

MODESIM – Novartis' Modeling & Simulation Computational Environment

Developing, Valuing & Maintaining our Technology Capabilities

Paul Lewandowski
Associate Director BIM
M&S IT Account Manager

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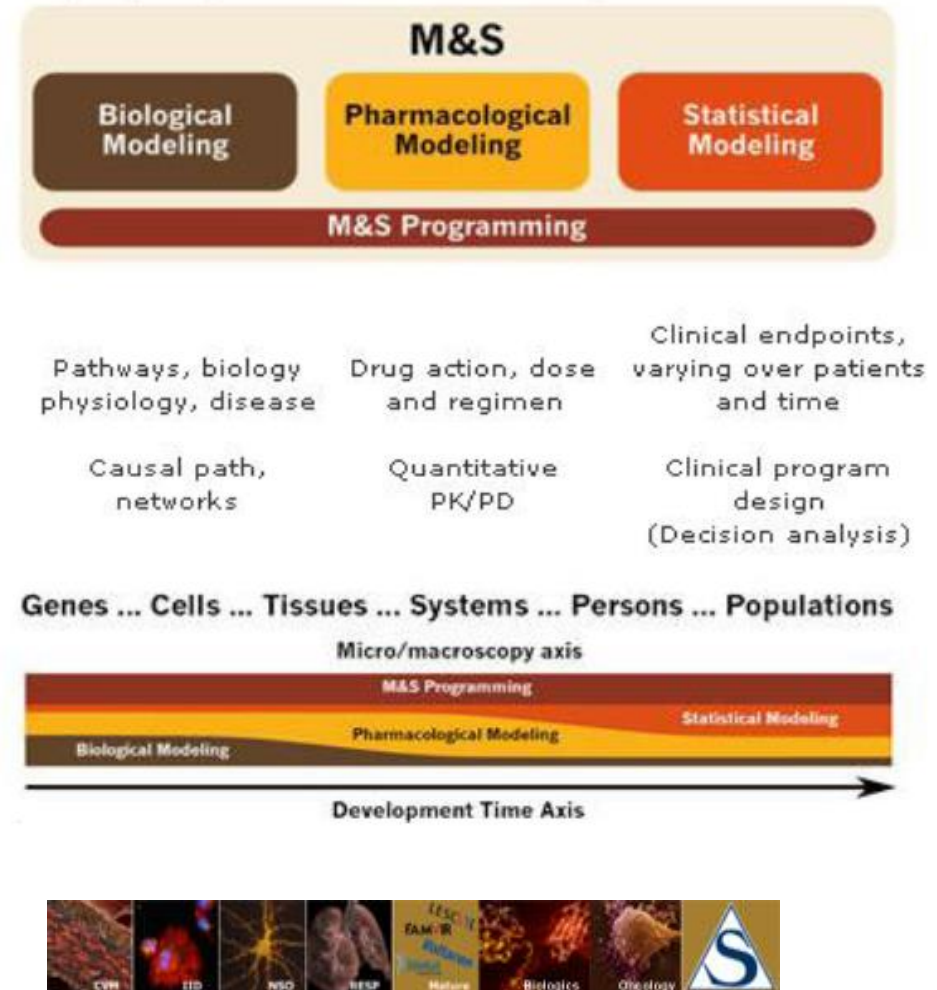
What is MODESIM

- Short form of MODE_ling and SIM_ulation
- Globally accessible computation environment developed for and used primarily by the M&S Global Line Function
 - Core is High Performance Compute Cluster - GxP
 - Additional software applications built around the compute cluster to extend capabilities
- Access is also granted to other Scientific Groups in Novartis

M&S Organization at Novartis

- Global line function of over 80 associates
- Support learning and decision making throughout development
- Led by Donald Stanski since 2005
- Integrate principles of biology, pharmacology, and statistics to explain and predict the quantitative consequences of decisions through the application of mathematical models.
- Further organized into Clusters to offer specialized support to Franchises and Therapeutic areas

Subgroups represent areas of internal expertise.



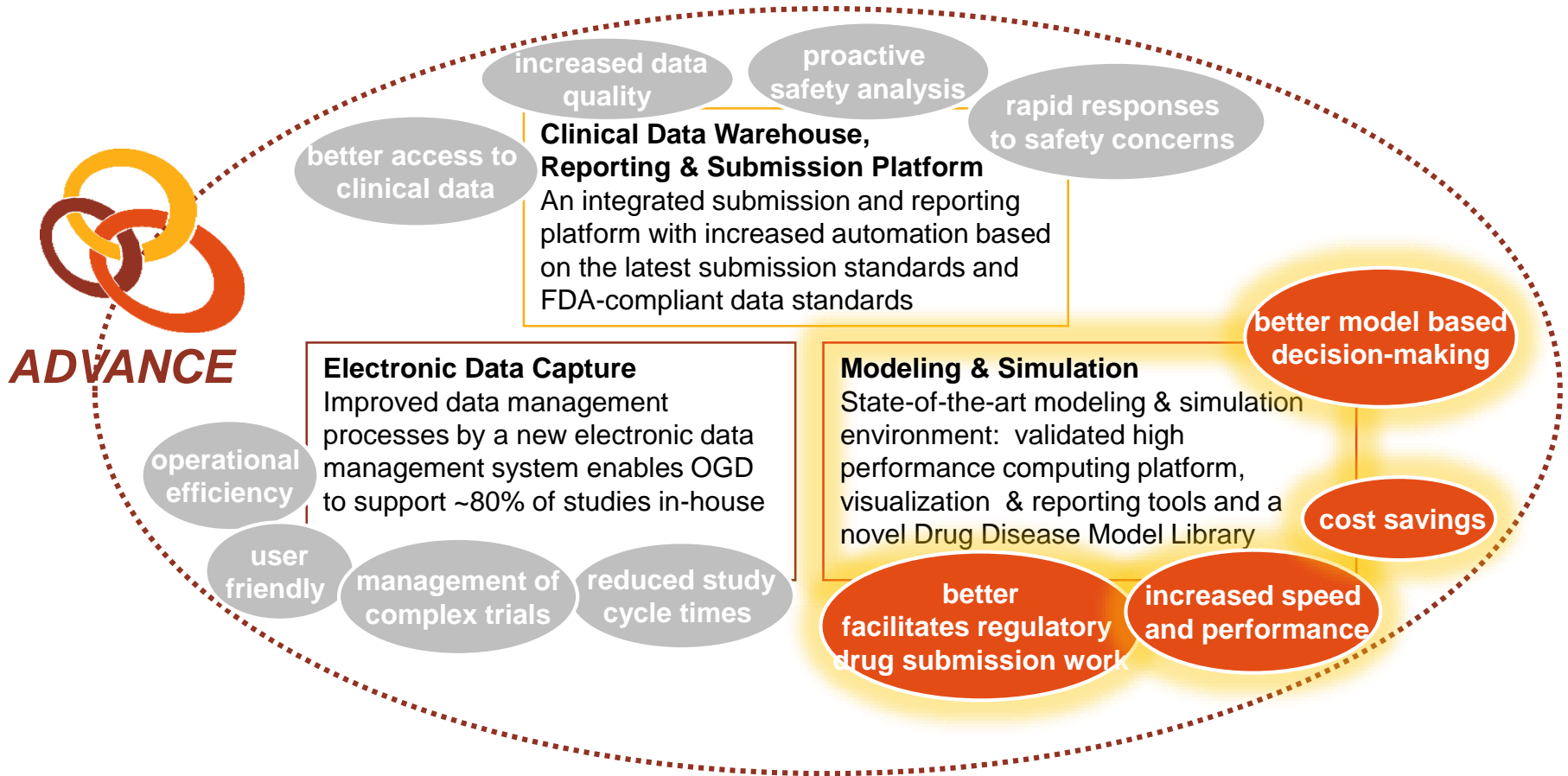
Why MODESIM?

- Existing GxP computational environment insufficient and underpowered.
- Computational bottlenecks were a result and constraint. Reduced ability to deliver
- Users forced to rely on laptops – produced limited results
- Proliferation of desktop packages
- Tool selection founded on “religious beliefs”
- Existing methods not easily reproducible or auditable
- Management consulting assessment confirmed all the above and paved the way for Modeling & Simulation workstream’s inclusion to ADVANCE

ADVANCE

Delivering new and improved capabilities to Novartis Development

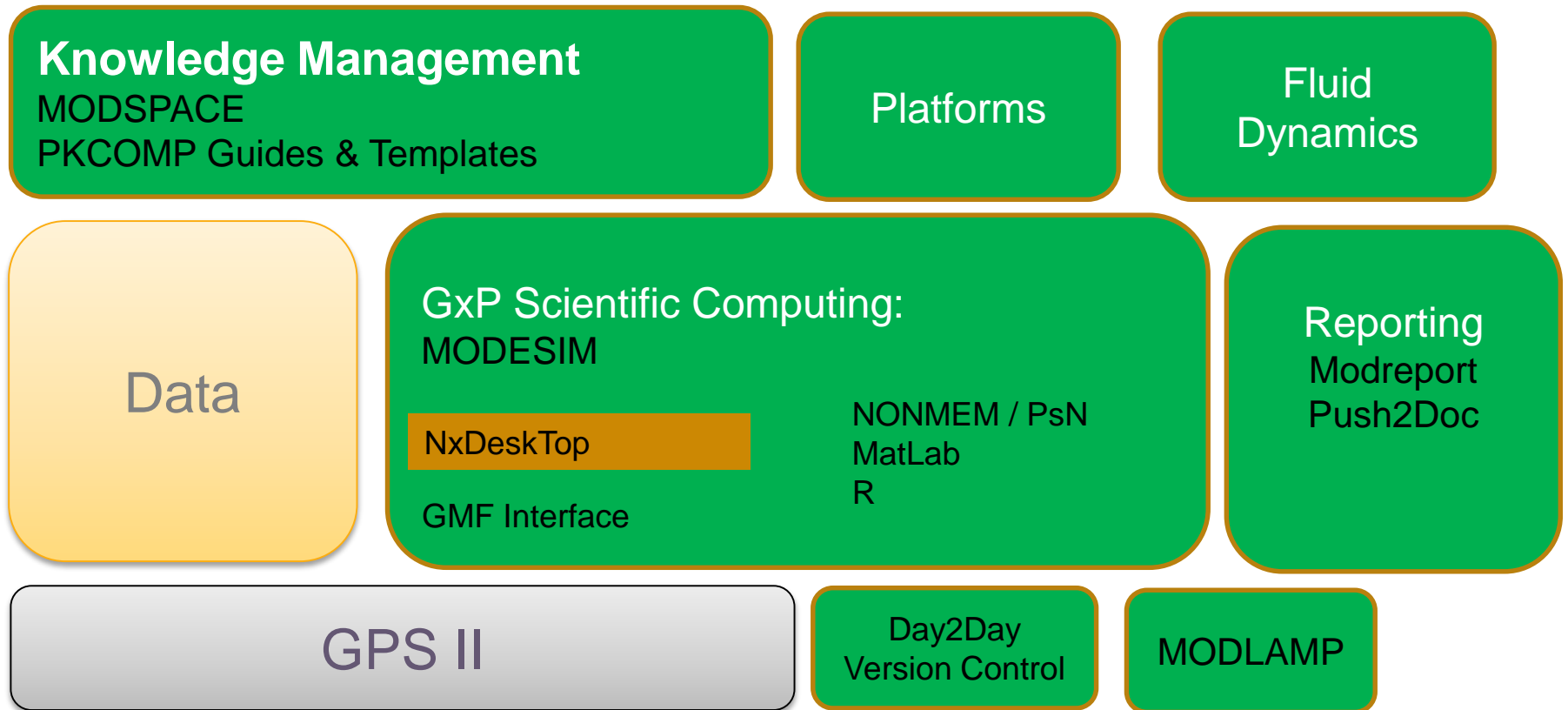
ADVANCE's 3 domains



Modeling & Simulation Strategic Roadmap Focus Areas

- Foundation Platform – High Performance Computing
- Reporting and Visualization
- Knowledge Management
- Data Analysis and Exploitation

What we delivered, where we are today



MODESIM 2010 HPCE Statistics

Overall

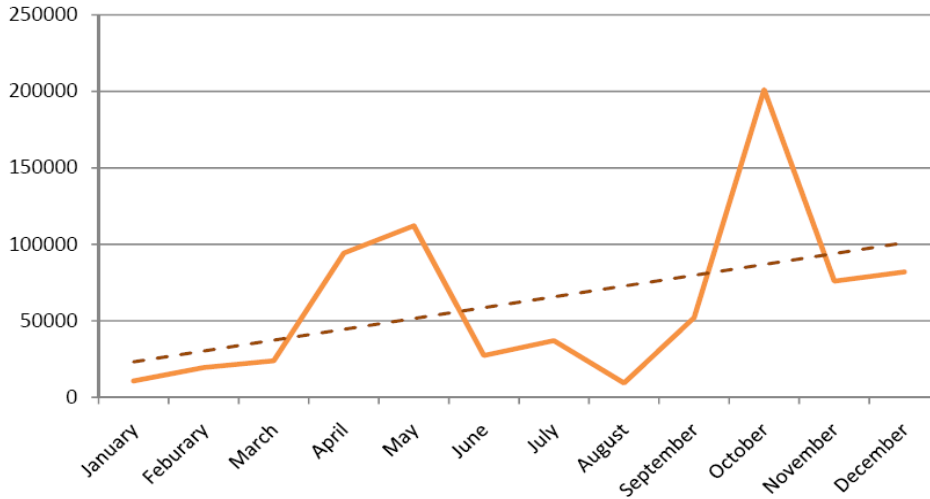
- From Jan 1 – Dec 31, 2010:
 - 1'133'103 jobs completed
 - 45.2 years worth of computations performed
 - 35.8% of global cluster capacity used
 - 198 users across CH, US, China, UK and India (31% increase from 2009)
 - 41% Modeling and Simulation
 - 26% Oncology
 - 14% IISO (Statistical Methods)
 - Biggest users
 1. 10.97 years
 2. 2.66 years
 3. 1.96 years
 - What's important - utilization is resulting in business value

MODESIM

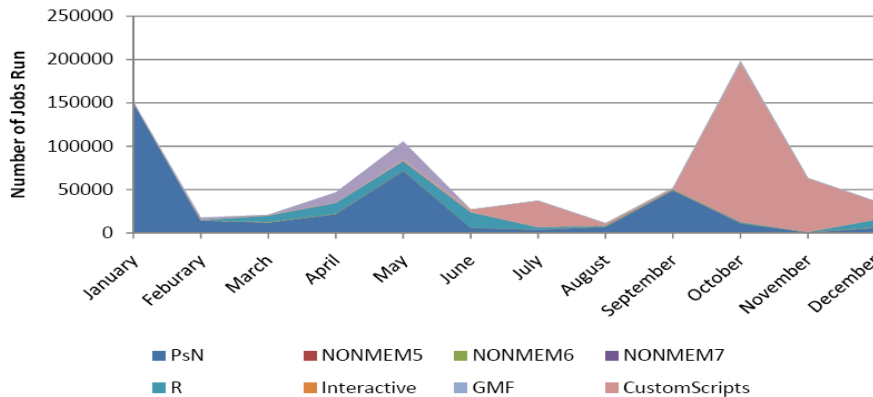
Jobs Run

1.1. Basel (Regulatory) Cluster

1.1.1. Number of Jobs Run

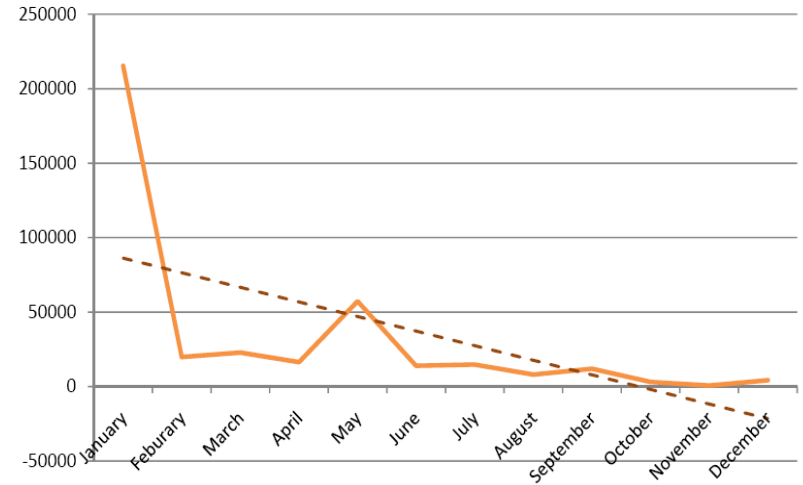


1.1.2. Application Usage

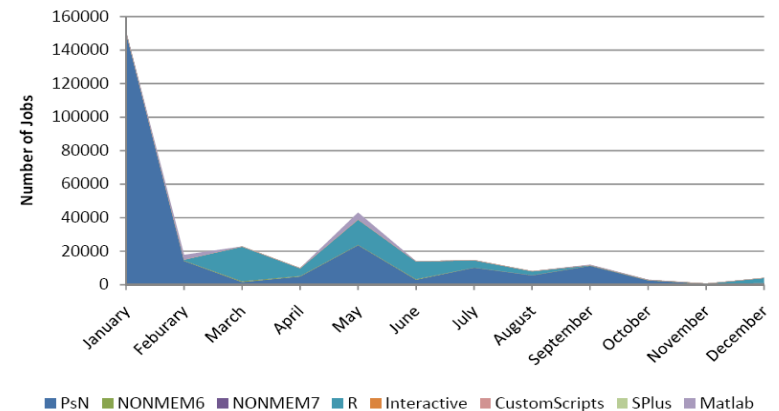


1.2. East Hanover (Exploratory) Cluster

1.2.1. Number of Jobs Run



1.2.2. Application Usage

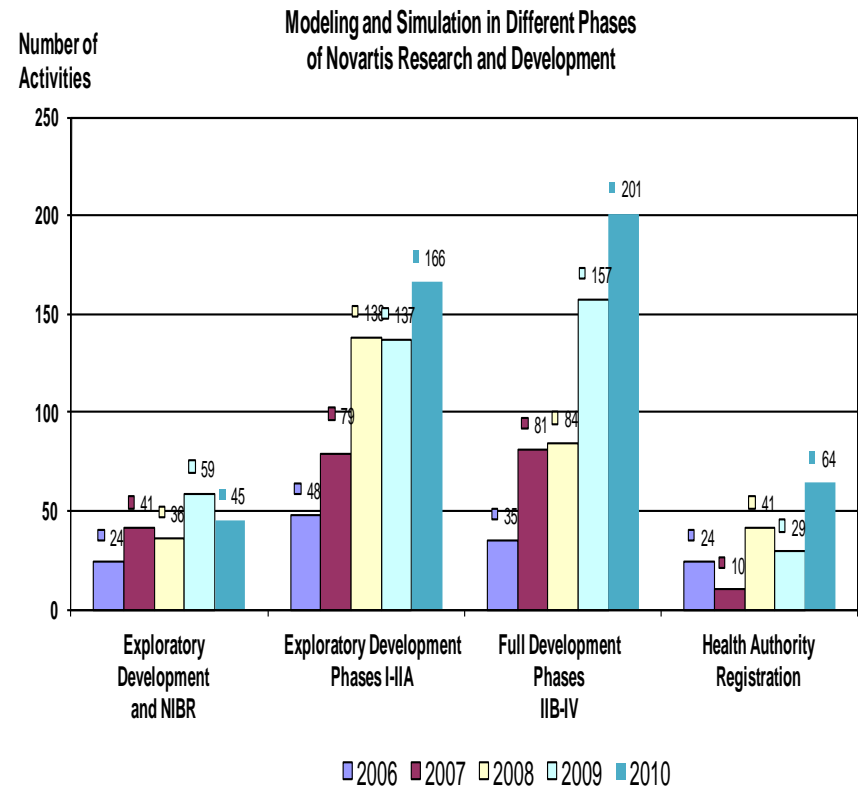


Approach to Projects - Identifying Value/Benefit

- We must demonstrate we have delivered the projected benefits
- These benefits need to include both qualitative and quantitative measures
- **All** IT projects must “prove” that the systems deployed achieve the savings/capabilities projected at the start of the project.
- MODESIM well positioned to capture and demonstrate this value
- Finance/upper management will reduce spending in areas that do not have a positive impact on the bottom line
- If we can demonstrate value, it will be easier to get funding in the future
- It will help management, in other areas, understand why investing in M&S is important
- It will help answer many of the questions I get regarding: “What does that M&S group do anyway?”
- This is a win-win situation for both M&S and DI

Modeling & Simulation - 5 Yr Results

- In 2010 M&S completed 476 modeling activities in support of Projects and Platforms, a 25% increase over 2009.
- Consistent upward 5 year trend
- Productivity gains were achieved concurrent with ADVANCE program/project 2008->2010



Core M&S Principles

These principles should also apply to our technology.

1. Identify the **relevant questions** in drug research/development for M&S
 - How do we value and prioritize our technology capabilities?
2. Perform the work at the **highest scientific quality**.
 - The quality of our modeling depends on the quality of our technology and keeping it in shape.
3. Deliver the **results on time** to impact drug research/development decision making.
 - We need to deliver on time
 - Overall time needed is low, always a lead time.
 - Excuses would not be acceptable for modeling activities.
4. **Communicate** results in a clear, articulate manner.
 - Its a collective responsibility to support our environment.
 - Efficiency gains are multiplied when experience is shared
5. **Measure the value** of M&S scientific effort on the drug research development process and decision making.
 - We should appreciate the value we get from MODESIM.
 - If we cannot demonstrate value we will loose IT support

M&S Application / System Stewardship

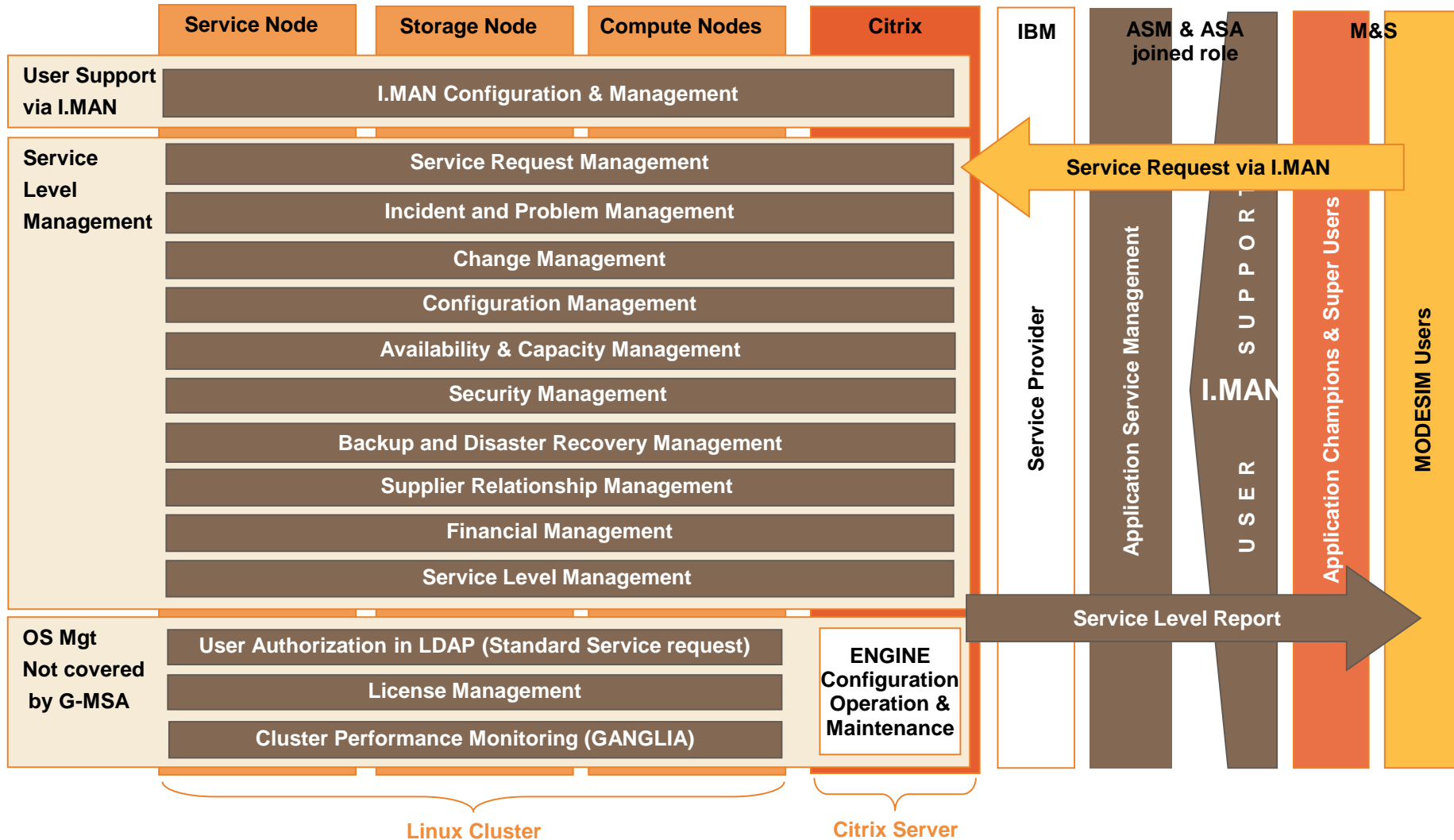
Perform the work at the **highest scientific quality**.

- The quality of our modeling depends on the quality of our technology and keeping it up to date.

- Applications/systems cost time and money to maintain
 - We are all responsible for managing, maintaining and improving these capabilities
- Application/System Owner responsibilities
 - Business case / Value management
 - Release planning (new / update / retire)
 - Test management
 - Documentation, training and user support (incl. GMF)
- Others support by
 - Develop / maintain test scripts
 - Dry run test scripts
 - Formally run test scripts
 - Documentation, training and user support (incl. GMF)
- Systems
 - MODESIM (GxP)
 - MODSpace DDML
 - MODReport (GxP)
 - Push2Doc (GxP)
 - MODLamp
- Applications
 - NONMEM
 - PsN
 - R
 - MatLab
 - S-Plus
 - Berkley Madonna
 - Census

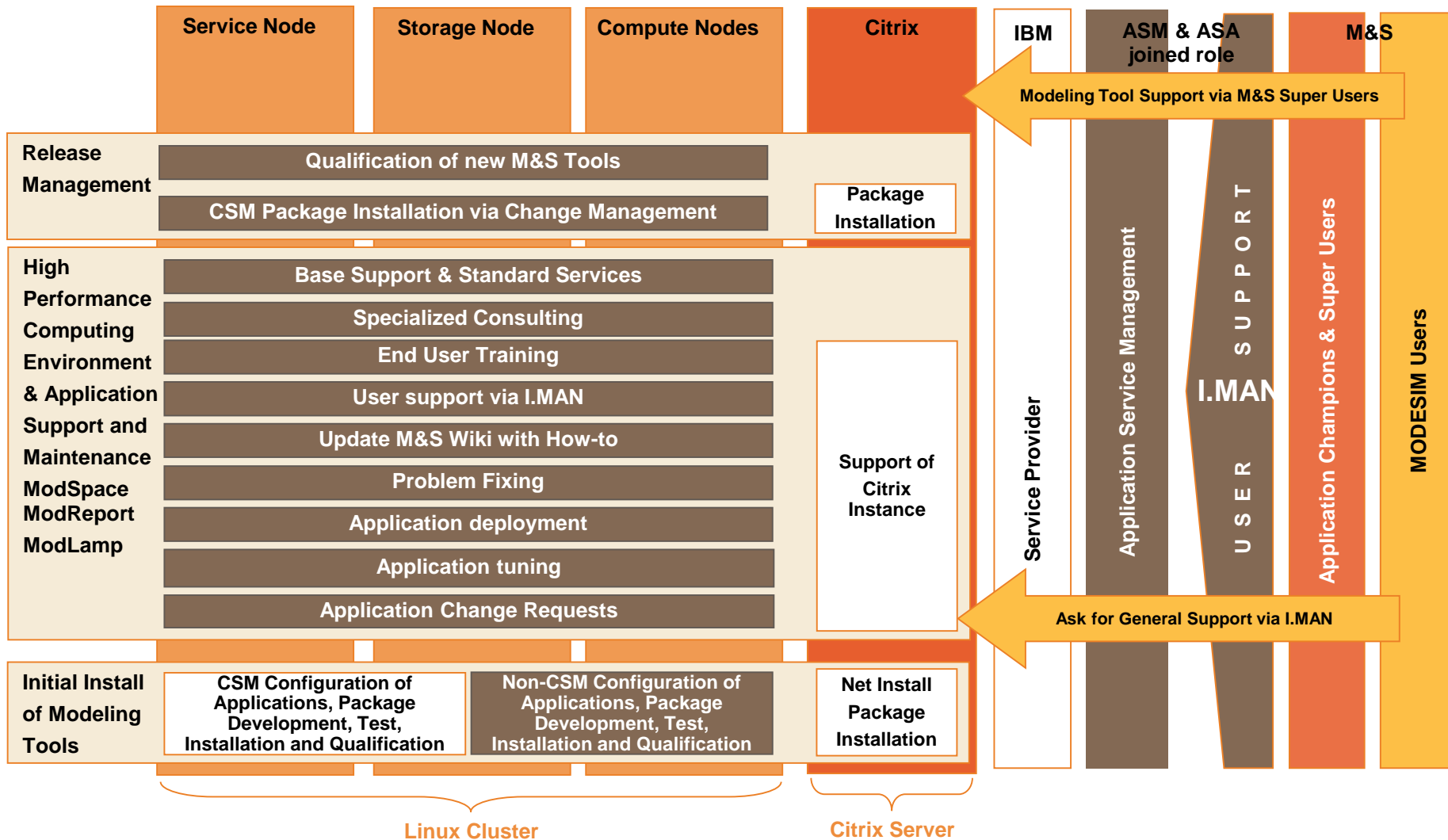
MODESIM Support Model

IT Managed Support Services

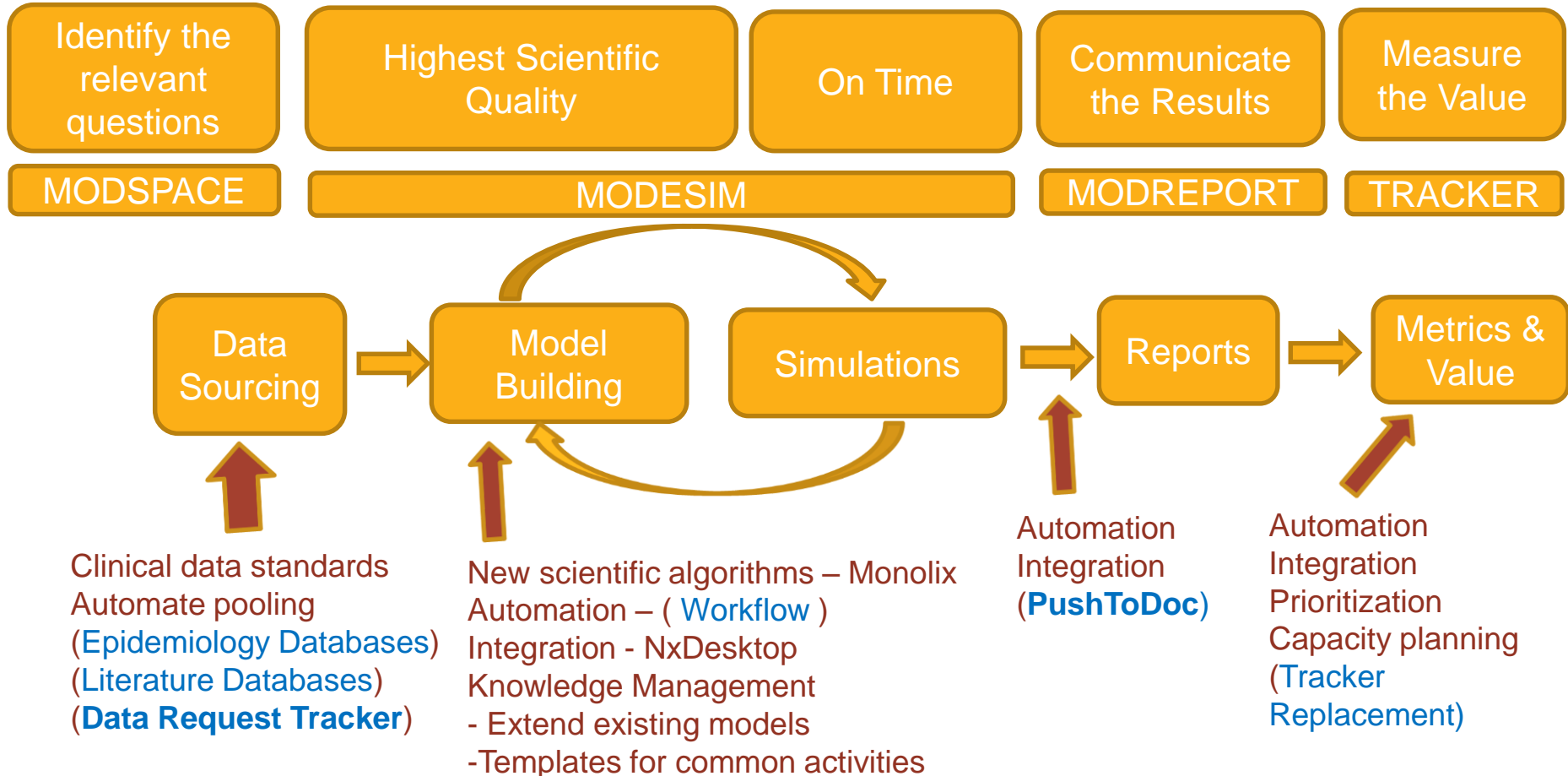


MODESIM Operational Support Model

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Where the Opportunities to Improve Lie



Identify the most common activities and make them as efficient and easy as possible

Compliance, consistency, best practice, continuous improvement