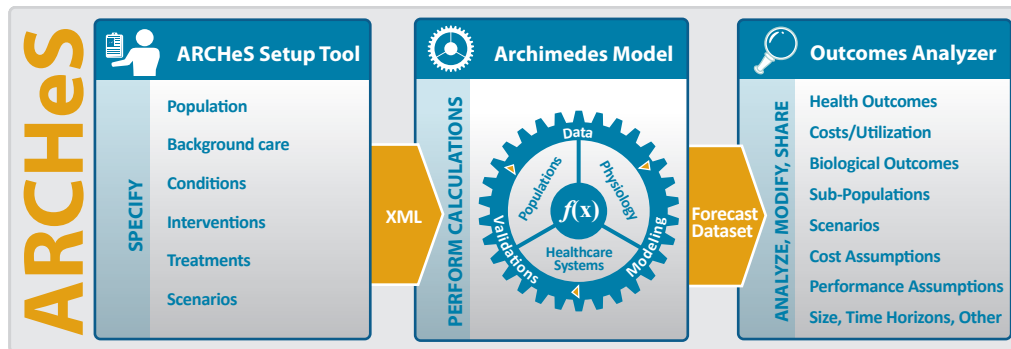


# ARChES Setup Tool

The ARChES Setup Tool is a key component of ARChES Innovator, an online application that gives users access to much of the Archimedes Model. ARChES consists of three parts: the ARChES Setup Tool, the Archimedes Model, and the Outcomes Analyzer.



The ARChES Setup Tool enables users to setup their own virtual clinical trial using a comprehensive web interface with intuitive editors to:

- define a study population
- specify background care
- select current conditions
- apply standard or custom interventions
- set up a multi-scenario study

## Defining Study Population

- Define complex inclusion/exclusion criteria to identify subjects based on biomarker values, existing medical conditions, and current medication use
- Get instant graphical feedback and mean population characteristics as well as proportion of the U.S. population corresponding to inclusion/exclusion criteria
- Adjust population characteristics to match a known population profile
- Specify background care
- Turn on or off categories of standard care that are based on current guidelines and calibrated to U.S. levels

*“With the development of ARChES, we are ushering in a new era in medical decision making that may transform the quality and efficiency of healthcare for all Americans.”*

Risa Lavizzo-Mourey, MD, MBA  
President and CEO  
Robert Wood Johnson Foundation

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# ARChES Setup Tool

## Conditions & Risk Factors:

- Coronary artery disease
- Stroke
- Diabetes and complications
- Obesity
- Metabolic syndrome
- Hypertension
- Dyslipidemia
- Smoking

## Existing drug interventions:

- ACE
- ARB
- Beta blocker
- CCB
- Thiazide
- Simvastatin
- Atorvastatin
- Metformin
- Sulfonylurea

## Custom interventions based on:

- Weight
- SBP
- Total cholesterol
- HDL
- Triglycerides
- HbA1c

## Defining Interventions

### • Standard interventions

- Four classes of antihypertensive medications
- Dyslipidemia medications
- Diabetes medications (including insulin, metformin, glitazones, sulfonylureas)
- Diabetes diet
- Aspirin

### • Custom interventions

- Design interventions by specifying effects on biomarkers:
  - Weight
  - Systolic blood pressure
  - Total cholesterol
  - HDL cholesterol
  - Triglycerides
  - HbA1C
- Account for “pleotropic” effect (additional effect on outcomes mediated by biomarker physiology)
- Set eligibility criteria for each intervention

## Specify Results of Interest

### • Reported as population aggregates annually over 20 years of simulated time

- Mean values of 13 biomarker trajectories (e.g. total cholesterol, BMI, HbA1c)
- Incidence of 13 health outcomes (e.g. MI, stroke, CKD) reported as cumulative and Kaplan-Meier incidence
- Medical costs
- Life years and quality-adjusted life years (QALYs)
- Cost-effectiveness measures such as cost/QALY and cost/ event averted

## Set Up Study Design:

- Specify up to three scenarios per simulation in addition to a control based on background care
- Set compliance levels for interventions in each scenario

When a study request is submitted, it is queued for a simulation on the Archimedes Model. The simulation generates health and economic outcomes, and these results are reported back to users through the Archimedes Outcomes Analyzer.

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