacific_VF_A4_Digital.pdf
[33] Nature, 2024. Can South Korea regain its edge in innovation? [online] Available at: https://www.nature.com/articles/d41586-024-02689-8

**The pace of innovation has outstripped current regulatory reimbursement and pricing processes, which are no longer fit for purpose.**

# 2.4 Recommendations

To fully realise the significant benefits of precision therapies for patients, the healthcare system, the public, and the economy, South Korea needs investment and collaboration between all stakeholders. This paper outlines three key recommendations:

1 Create a regulatory environment that promotes innovation

2 Promote strong genomic data architecture and legal frameworks for R&D

3 Expand awareness and education on precision therapies

**Recommendation**

## 2.4.1 Create a regulatory environment that promotes innovation

### Description

Build a framework that integrates the public sector and industry to foster innovation and expand access to precision therapies

### Key stakeholders

Government, pharmaceutical industry, R&D organisations, industry representative and patient advocacy groups

### Barriers addressed

*Market access, pricing and reimbursement*

### Impacts

- Increase patient advocacy group participation in pricing and reimbursement negotiations
- Revise the Health Technology Assessment (HTA) evaluation framework to account for broader benefits beyond Quality-Adjusted Life Year (QALY) gains including patient well-being, workforce participation and reduced social welfare costs
- Strengthen reimbursement and pricing frameworks to better accommodate innovative treatments, including a single reimbursement and pricing pathway for drug-device combination therapies and companion diagnostics.
- Expand National Health Insurance coverage for diagnostic testing to improve access to precision therapies and reduce reliance on smaller, less effective testing processes.
- Expand pay-for-performance schemes across a broader range of medical conditions.

Recommendation

## 2.4.2 Promote strong genomic data architecture and legal frameworks for R&D

### Description

Strengthen data privacy laws and establish effective genomic data infrastructure to enhance R&D in precision therapies

### Key stakeholder

Government, healthcare sector, pharmaceutical industry, R&D organisations.

### Impacts

- Improve genomic data access laws to encourage R&D while ensuring patient privacy to increase patient willingness to share their data
- Standardise genomic data collection across healthcare institutions to streamline analysis and reduce manual effort

### Barriers addressed

*Insufficient data laws and infrastructure*

Recommendation

# 2.4.3 Expand awareness and education on precision therapies

## Description

Increase education and understanding of precision therapies among healthcare professionals, patients, the public and government officials

## Key stakeholder

Government, patient advocacy organisations, healthcare professionals, physician colleges, public health experts and educators

## Impacts

- Develop clinical guidelines to clarify the role of diagnostic testing and precision therapies in patient care, promoting wider use by healthcare providers
- Designing and implementing practical training modules to educate physicians about precision therapies, in collaboration with relevant physician organisations and key opinion leaders
- Raise public health literacy on genomics through public health campaigns and consider introducing genomics education in school curriculums
- Make health information more accessible for patients, including clearer communication on care pathways and clinical trial information in accessible language, easily understood by the public

## Barriers addressed

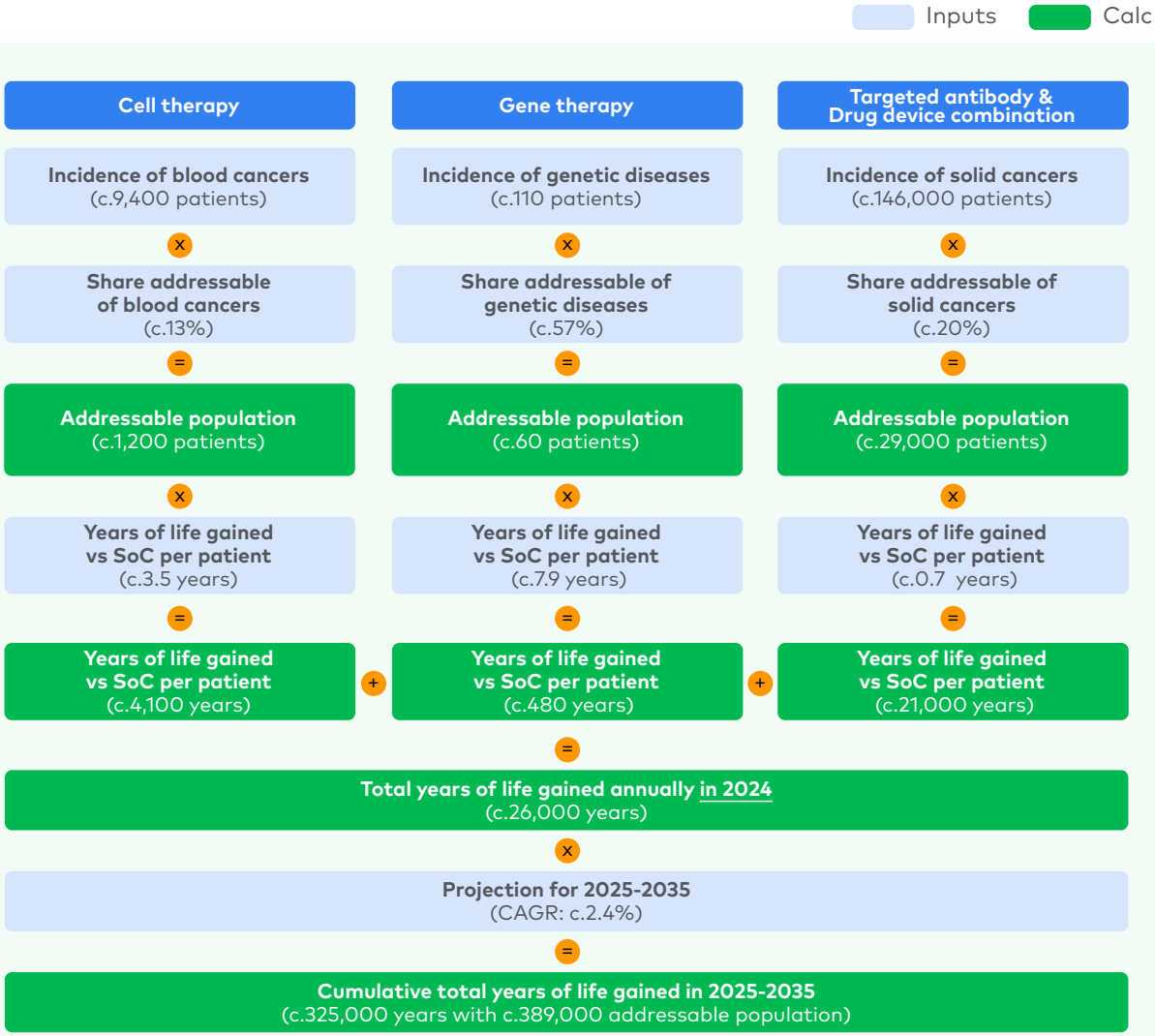
*Low awareness of precision therapies among stakeholders*

# 3.0 Appendix

This 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

### 3.1.1 Total years of life gained




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 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)

**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 QALY 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

### 3.1.2 Avoided healthcare cost


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.

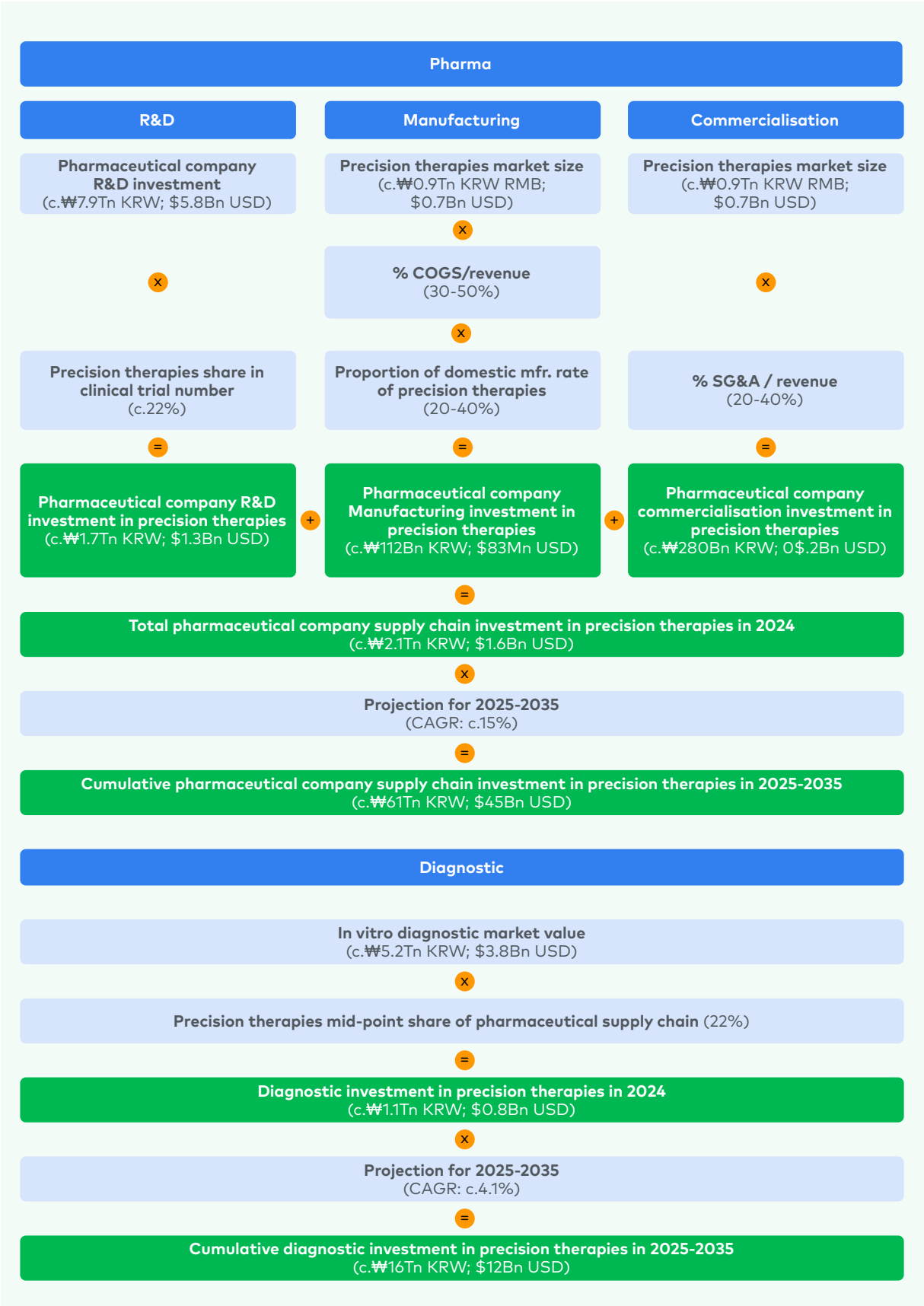
**For cell therapies, targeted antibody and drug-device combinations**

- 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

**For gene therapies**

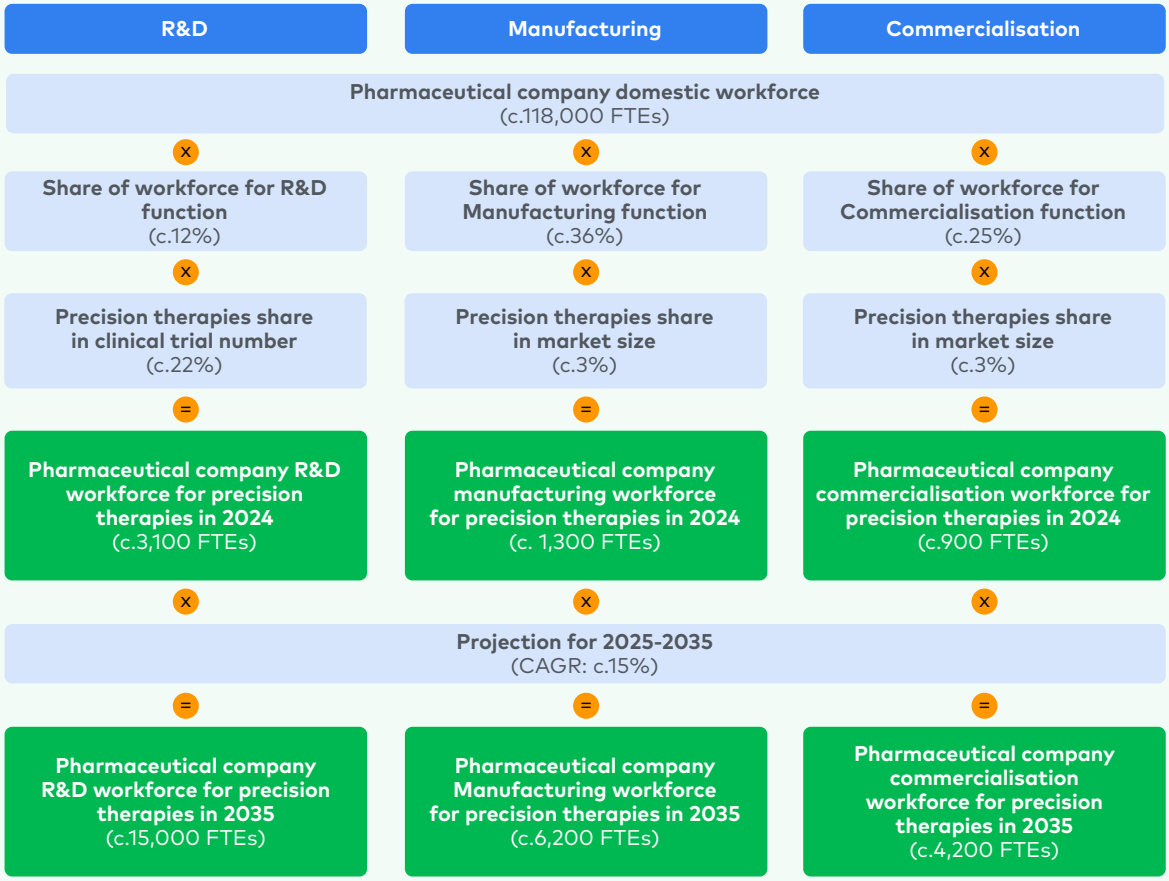
- The total addressable patient population was estimated by multiplying the incident population of patients with genetic diseases (estimated using peer-reviewed global studies) by the share of patients addressable by gene therapies (based on clinical trial data)
- Then we calculated the avoided healthcare 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)

### 3.1.3 Industry economic investment



- 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 as a proxy based on Pharmaprojects data)
- Manufacturing investment was estimated by multiplying total 'precision therapies' market size in 2024 by an estimated proportion of manufacturing spending (estimated through benchmarking % COGS of listed pharmaceutical companies with a 'precision therapies' focus in South Korea) and an estimated proportion of internal manufacturing rate of 'precision therapies' (estimated though benchmarking domestic mfr. Rate using market & financial reports)
- Commercialisation investment was estimated by multiplying the total 'precision therapies' market size in 2024 by an estimated proportion of SG&A spend (estimated through benchmarking listed pharmaceutical companies with a 'precision therapies' and oncology focus in South Korea)
- Diagnostics supply chain investment was estimated based on the total in-vitro market value and applying of 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 Full Term Employment (FTE)

### 3.1.4 FTE




- The total number 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 South Korea in R&D functions in 2024 (estimated by multiplying the total pharmaceutical company workforce by share of R&D functions of 300 listed pharmaceutical companies in China in 2017 as proxy) 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)
- Jobs supported in manufacturing were estimated by multiplying the total number of employees in the pharmaceutical company in South Korea in manufacturing in 2024 (estimated by multiplying the total pharmaceutical company workforce by share of commercialisation in South Korea in 2019 as proxy) by the proportion of the overall pharmaceutical market size attributable to 'precision therapies' (estimated through benchmarking 'precision therapies' share in Japan as a proxy) and the proportion of internal manufacturing rate of 'precision therapies' (estimated though benchmarking domestic manufacturing rate of monoclonal antibodies)
- Jobs supported in commercialisation were estimated by multiplying the total number of employees in the pharmaceutical company in South Korea in commercialisation in 2024 (estimated by multiplying the total pharmaceutical company workforce by share of commercialisation in South Korea in 2019 as proxy), and the proportion of the overall pharmaceutical market size attributable to 'precision therapies' (estimated through benchmarking 'precision therapies' share in Japan as a proxy)

# References


| Author(s); Organisation | Title | Year |
|---|---|---|
| American Society of Gene & Cell Therapy | Vectors 101 | 2024 |
| Assistant Secretary for Planning and Evaluation (ASPE) | International Prescription Drug Price Comparisons: Estimates Using 2022 Data | 2024 |
| AstraZeneca | Precision medicine | 2024 |
| Baynam, G., Gomez, R. and Jain, R.; Frontiers in Genetics | Stigma associated with genetic testing for rare diseases-causes and recommendations. Frontiers in Genetics | 2024 |
| Cancer Gene Therapy | CAR T therapies in multiple myeloma: unleashing the future | 2024 |
| Cappell, K.M. and Kochenderfer, J.N.; Nature Reviews Clinical Oncology | Long-term outcomes following CAR T cell therapy: what we know so far. | 2023 |
| Crump, M. et al.; Blood | Outcomes in refractory diffuse large B-cell lymphoma: Results from the international SCHOLAR-1 study. Blood | 2017 |
| DHAC (AUS) | Minister for Health and Aged Care press conference | 2024 |
| European Commission | Rare diseases | 2024 |
| Grand View Research | South Korea Clinical Trials Market Size & Outlook, 2023-2030 | 2023 |
| Institute for Health Metrics and Evaluation (IHME) | Global Burden of Disease (GBD) Data | 2024 |
| IQVIA | The global use of medicines 2024: Outlook to 2028 | 2024 |
| Jackson, S. and Trakhtenberg, I.; Standford University Press | Predictable Winners | 2025 |

| Author(s); Organisation | Title | Year |
|---|---|---|
| Kesireddy, M. and Lunning, M.A.; Oncology | Relapsed or refractory diffuse large B-cell lymphoma: "Dazed and confused | 2022 |
| KHIDI (South Korea) | Market analysis of Korea's pharmaceutical industry | 2020 |
| Kwon, A. et al.; Healthcare Informatics Research | Current Health Data Standardization Project and Future Directions to Ensure Interoperability in Korea. Healthcare Informatics Research | 2024 |
| Lee, M. et al.; Journal of Korean Medical Science | Quantitative Analysis of SMN1 Gene and Estimation of SMN1 Deletion Carrier Frequency in Korean Population based on Real-Time PCR | 2004 |
| Lee, D.Y., et al.; Frontiers in Pharmacology | Variables affecting new drug prices in South Korea's pricing system. Frontiers in Pharmacology | 2024 |
| Lee, S. O. et al; Journal of Korean Medical Science | Utilization Patterns of Coagulation Factor Consumption for Patients with Hemophilia | 2016 |
| Lymphoma Coalition | Health Literacy in Asia-Pacific. | 2023 |
| Memorial Sloan Kettering Cancer Center | Off-the-shelf CAR cell therapy for multiple myeloma shows promise | 2024 |
| Ministry of Food and Drug Safety | (2018-2023) Drug approval report | 2024 |
| Ministry of Science and ICT | Biotechnology in Korea | 2022 |
| Mivision | Landmark government funding for Luxturna IRD treatment | 2022 |
| Nature | Can South Korea regain its edge in innovation? | 2024 |
| NIH | Researchers generate the first complete, gapless sequence of a human genome. | 2022 |
| OECD | Towards an Integrated Health Information System in Korea | 2024 |
| OncLive | Quadruplet therapy and early-line CAR T-cell therapy approvals mark shifting standards in multiple myeloma | 2024 |

| Author(s); Organisation | Title | Year |
|---|---|---|
| Park, J. E. et al.; Annals of Laboratory Medicine | Carrier Frequency of Spinal Muscular Atrophy in a Large-scale Korean Population | 2020 |
| Pharma GoBoldy | The Economic Impact of the U.S. Biopharmaceutical Industry: 2015 National and State Estimates | 2017 |
| Rare Cancers Australia | Belinda trial: CAR-T therapy delivered earlier for relapsed/refractory aggressive non-Hodgkin lymphoma patients | 2024 |
| Retina Australia | Retinitis Pigmentosa | 2025 |
| Rim, T.H. et al; BMJ | Four-year nationwide incidence of retinitis pigmentosa in South Korea: a population-based retrospective study from 2011 to 2014. BMJ. | 2017 |
| Sheykhhasan M. et al.; Nature | CAR T therapies in multiple myeloma: unleashing the future | 2024 |
| Single, A. et al.; Research Involvement and Engagement | Patient advocacy group involvement in health technology assessments: an observational study | 2021 |
| Statista | Global spending on precision medicine treatments from 2020 to 2027 | 2024 |
| Wongchaisuwat, N. et al; Saudi journal of ophthalmology | Retinitis pigmentosa GTPase regulator-related retinopathy and gene therapy. Saudi journal of ophthalmology | 2023 |
| World Bank | GDP / Health expenditure / Currency / CPI | 2024 |
| Young, K. et al.; Cancer Research and Treatment | Socioeconomic Burden of Cancer in Korea from 2011 to 2015. Cancer research and treatment. | 2020 |
| Yoon, J. A. et al; unpublished | Duchenne Muscular Dystrophy in South Korea Based on Data from the National Health Insurance Database: Corticosteroid use and Bone Health Management | 2023 |

# Partner profiles

## Stephanie Newey

Stephanie Newey serves as the head of L.E.K. Australia as well as a coleader of the Australian Healthcare practice. Stephanie has more than 20 years of experience in strategy and consulting, with deep expertise in biopharmaceuticals, life sciences, medtech and digital health.

## Helen Chen

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.

## Yuta Inokuchi

Yuta Inokuchi is a partner & the head of L.E.K. Japan and specializes in healthcare and life sciences. He has extensive experience advising corporates and investors on growth strategy and transactions across pharma, biotech, medtech, diagnostics, CRO/CDMO, and research tools.

## Manoj Sridhar

Manoj Sridhar is a partner and is dedicated to the firm's Life Sciences and Healthcare practice. Manoj has deep expertise in strategy development, performance improvement and organisational design, and has advised pharmaceutical, medical technology and government clients on a range of strategy and M&A projects in Australia.

## Tara Naguleswaran

Tara Naguleswaran is a senior member of the firm's Australia Healthcare Practice.She advises corporate and private equity clients on strategy, M&A, and organisational performance.

LEK™