# 革新的医薬品の未来を切り拓く

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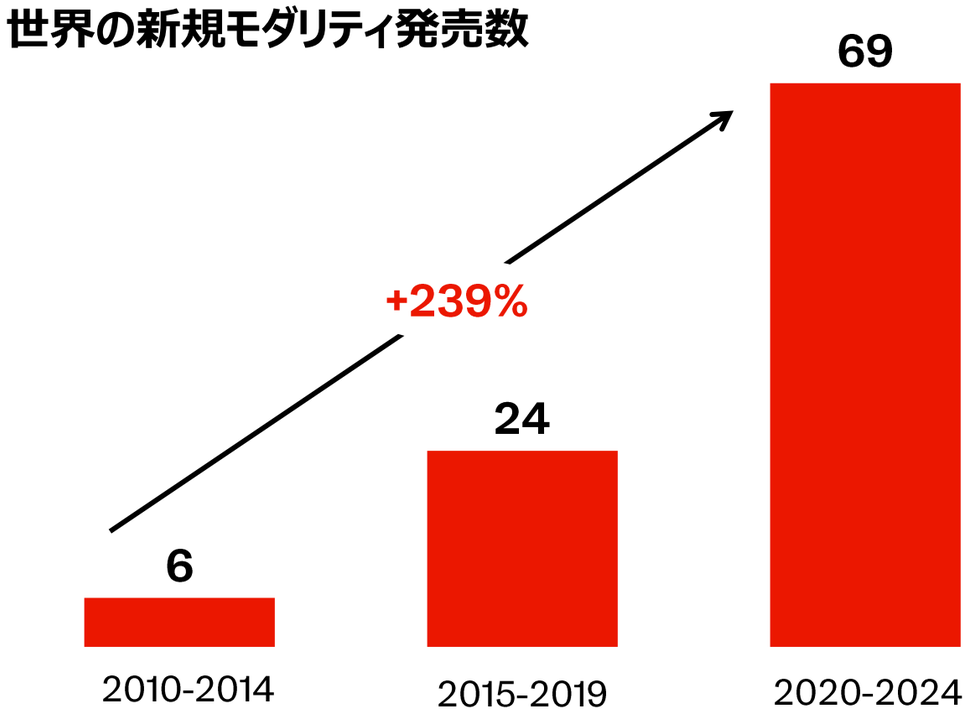
# 新規モダリティの進展は
# 世界中でより多くの命を救い
# 人々の生活を向上させます




Note: Duplicates of indications for the same product are not counted; each product is counted as one
Source: Evaluate pharma ; Third party analysis (The company name is not a subject to disclose based on the master service agreement)

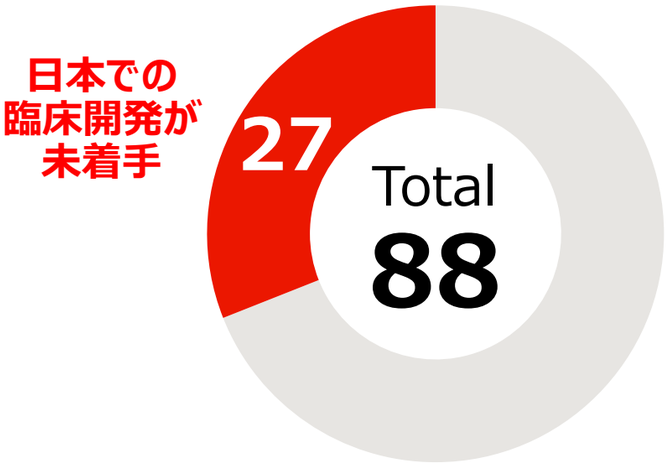
- 細胞治療
- 遺伝子治療
- 抗体薬物複合体
- 多重特異性抗体
- 経口ペプチド
- DNA/RNA 治療
- ゲノム編集

等

# しかしながら、日本では新規モダリティのドラッグロスが拡大傾向にあり、患者さんが治療機会を失う可能性があります

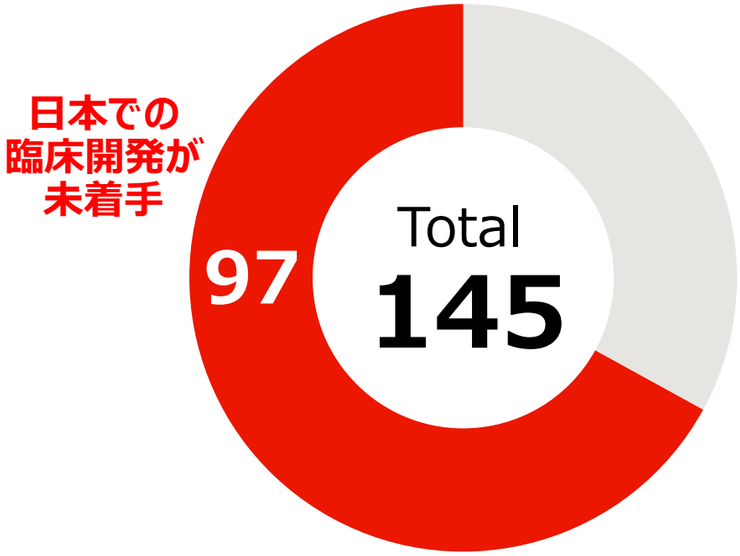
**現在のドラッグロス: 31%**

**グローバルで承認・上市済みの新規モダリティ数** (2014- )




**将来のドラッグロス: 67%**

**グローバルで開発後期品の新規モダリティ数** (-2030 )




Note: Products with indications for diseases that also exist in Japan as of February 2025. For marketed products, only products confirmed to have been marketed since 2014 were counted.
Source: EvaluatePharma; Third party analysis (The company name is not a subject to disclose based on the master service agreement)

# 革新的価値を示す再生医療等製品を患者さんに届けるためには、それらを適切に評価する制度が必要です

**細胞療法の分子特性がもたらす臨床効果の差異が評価されない**

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高い臨床効果を示す細胞療法では分子（遺伝子、細胞など）の構造的・機能的な違いも新規性として評価

**既存治療と大きく異なる患者アウトカムを評価する基準がない**

↓

一回の治療による高い臨床的効果（治癒の可能性、長期の効果）を評価する基準を設定

**革新性が高い領域であるにも関わらず有用性加算が減額される**

↓

特定の再生医療等製品に対する有用性加算の減額ルールの廃止

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# 革新的医薬品の創薬における日本のリーダーシップを高めるために

新規モダリティの価値を評価する加算ルールを早急に導入

業界の意見を取り入れ意思決定における予見可能性と透明性を確保

日本の競争力を高める創薬エコシステムの構築に向けた中長期的な計画を策定

# Thank you

# Leading where medicine is going

**Sarah Brennan**
Company Group Chairman,
Global Commercial Strategy Organization,
Innovative Medicine

Public Private Council
June 26, 2025

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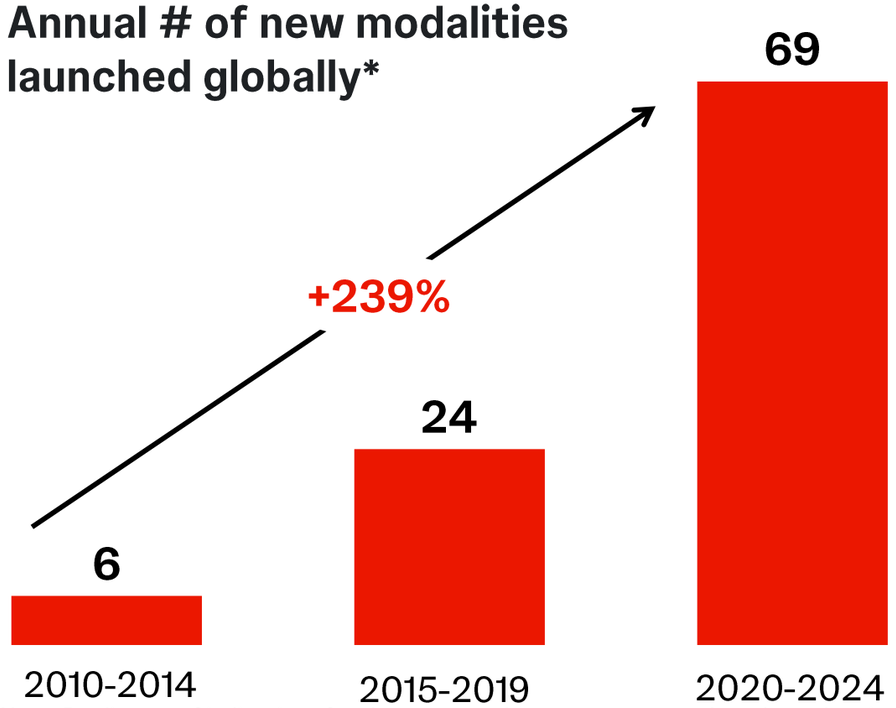
# The rise of new modalities globally is showing real promise to save and improve more lives

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- Cell therapies
- Gene therapies
- Antibody-drug conjugates
- Bi-/Tri-specific antibodies
- Oral peptides
- DNA/RNA treatment
- Genome editing
- Etc...

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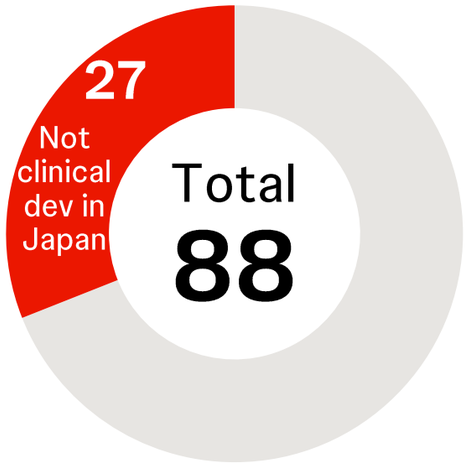
# … yet growing drug loss for new modalities in Japan threatens progress for patients

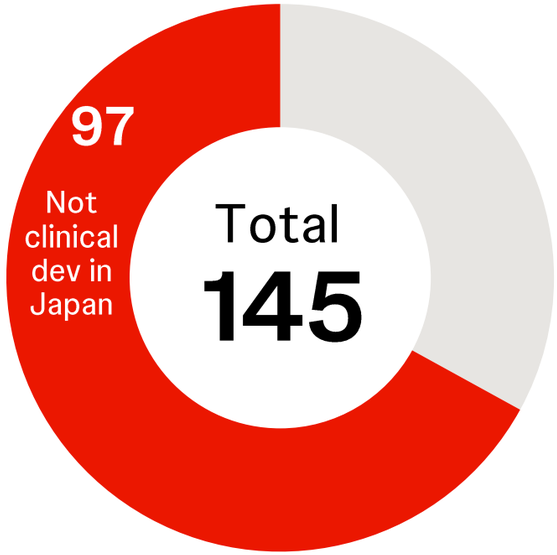
**Current drug loss: 31%**

**Number of approved/launched NMs in Global** (2014- )




**Future drug loss: 67%**

**Number of late-stage NMs development in Global** (-2030 )

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# We need a system fit to evaluate transformational regenerative medicines for patients

**Clinical differences in molecular profiles not recognized**

↓

**Evaluate structural and functional differences for cell therapy with superior efficacy**

**No criteria in place to assess and value different patient outcomes**

↓

**Add new premium for specific clinical outcomes (potential cure, long-term complete response) of one-time therapy**

**Usefulness premium reduced despite ongoing value generation**

↓

**Discontinue the rule to adjust the premium for regenerative medicines**

# Elevate Japan’s biopharmaceutical leadership

- Urgently reset the innovation premium to evaluate and reward new modalities
- Ensure predictability and transparency in decision-making with industry perspectives
- Commit to long-term plans to foster Japan’s competitive drug discovery ecosystem

# Thank you