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SCAN ME

# R-S-S Regulatory Scientific and Health Solutions

**Excellence in Service | Expertise in Every Detail | Value in Every Project**

At R-S-S, our highly experienced team of former FDA, EMA, and MHRA staff bring their combined technical and regulatory experience to every project.

Our comprehensive clinical development plans are meticulously crafted to ensure optimal outcomes. From early development stages like PK/PD and dose identification through optimal Phase I/II and Phase III studies, R-S-S offer excellent value for exceptional scientific input.

We specialize in rare/orphan diseases, offering accelerated drug development pathways that meet the unique challenges of these requirements.

## R-S-S Services

- **REGULATORY CLINICAL & MEDICAL SERVICES**
- **PK/PD & PB PK MODELLING**
- **SCIENTIFIC ADVICE & STRATEGY**
- **BIOSTATISTICS & PROGRAMMING**
- **DATA MANAGEMENT SERVICES**
- **HEALTH ECONOMICS & MARKET ACCESS**

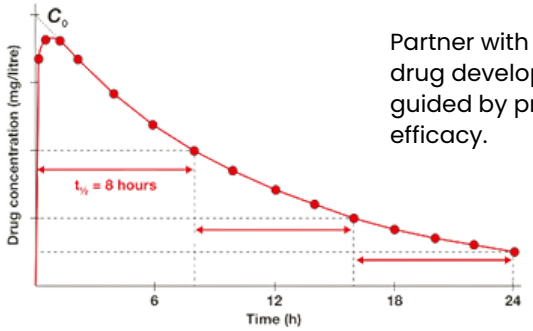
Zurich Switzerland | Birmingham UK | Amsterdam Netherlands | Princeton, NJ USA

## PK/PD Modelling & Simulation

We excel in Pharmacokinetic/Pharmacodynamic (Pop PK/PD) Modelling and Simulation, a vital component of drug development. Our expertise can support to delineate the intricate relationship between drug dosage, exposure and therapeutic effects.

Our cutting-edge Pop PK/PD modelling, **Physiologically based PK modelling (PB PK)** and simulation services are designed to:

- **Optimize dosing regimens** for maximum efficacy and safety
- **Enhance the therapeutic potential** of new drugs
- **Support informed decision-making** throughout the drug development process




Partner with us to ensure your drug development journey is guided by precision, safety, and efficacy.

## Artificial Intelligence & Machine Learning

R-S-S have developed ML models that can be used to predict the chance of successful FDA/EMA approval as well as reimbursement using historical data. Talk to us to find out where your drug development program fits in amongst others and if your data can be used in our model.

- **Generating Systematic Literature Reviews (SLR's)**
- **Predicting Chances of Submission Success**
- **AI & ML Solutions for Medical Devices & Diagnostics**
- **AI & ML Solutions in Data Mining & Pattern Recognition**
- **AI & ML Solutions for Health Economics**

AI

## Statistics & Statistical Programming

At R-S-S, we follow necessary GCP and regulatory standards (FDA , EMA, MHRA) for our programming (SAS, R, other). This includes ADaM, SDTM and CDISC standards. These are essential for any initial regulatory package and increases the value of assets when it is time for submissions. Talk to us about your needs.

We leverage advanced statistical techniques, including Bayesian methods, to design innovative clinical trials.

Our expertise spans adaptive trials, platform trials (umbrella and basket), stratified designs, biomarker response designs, and adaptive dose escalation designs.

## Setting the Standard in Excellence & Value

Partner with R-S-S and experience the difference. Our technical solutions are at the forefront of innovation, leveraging cutting-edge artificial intelligence and machine learning capabilities. These advanced technologies enable us to provide precise, data-driven insights and solutions that enhance the efficiency and effectiveness of drug development processes, including scientific advice, trial design, clinical development plans and strategic consultancy.

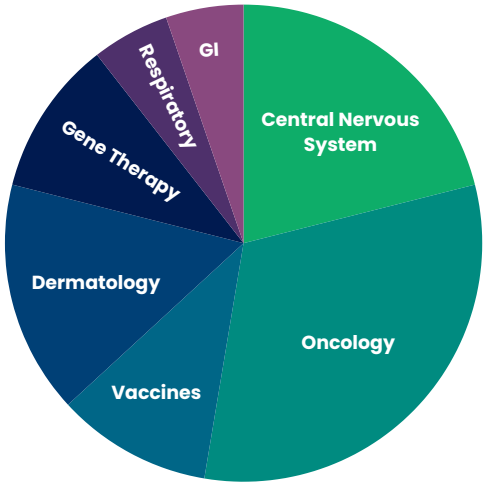
## Investment Risks: A Biotech and Investor Concern

Biotech companies should meet Health Technology Assessment (HTA) standards to secure investment and market access for their drugs. R-S-S offers early-stage valuation of a drug's cost-effectiveness, helping companies align with HTA criteria. This enhances investor appeal and improves chances of reimbursement. Contact us to learn more.

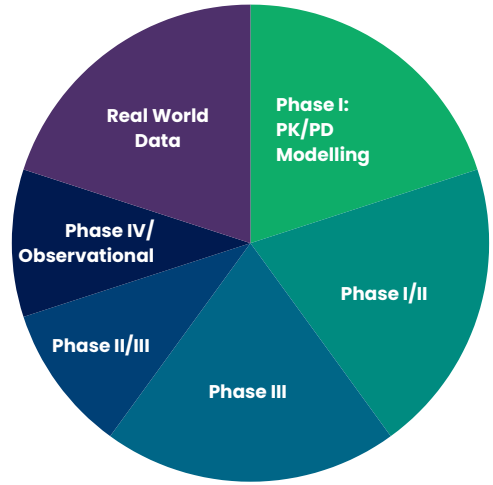
## Scientific Advice for Drug Licensing & Re-imbursement

- NEW DRUG APPLICATIONS & SUBMISSIONS
- CLINICAL TRIALS APPLICATIONS (CTA)
- HEALTH TECHNOLOGY ASSESSMENT
- CLINICAL STUDY DESIGN & PROTOCOL ASSISTANCE
- JOINT SCIENTIFIC ADVICE FOR LICENSING AND HTA
- MEDICAL REPORT WRITING
- CLINICAL EXPERTISE

### Experience by Therapeutic Area




### Experience by Phase

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