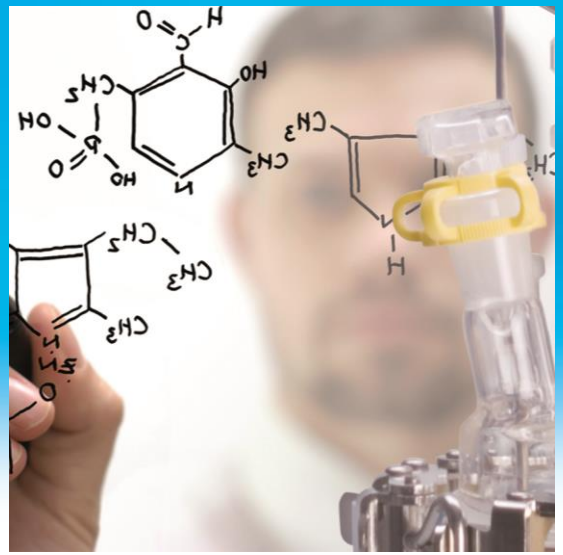
Collaborations in development and implementation of enabling technology to support PR&D



Council for Chemical Research

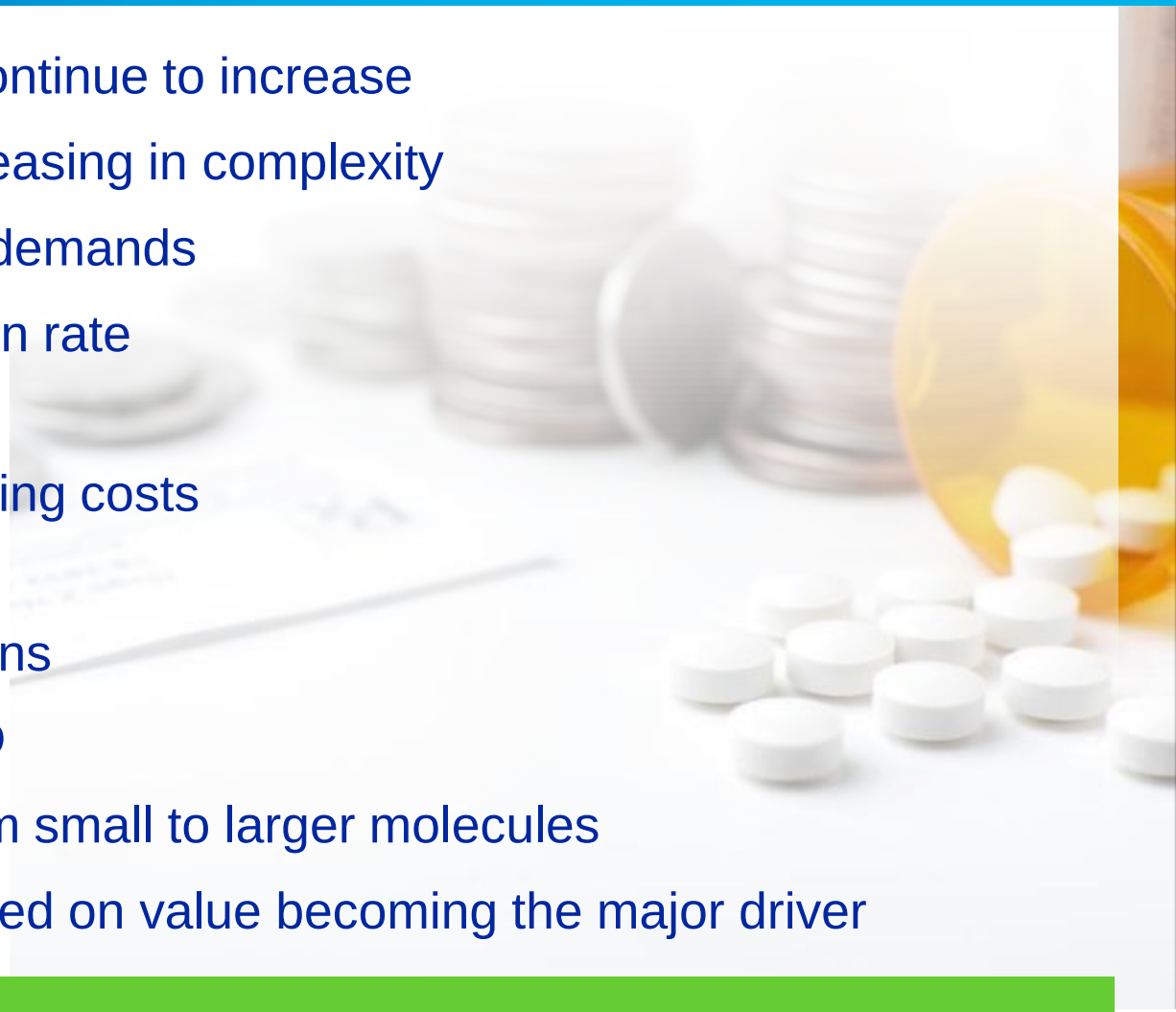
June 2013

Henry Dubina

METTLER TOLEDO

Challenges in Today's Pharma Industry

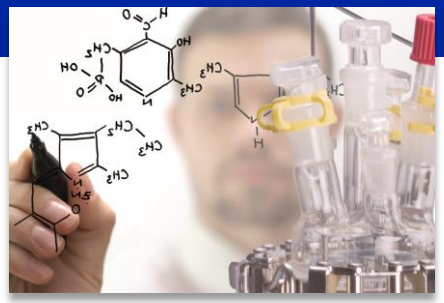
- Development costs continue to increase
- Synthetic targets increasing in complexity
- Increased regulatory demands
- High candidate attrition rate
- Cost pressures
  - Higher manufacturing costs
  - Lower payer costs
- Major patent expirations
- Cost competitive R&D
- R&D funding shift from small to larger molecules
- Patient outcomes based on value becoming the major driver



As pressures on the industry increase, new methods of working are required.

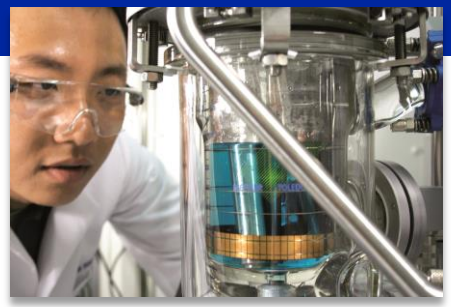
MTAC – a Pathway to Innovation

Early Phase Development



- Develop compounds
- Establish route
- Provide material early phase clinical trials

Design and Process Development



- Develop the process
  - Optimized
  - Safe
  - Robust

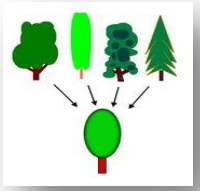
Scale-up and Manufacturing

- Establish scalable parameters
- Reduce batch failures
- Reduce cycle time

METTLER TOLEDO works with industry to address these challenges, providing solutions that deliver:

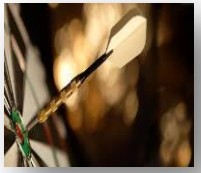
Faster | Lower Cost | Higher Quality | Increased Knowledge

Impact on Chemical Development



GENERALIZE

- Generalization – non-experts need to use information-rich technologies



UNDERSTAND

- In-depth understanding – more and better information has to be available during entire development process

DECIDE

- Faster decision making – quickly turn data into information to shorten your experiment timelines and seamless sharing across organization

COMBINE

- Combination of information – more and more analytical (PAT) technologies are used to understand the process

Trends from a Vendor Perspective

- Products need to be easier to use, increasing adoption velocity
- Low training requirement for utilization
- Decreased product complexity (& facilitation), "turn it on & get started "
- Total solution robustness is mandatory
- Value based pricing essential - (ROI needs to be short term and measurable)
- Bidirectional open software based on industry standard communications, data structures, etc. (OPC, RT analysis options and Allotrope……)
- "Open" innovation model required that focuses on key customer issues
- Software, information and data communication surrounding the customer workflow to ELN, LIMS, etc.

Pfizer LOTF – Mettler Toledo Engagement

2006 -2007 | 2008 | 2009 | 2010 | 2010 | 2011 | 2012 | 2013 | 2014+

Development of LOTF Vision

LOTF Vision enabling technology mtg MT-Pfizer

1st commercial mtg Agree final specs , up-time, price position

$

Prototype delivery and evaluation

Product Improvements

Development of prototype labs

Multi-year contract negotiation

$

iC Data Center Print to ELN

Pfastrack/EasySampler Specification and development

Implementation
Deployment of ready technologies

Optimization and sustainment of LOTF

Eq uptime, hardware/ sftw upgrades, training, etc.

Further evolution of enabling technologies

EasySampler, EasyMax with HFX, etc.

Continued development of LOTF culture

Technology In Use

PAT Platform

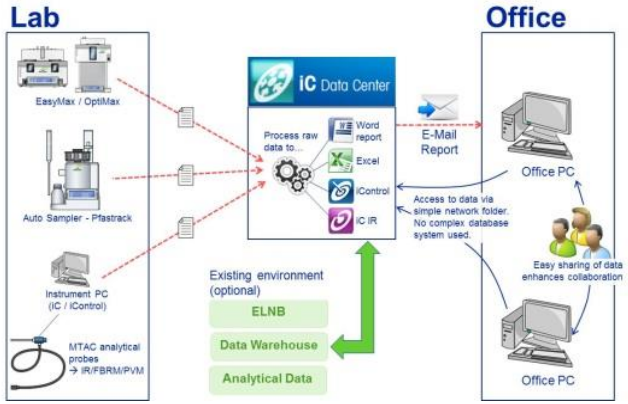
PVM

FBRM

ReactIR

Software Platform

iC Software Suite



Reactor Platform

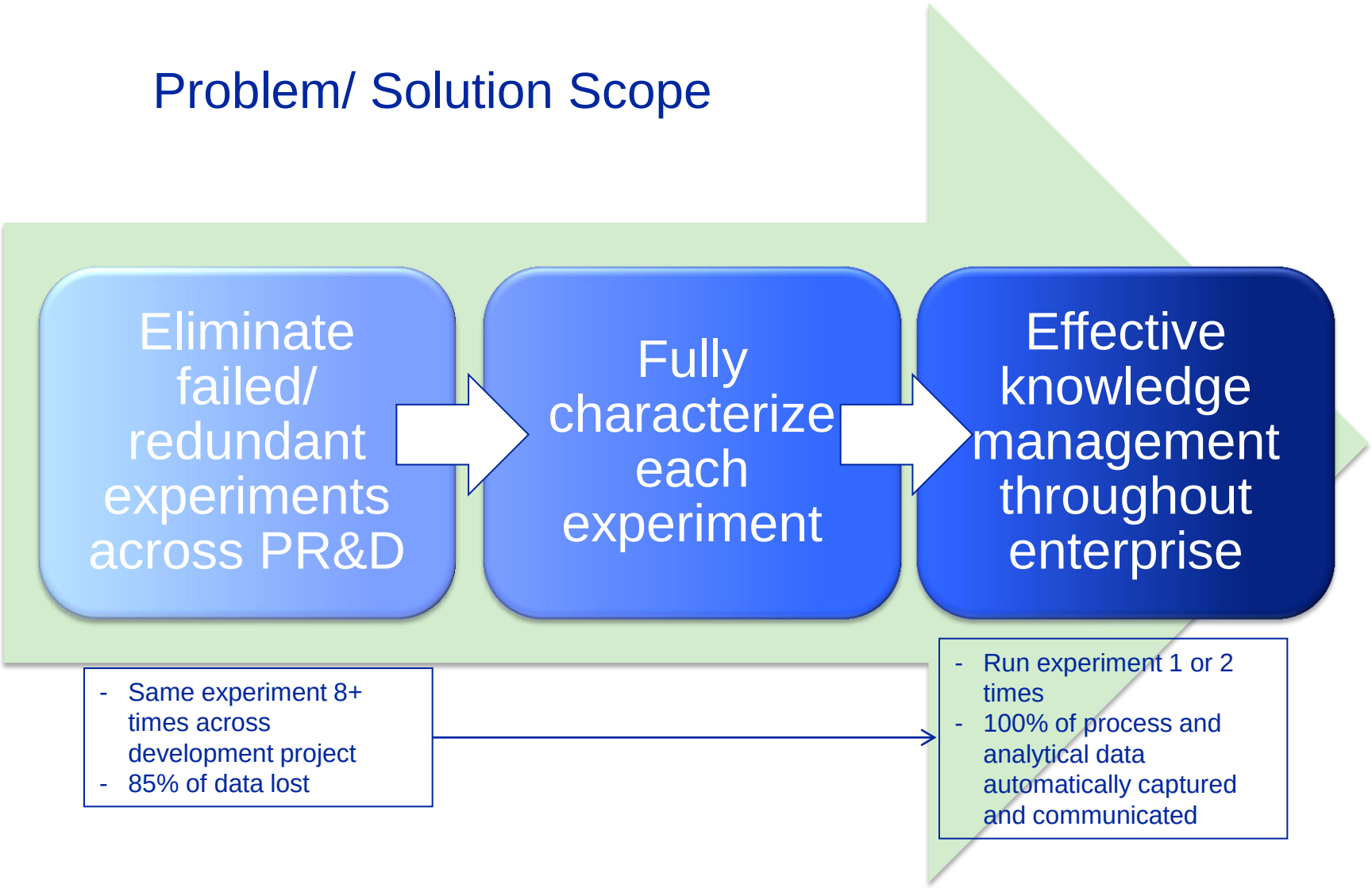
EasyMax

OptiMax

Identified strategic platforms for success

Ex: Need - Increase Development Productivity

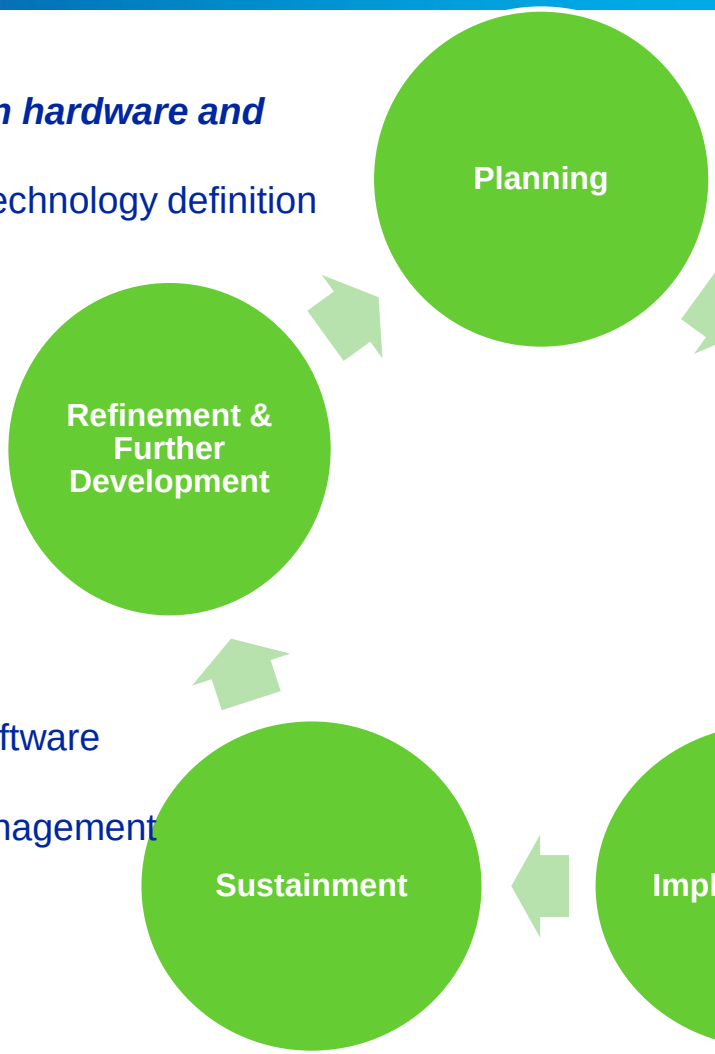
Problem/ Solution Scope



Secrets of Success

- Top Down + Bottom Up commitment
  - Vision to change
  - Alignment of a core team
  - Change management
  - Joint customer/ vendor management engagement
  - Share knowledge/ financial risk (in some cases IP)
- Prototype lab
  - Various equipment vendor evaluated
  - Continual feedback (sometimes ugly)
  - Iterations
- Strong MTAC Engagement/Integration
  - Right person for the job – MTAC change management
  - Invited to LOT department meetings
  - Badge to allow TAC into lab
  - Feedback to management
  - Quarterly Leadership meetings
  - Management survey to chemists and feedback to MT

Pfizer & Other LOTF - A Living Organism



Improvements in hardware and platforms
- New enabling technology definition
- Sustain ROI

Platform Development
- Usability
- Robustness

Platform Refinement
- Adoption
- Total solution
- Data/ Information Capture
- Resolving Gaps

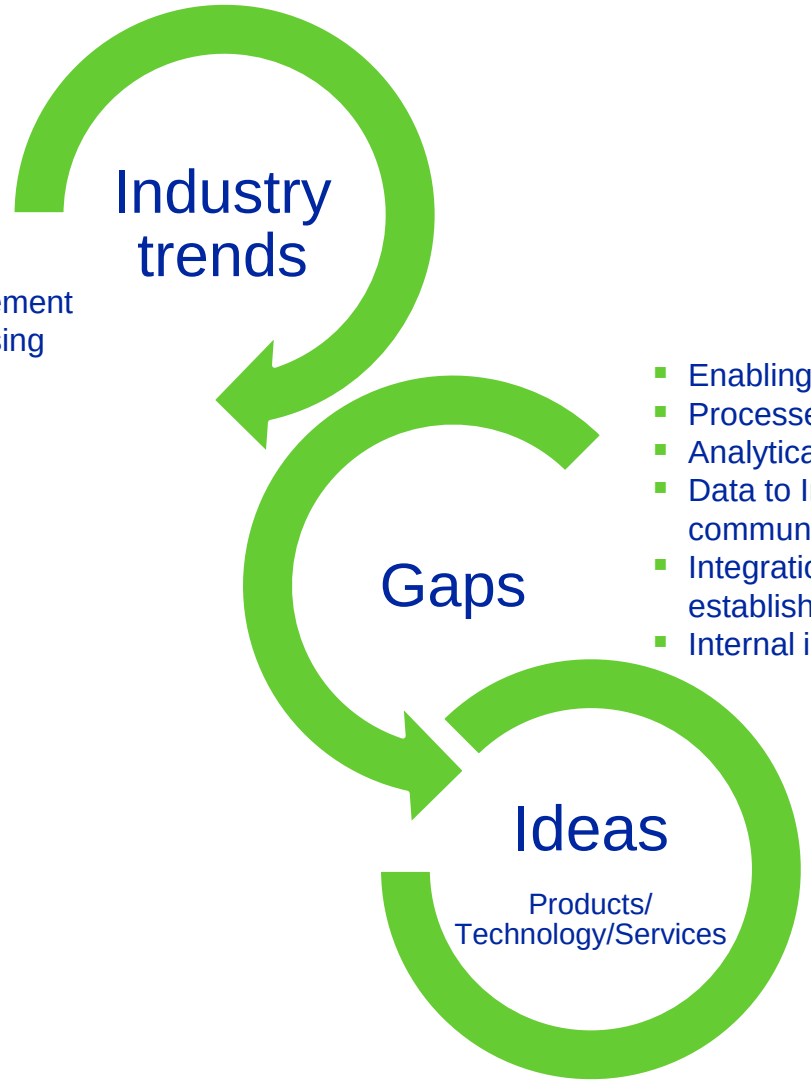
Change management / Adoption (training)
- Service/ uptime
- Data/ Information Capture
- Resolving Gaps

Sustainability
- Hardware & Software Maintenance
- Knowledge management
- Delivers ROI

Requirements and priority continued to evolve throughout the implementation

Current BioPharma Business Dynamics

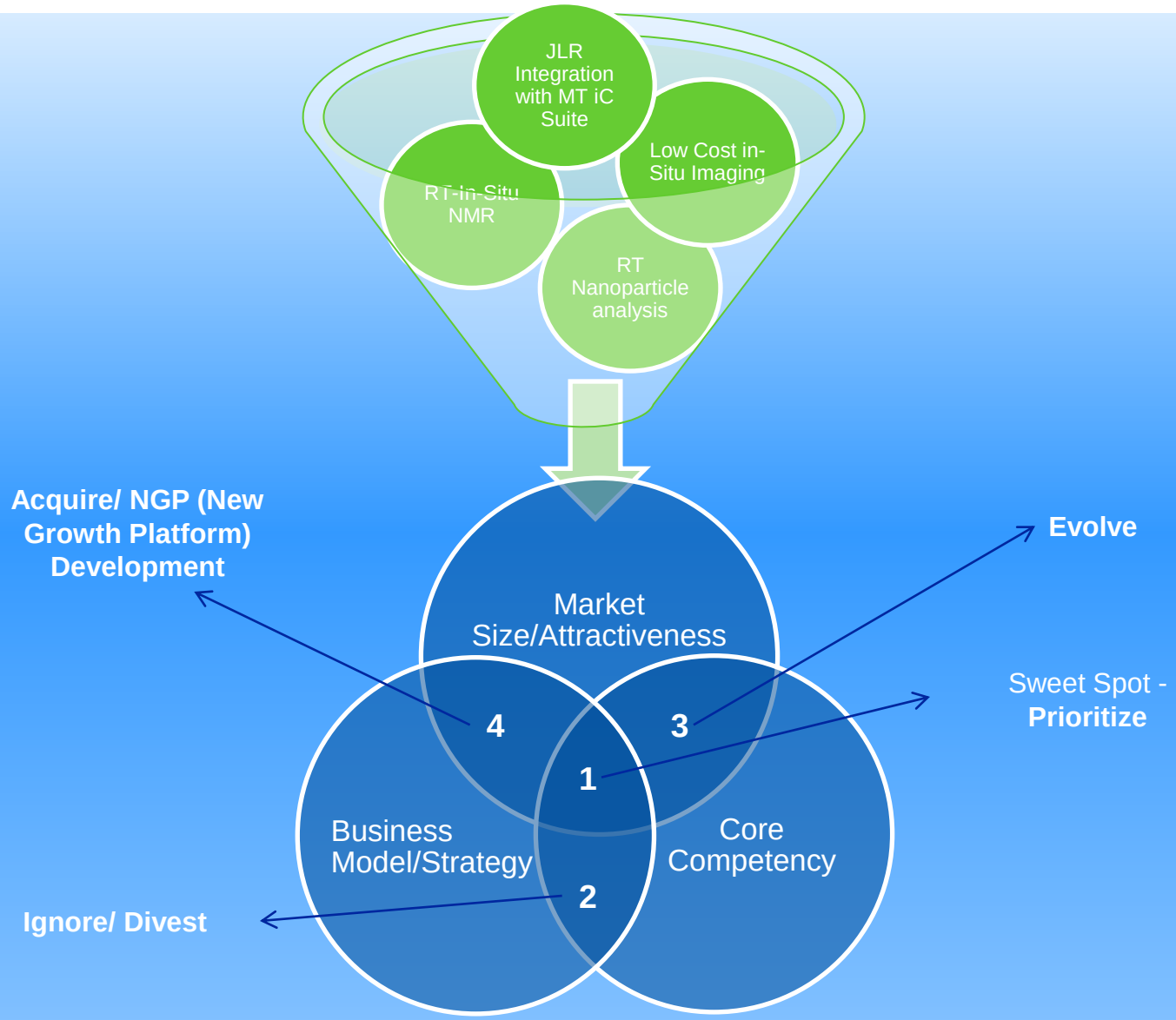
- R&D Productivity Improvements
- Speed to scale (first time) / market
- Knowledge management
- Continuous processing
- Biomedicines



- Enabling Technology
- Processes/ workflows
- Analytical methods (Bio)
- Data to Information/ communications
- Integration with established infrastructure
- Internal inertia

All supported by proactive change management

Strategic Alliance Driven Innovation



Mettler-Toledo AutoChem Core Competencies

- in-Situ Analytics technology / know-how
  - FTIR for reaction and process monitoring
  - Probe based particle characterization and imaging
- Probe technology (analytical, performance, sealing, vessel interface, robustness cleaning, safety)
- Automated Lab Reactors (innovations in heating, cooling, dosing and stirring control)
- Calorimetry
  - Heat Flux – an emerging technology that delivers high accuracy, direct energy measurement
  - Heat Flow
- in-Situ Sampling probe (Pfastrack/EasySampler)
- Software (UI, digital and analog signal processing algorithms, applications, control algorithms)
- World class technology and application experts with industry experience

MT: Open Innovation Model in Early Development

Industrial Partners knowledge, head counts & money

"Pains"

Market potential?

Scope

Ideation

IP

M100

Technologies

Proof of concept

Technology Partners (external or internal)

IP, Spectra, AnaChem, MTCS, AC SW Center

Universities

Technology Consultants

Conclusions

- Collaborations provide an opportunity develop key enabling technology that directly addresses important gaps in customer processes
  - Allows the vendor to intimately understand the "real" needs and rapid communications on "fit-gap" so in the end the customer gains a key solution
  - Cost and time frame effective (when considering the ENTIRE product in the end)
- Project priority must be have the same level of importance in both organizations. There must be a strategic fit
- The vendor needs to constantly assess the general marketability of the commercialized product ….. More than one partner customer needs to be involved……but not too many
- Allows development of vendor's corporate technology vision with inclusion of significant customer input
- Industrial funding on the million dollar magnitude is no longer available Sharing resources and de-risking new technology development is a beneficial approach from both sides.
- Changes the relationship from vendor-customer to partners allowing for a far greater ownership of equipment roll out and initiative sustainment