



&

the Total Product Life Cycle

“From Paper Napkin to Commercialization”

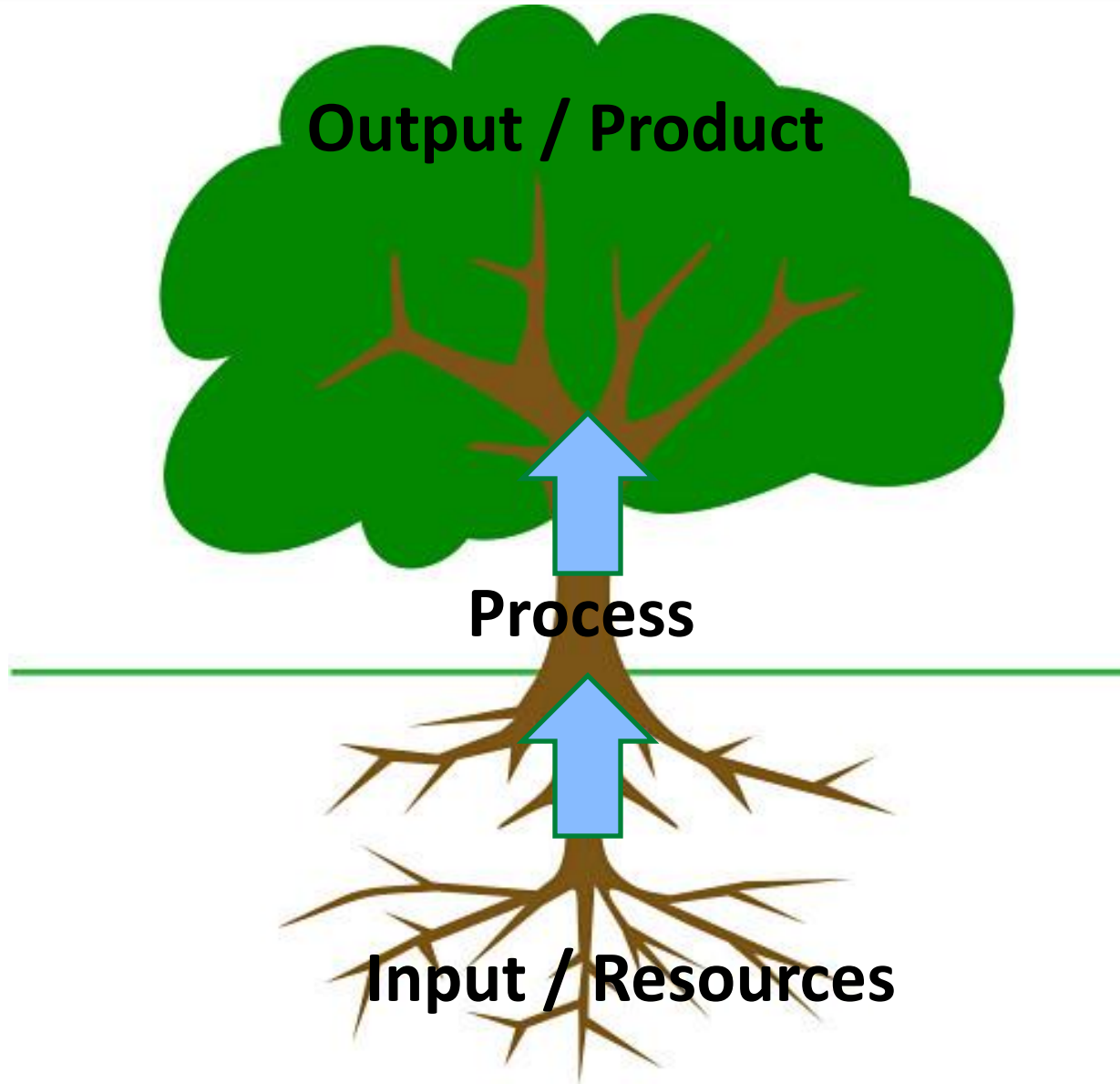
Who We Are:

- TriE Medical, Inc is a full service medical design and development company.
- Clients range in size from:
 - Single Inventors
 - Start-up Companies
 - Mid Size Companies
 - Multi-national companies
 - Physicians
 - Researchers

Overview of TriE Medical

- TriE works under a Quality management system to ensure quality product & documentation to meet FDA standards.
- TriE comes along side our clients at any stage in the Total Product Life Cycle.

TriE & the Total Product Life Cycle



Product Initiation

- Laying the Ground Work
- Product Development Plan
- Project Kickoff
- Regulatory Path Review
 - (510(k), PMA, MDD)
- Intellectual Property Review



Concept

- Requirements Defined
- Specifications Drafted
- Initial Failure Mode Effects Analysis
- Mechanical Concepts Drafted
- Software Platform Determined
- Design for Manufacturing (DFM)



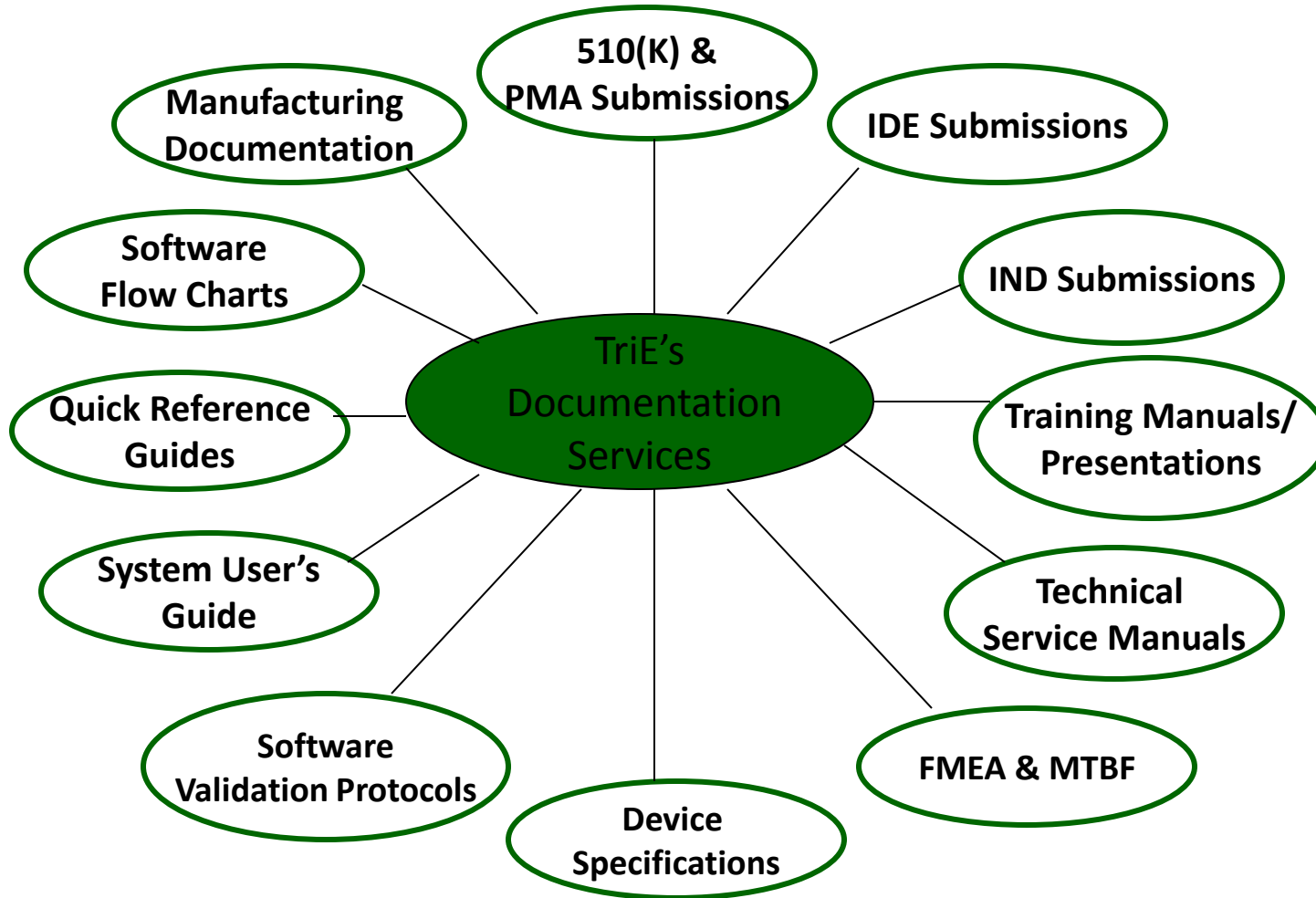
Design / Development

- Update Specifications
- Electronic Design
- Mechanical Packaging
- Material Selection
- Software Code Written
- Design Documentation
- Prototype Integration
- Functional Prototype
- Test Plans Established



Documentation

TriE maintains internal design controls to ensure regulatory compliance.



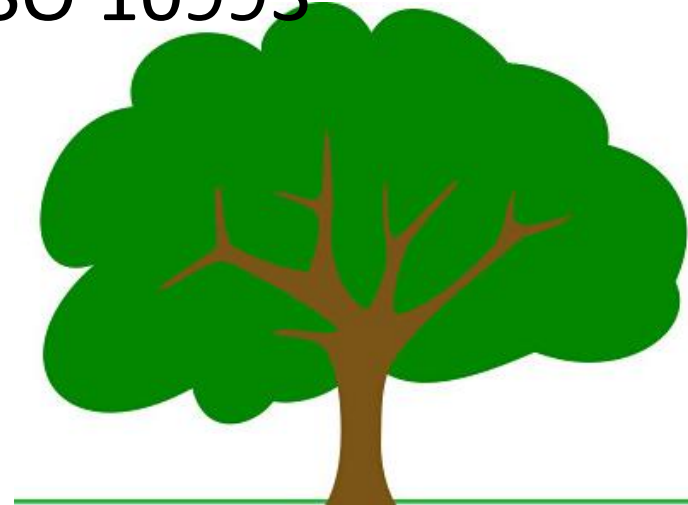
Design Verification

- Bench / Performance Testing
- Study Reports Written
- Design Refinement / Improvement
- Preliminary ESD testing
- Preliminary Hi-pot testing



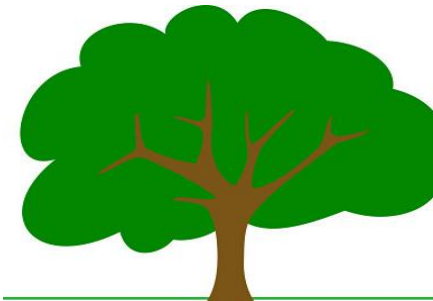
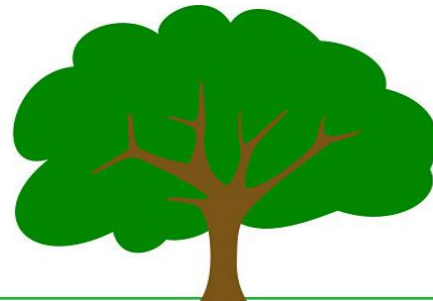
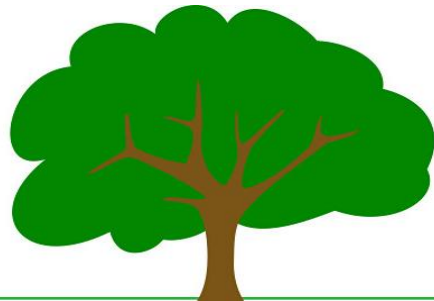
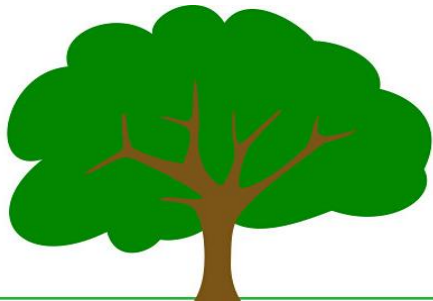
Validation & Clinical

- Acceptance Criteria Determined
- Validation Protocol Written / Executed
- Certified Safety Testing per IEC60601-1 & -2
- ISTA Testing
- Biocompatibility Testing per ISO 10993
- User Feasibility Studies
- Clinical Studies (If Applicable)
- Regulatory Submission

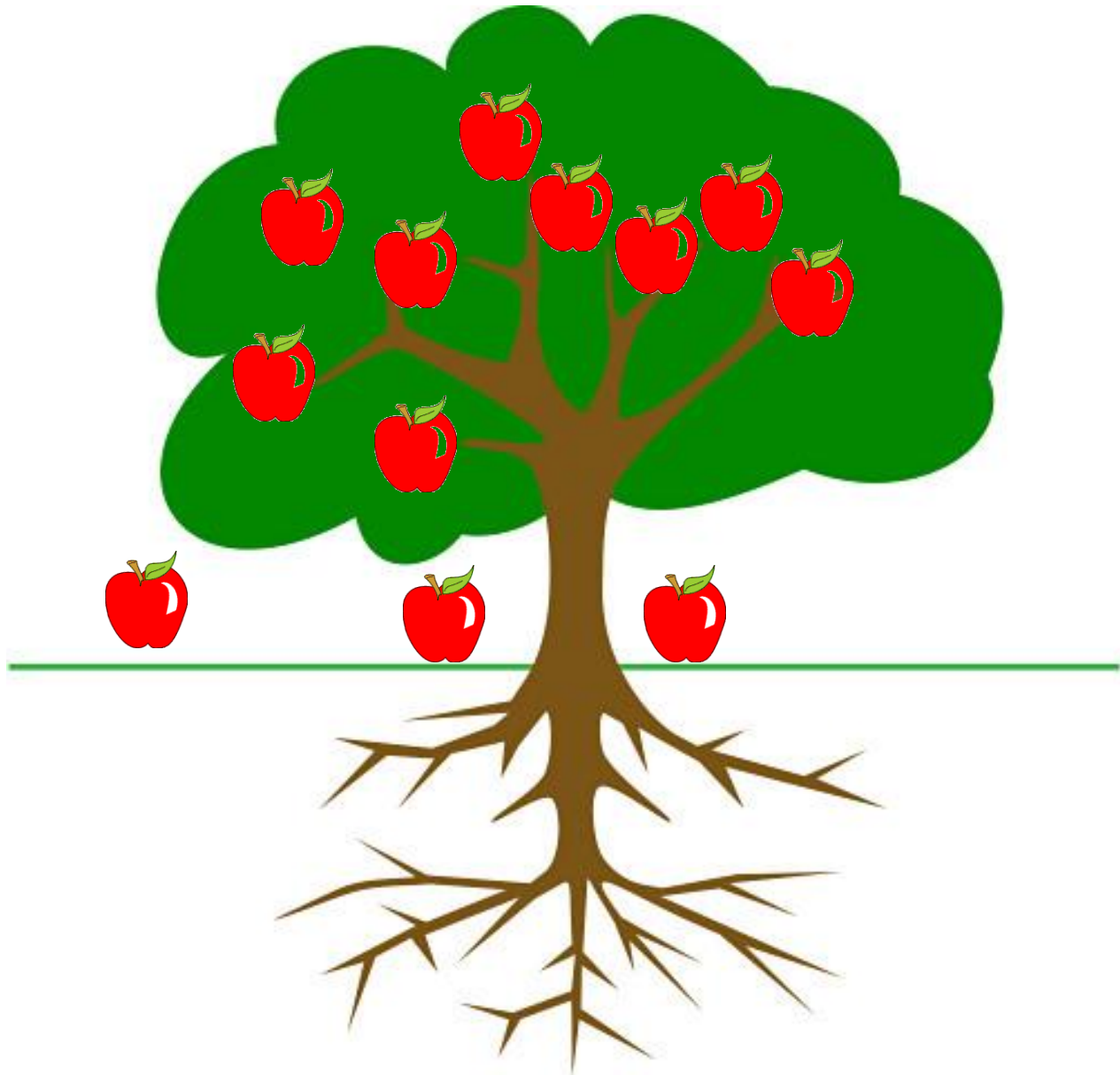


Pilot Build

- Manufacturing Plan
- Assembly Instructions
- Test Fixtures Developed
- Process Control Refinement
- Device History Record Established



Production



TriE's Objective



Thank You!

From More Information on TriE Medical's
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