Regulatory Science as a Subset of Translational Science

Translational Science
The application of the scientific method to address a health need.

Regulatory Science
The application of the scientific method to improve the development, review, and oversight of new drugs, biologics, and devices that require regulatory approval prior to dissemination.
Translational Research Taxonomy
(Agurs-Collins et al., 2008)

T1: Discovery to candidate health application

T2: Health application to evidence-based practice guidelines

T3: Practice guidelines to health practice

T4: Practice to population health impact
Analogues of The Divisions of Translational Science are Found in Regulatory Science

Translational Science
T1  T2  T3  T4

Regulatory Science
RS1  RS2  RS3  RS4
Analogues of The Divisions of Translational Science are Found in Regulatory Science

RS1: Preclinical Evaluation of Safety and Efficacy

RS2: Clinical Trial Design and Analysis

RS3: Post-marketing Review of Safety and Optimal Utilization

RS4: Health Policies
Analogue of the multidisciplinary expertise required for translational science are found in regulatory science:

- Epidemiology
- Basic Investigation
- Biostatistics
- Bioinformatics
- Medical Informatics
- Protection of Human Subjects
- Research Pharmacy
- Bionutrition
- Regulatory Knowledge
- Public Health
- Clinical Investigation
Implications of Conceptualizing Regulatory Science as a Subset of Translational Science

1. Training: Existing Translational Science Training Programs may provide core elements for the training of Regulatory Scientists.

2. Scientific Exchange: Existing Translational Science Meetings may provide opportunities for disseminating new knowledge.
Implications of Conceptualizing Regulatory Science as a Subset of Translational Science

3. Finding an Academic Home: Existing Translational Science Centers and Institutes may be inviting and supportive homes for Regulatory Scientists.

4. Finding a Place to Publish: Existing journals focusing on translational science may provide opportunities for publishing regulatory science scholarship.
The 8 Priority Area in the FDA’s 2011 Strategic Plan for Regulatory Science

1. Modernize Toxicology to Enhance Product Safety *(RS1)*

2. Stimulate Innovation in Clinical Evaluations *(RS2)* and Personalized Medicine *(RS3)* to Improve Product Development and Patient Outcomes

3. Support New Approaches to Improve Product Manufacturing and Quality *(RS1)*
The 8 Priority Areas in the FDA’s 2011 Strategic Plan for Regulatory Science

4. Ensure FDA Readiness to Evaluate Innovative Emerging Technologies (RS1)

5. Harness Diverse Data Through Information Sciences to Improve Health Outcomes (RS2, RS3, RS4)

6. Implement a New Prevention – Focused Food Safety System to Protect Public Health (RS1, RS3, RS4)
The 8 Priority Area in the FDA’s 2011 Strategic Plan for Regulatory Science

7. Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security (RS1, RS2, RS3, RS4)