

The **KMR R&D Advantage Program** is a portfolio level benchmarks and analytics program designed to provide senior management with perspective on key changes in R&D over the last several years.

The foundation of this program is our extensive work in biopharma where we have **25+ years of collaborating** with industry and developing standardized methods and approaches for comparative peer assessments.

Our flagship study, **R&D Insights & Analytics Report**, provides reliable benchmarks that are useful in goal setting and understanding how different approaches to R&D are impacting productivity.

This is a **high level assessment** examining both research, development and encompassing performance on cycle times, success rates, productivity, value and clinical drug development.

## OUTLINE

### Section 1: R&D Investment

- R&D Spending
- R&D Spending As % of Sales

### Section 2: R&D Productivity

- R&D Spending Per NME Approval
- NME Approval Per R&D Spending
- New Product Sales Per R&D Spending
- New Product Sales Per NME Approval

### Section 3: Clinical Development Pipeline

- Active Trials
- Pipeline By Therapy Area
- % Oncology Pipeline
- % Large Molecule Pipeline
- % Rare Disease Pipeline
- % Pediatric Pipeline
- % Pipeline In Emerging Market

## Section 4: Cycle Time

### R&D Cycle Time

- R&D Cycle Time
- Discovery Cycle Time
- Development Cycle Time
- Development Cycle Time By Phase
- Development Cycle Time By Molecule Size
- Development Cycle Time By Phase & Molecule Size
- Development Cycle Time By Therapy Area
- Development Cycle Time By Phase & Therapy Area

### Regulatory Cycle Time

- NME Registration Cycle Time
- NME Registration Cycle Time By Characteristic (Molecule Type, Onc, Top 20)
- NME Registration Cycle Time By Region
- NME Registration Cycle Time By Region & Expedited Status
- NME First Region Filing To Second Region Filing Cycle Time
- NME First Region Filing To Second Region Filing Cycle Time (US To EU & EU To US)

### White Space Cycle Time

- NME Start Phase To Database Lock
- White Space: Phase Database Lock to Start Next Phase

## Section 5: Success

- NME Success
- NMEs Needed In Preclinical To Achieve 1 NME Approval Hypothetical NMEs
- NME Success & Impact Of Large Molecules
- NME Success By Molecule Size
- NME Success By Therapy Area
- NME Success By Stage
- NME Early Development Success
- NME Late Development Success
- NME Success By Stage & Molecule Size
- Early Development NME Success & Impact Of Large Molecules
- Late Development NME Success & Impact Of Large Molecules
- Early Development NME Success By Molecule Size
- Late Development NME Success By Molecule Size
- NME Success By Stage & Molecule Size: Change In %
- NME Success By Phase
- NME Success By Phase: Change In %
- Success Rate To Achieve 1 NME Approval By Phase
- NMEs Needed To Achieve 1 NME Approval By Phase Hypothetical NMEs
- NME Success & Impact Of Large Molecules By Phase

- Small NME Success By Phase
- Large NME Success By Phase
- NME Success By Phase & Therapy Area

### Section 6: NME Approvals

- NME Approvals
- Total NME Approvals By Company Size
- Total NME Approvals: % Top 20
- NME Approvals Per Company Top 20 Biopharmaceutical Companies
- NME Approvals Per Year Top 20 Biopharmaceutical Companies
- NME Approvals By Characteristic (Molecule Type, Onc, Rare, Combo)

### Section 7: Value - Ethical Pharma Sales

- Ethical Pharmaceutical Sales
- Ethical Pharmaceutical Sales By Molecule Size
- Ethical Pharmaceutical Sales By Biologic Category
- Ethical Pharmaceutical Sales By Therapy Area
- Top 3 Product Sales As Share Of Total Sales
- Top 3 Product Sales
- Sum Of Top 3 Product Sales

### Section 8: Value – New Product Sales & NME Product Sales

- New Product Sales
- Year 5 Sales For NME Approvals By Approval Year
- Year 5 Sales For NME Approvals By Approval Year & Molecule
- Year 5 Sales By NME Approval Characteristic (Molecule Size, Onc, Rare, Combo)
- Year 5 Sales By NME Approval FDA Characteristic (Expedited, First-In-Class)
- Year 5 Sales By Biologic Category
- NME Sales By Year On Market
- NME Sales Per NME Approval By Year NME Approved
- % Early Blockbuster NME Approvals
- % Early Blockbusters By TA

