

[58] THE EXPONENTIAL VALUE AND GROWTH OF MODEL-INFORMED DRUG DEVELOPMENT IN PHARMA R&D

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Question for Service provider category are:

- **Main Service:**

Certara is a leading decision-support technology and consulting organization that leverages model-informed drug development and regulatory science to optimize R&D. 90% of all novel drugs approved by the US FDA in the past 3 years were supported by Certara software or services. We have written 70 successful global regulatory submissions in that time.
- **Key Strengths:**

Certara's team have informed the development of the most groundbreaking therapeutics, including immune-oncology products, rare and orphan disease treatments, pediatric products, gene therapies, and CAR T cell therapies. We develop and leverage cutting-edge modeling & simulation technology focused on drug performance assessment, disease characterization, clinical trial optimization, and achieving regulatory and payer success.
- **Experience with Israeli Companies:**

Certara provides a wide range of consulting services across Teva, including performing modeling and simulation that supported many new drug approvals, and the writing of regulatory submission documents (IND, NDA, MAA). Additionally, Certara is working with a range of smaller companies and academic institutions, including the Weizmann Institute of Sciences.
- **Key Markets:**

Certara is global, with 1,500 companies, academic institutions, global non-profits, and leading regulatory agencies that span 60 countries. Model-informed drug development has evolved from an academic nicety to a regulatory imperative.