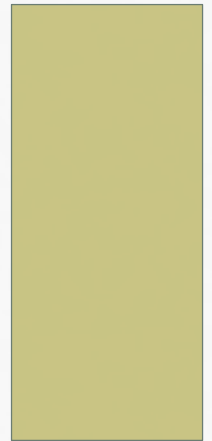


# SANOFI CLINICAL PROCESS OPTIMIZATION AND AUTOMATION INITIATIVE

MICHAEL ROBBINS & ADAM RADZISZEWSKI – SANOFI  
VASU RANGANATHAN – ARBORSYS GROUP  
MARC WILSON - APPIAN



# AGENDA

- Business Drivers
- Mission
- Best-of-breed Methodology/ Approach
- Example Governance & Team Structure
- BPMS Capability
- BPMS Delivery Service
- Next Steps

# BUSINESS DRIVERS

- Optimized and Consistent Global Business Processes
- Improved Flexibility, Speed and Productivity of Clinical Operations
- Improved Data Quality and Knowledge Velocity
- Improved Interoperability: Internally and with Clinical Partners
- Improved Investigator Selection and Relationships
- Reduced Risk of Regulatory and Compliance Issues

# MISSION



## Standardize

- Achieve appropriate level of standardization for common business processes
- Eliminate process redundancy across clinical operations



## Streamline

- Identify opportunities for business process improvement and reduced complexity
- Leverage industry best practices



## Accelerate

- Leverage BPM methodologies and software tools to realize process improvement
- Develop and deploy process-driven applications

***Standardize, Streamline, and Accelerate processes for greater agility, transparency, and efficiency***

# SCOPE - CLINICAL PROCESSES



<ul style="list-style-type: none"> <li>• Study design</li> <li>• Study and Protocol Feasibility</li> <li>• Protocol preparation</li> <li>• Geography selection</li> </ul>	<ul style="list-style-type: none"> <li>• Protocol approval</li> <li>• Vendor contracting</li> <li>• Identify, Qualify and Select Site</li> <li>• Investigator contracting</li> </ul>	<ul style="list-style-type: none"> <li>• Site initiation</li> <li>• Site training</li> <li>• Patient enrollment</li> <li>• Patient treatment</li> <li>• Site monitoring</li> <li>• Source data</li> </ul>	<ul style="list-style-type: none"> <li>• Early Study Termination</li> <li>• Drug reconciliation</li> <li>• Final data collection</li> <li>• Site closure</li> <li>• Database QC</li> </ul>	<ul style="list-style-type: none"> <li>• Post Close-Out Site Interactions</li> <li>• End of Trial Notification</li> <li>• Statistical analysis</li> <li>• Results unblinding</li> </ul>
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Priority: Key areas of business benefit and pain points

<ul style="list-style-type: none"> <li>• Budget approval</li> <li>• Vendor selection</li> <li>• Data mgmt. and capture planning</li> <li>• Training</li> </ul>	<ul style="list-style-type: none"> <li>• recruitment</li> <li>• Data collection readiness</li> <li>• Develop Monitoring Plan</li> <li>• Trial registration</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical Safety</li> <li>• DSMB</li> <li>• TMF Audit</li> </ul>	<ul style="list-style-type: none"> <li>• Pharmaco-vigilance</li> <li>• Study Documentation Audit</li> </ul>	<ul style="list-style-type: none"> <li>• Results posting</li> <li>• Pharmaco-vigilance</li> </ul>
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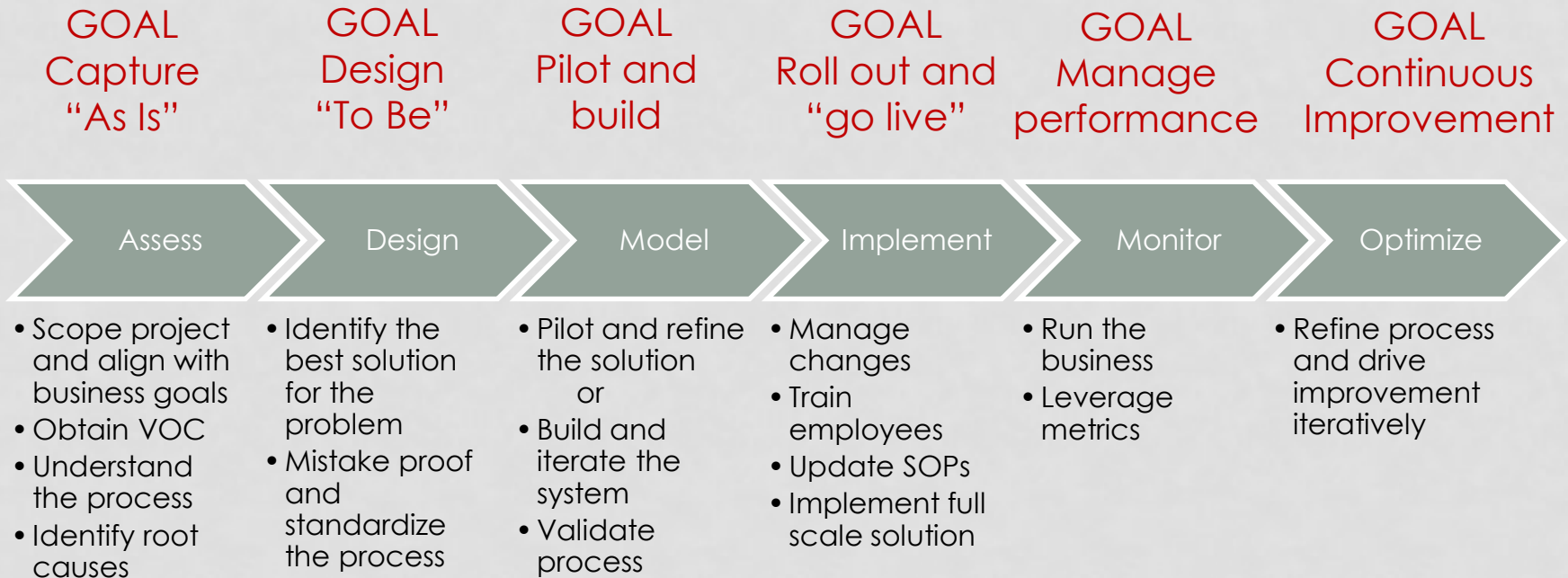
# METHODOLOGY HIGHLIGHTS

- A pragmatic business process improvement methodology designed to enable team members to efficiently Harmonize, Optimize and Automate targeted processes
- Methodology includes proven easy-to-use tools, templates and techniques that provide demonstrable value to the business



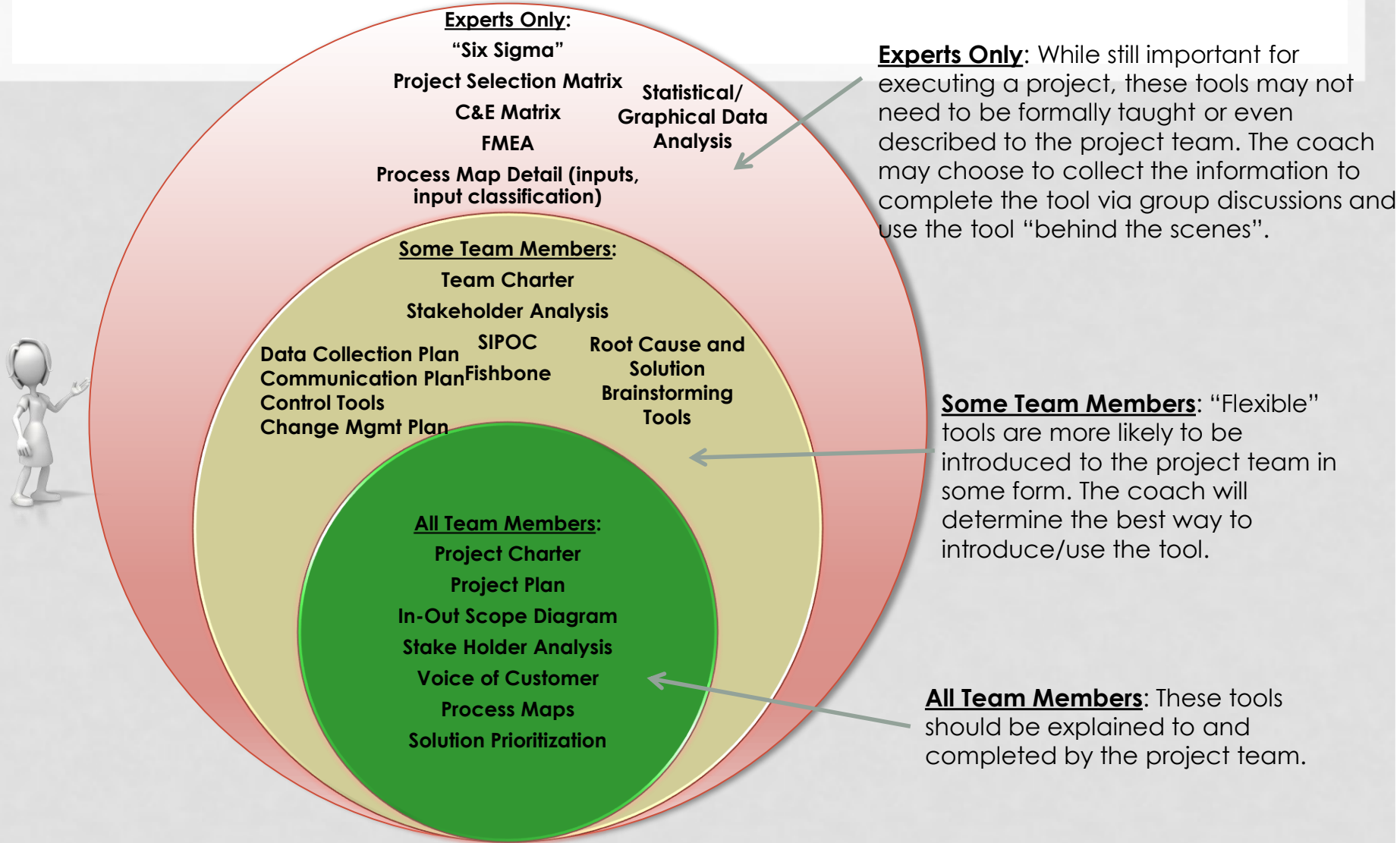
**process improvement experts will coach team members in use of methodology and tools during the projects and provide on-the-job training support**

# IMPROVEMENT METHODOLOGY: ADMIMO “BACKBONE”



***The specific tools used at the various stages will vary depending on the specific project needs***

# TOOLS APPLIED TO MEET SPECIFIC PROJECT NEEDS





# TOLLGATE EXPECTATIONS: DELIVERABLES



- Finalized project charter
- Clear understanding of project scope and deliverables
- Project kick off meeting and formalized project team
- In progress project plan and communication plan
- Completed stakeholder analysis
- Prioritized list of key customer requirements and inputs
- Baseline process performance
- Mapped current-state process
- Prioritized list of root causes

- Validated map of future process
- Validated list of planned process improvements and/or technology builds/changes
- In progress project plan (including new work plan for Design phase) and communication plan
- Estimated benefits summary
- Preliminary change management plan

- Pilot test/ prototyping/ POC completed
- Solution evaluated
- Solution refined and finalized
- Initial implementation plan (or updated project plan)
- In progress change management plan and communication plan
- Budget for solution approved

- Implemented solution
- Updated project plan
- Executed implementation plan
- Executed communication plan and change management plan
- Training/re-training completed
- KPIs and performance measures identified

- Ongoing metrics in place
- Control plan executed
- Project closed and handed off to process owner
- Team recognized
- Post-mortem conducted

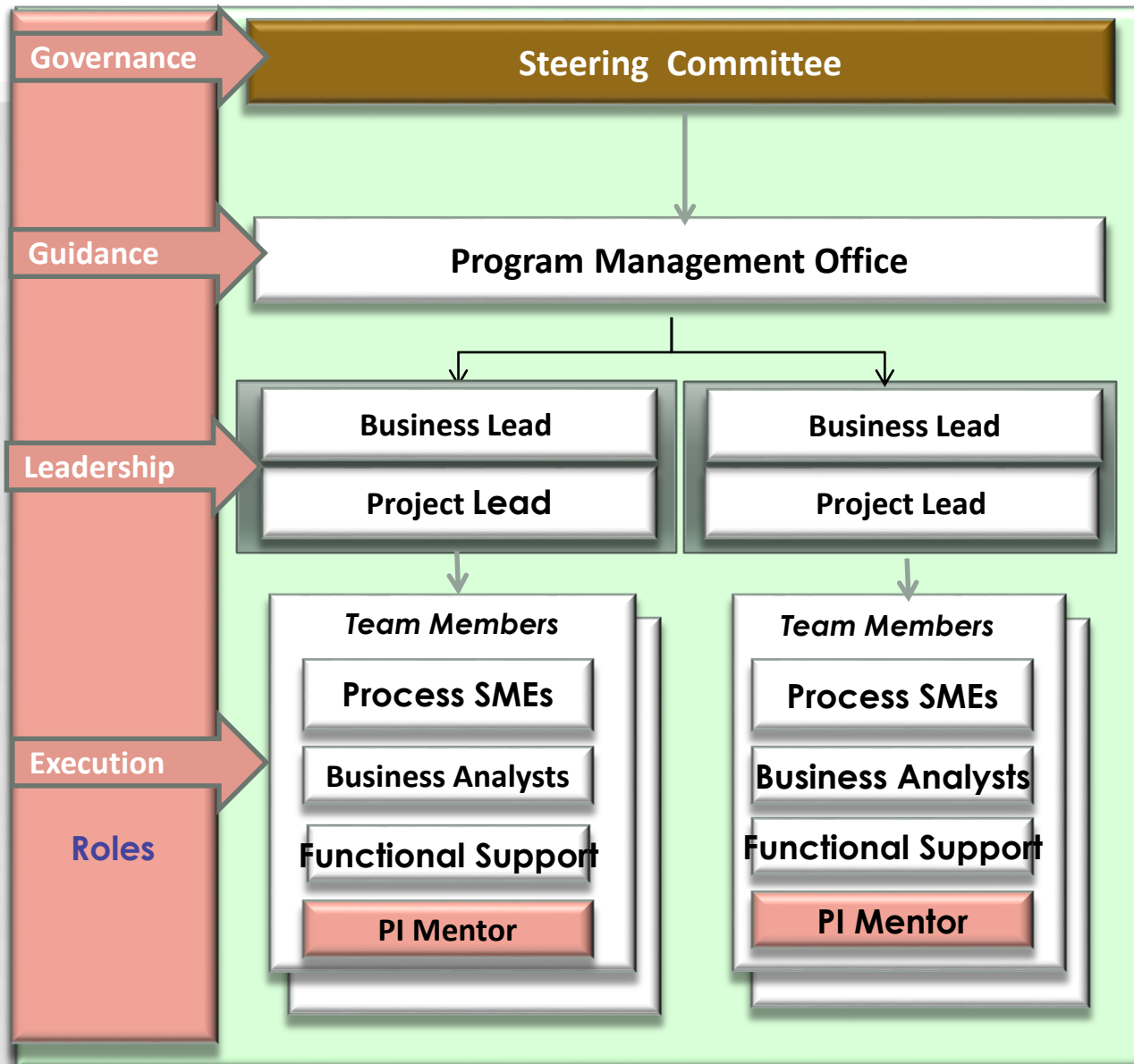
- Opportunities to translate improvements to other areas
- Project completion letter



# GOVERNANCE MODEL

<b>Strategic Governance</b>	<ul style="list-style-type: none"><li>❑ Strategic guidance and decisions raised through the Program Sponsor Committee</li><li>❑ First-level decision making team for strategic decisions</li><li>❑ Interaction with other Business Counsels</li><li>❑ Alignment with broader enterprise strategies and objectives</li></ul>
<b>Operational Guidance (PMO)</b>	<ul style="list-style-type: none"><li>❑ Guidance to process improvement teams on prioritization and alignment to operational needs</li><li>❑ First-level decision on operational process designs and proposed changes</li><li>❑ Raise appropriate decisions to the strategic governance body as applicable</li></ul>
<b>Execution - Tactical Decisions (Project Teams)</b>	<ul style="list-style-type: none"><li>❑ <u>Project Process Teams</u><ul style="list-style-type: none"><li>» Composed of Business Process Owners, Project Leads, Mentors, Business Analysts, and other SMEs</li><li>» Drive process design activities for process projects using methodology &amp; tools</li><li>» Ensure business value and process improvement objectives are met through standardization and streamlining</li><li>» Facilitate change management and training for successful implementation</li></ul></li></ul>

# EXAMPLE GOVERNANCE



Prioritize, approve and align projects with business strategy

Ensure projects are adequately resourced and structured and focused on delivering business value

Business Leads and Project Leads will work in partnership to drive the project to completion.

Project Teams will be tasked with executing ADMIMO methodology to Standardize, Streamline and Accelerate Process Improvement

# BPMS CAPABILITY

# BPMS ACCELERATOR

BPM Accelerator Team represents the solution delivery capability of the process project teams using Appian

- **Process Project Teams**

- Identifies processes that have been implemented in ways that are suboptimal or inconsistent with Sanofi goals
- Prioritizes the proposed work along a unified timeline
- Defines standardized & streamlined process flows across the enterprise (Assess & Design phases of ADMIMO)

- **BPMS Accelerator Team**

- Works from prioritized Roadmap
- Analyzes the current and proposed process models
- Collaborates with Process Teams
- Develops an optimized BPMS
- Delivers and implements the BPMS
- Assists in managing the organizational change

# BPMS ACCELERATOR PRACTICE ENGAGEMENT MODEL

- The Accelerator engagement model implements the Agile development methodology delivering highly focused customer engagement
  - Aligned to working directly with business units
  - Integrating supporting technology teams under comprehensive project plan
- The model implements five approval gateways that facilitate project governance and progress assessment
  - Accelerator Project Eligibility Gate
  - Requirements Confirmation Gate
  - Design Acceptance Gate
  - Business Acceptance / Validation Gate
- New proposals are evaluated by the Accelerator management team



# WHY BPMS?

- Detailed process insight (transparency & metrics)
- Process visualization & agility
- Centralized business process control



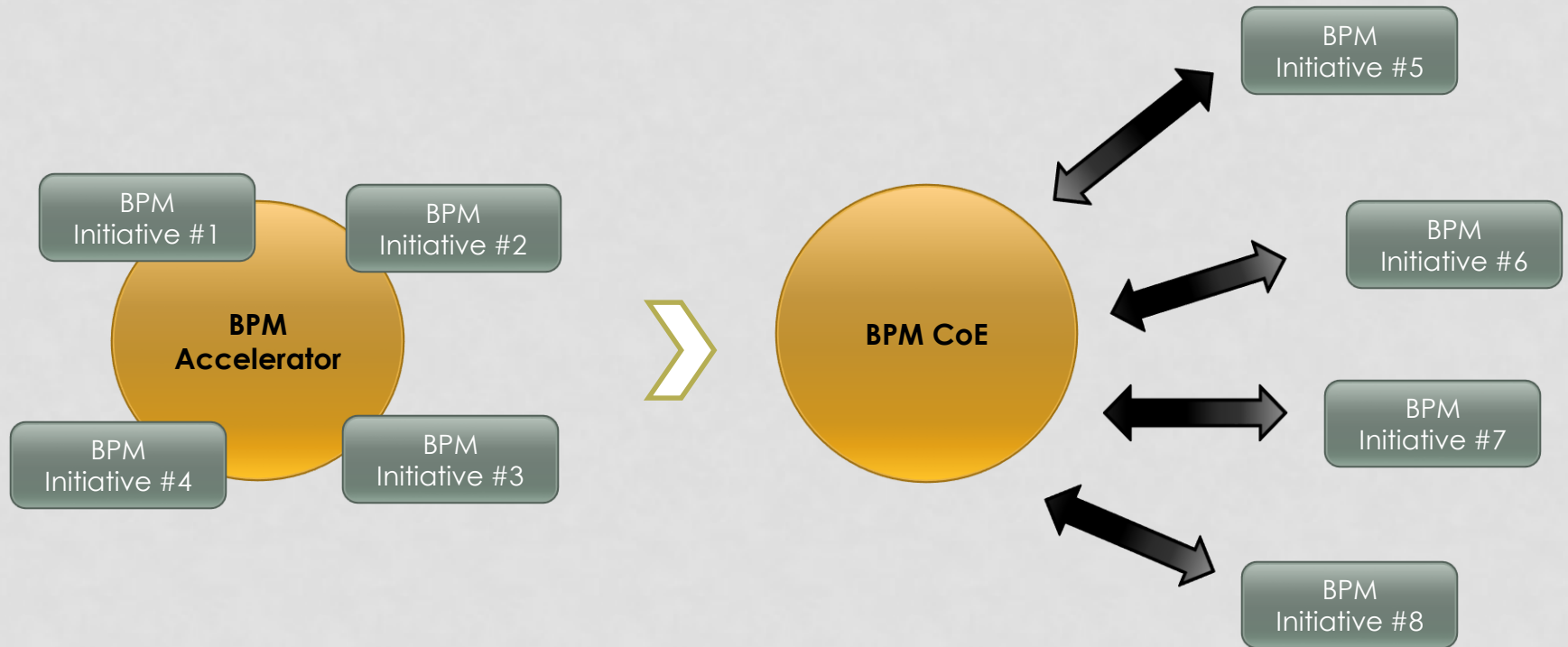
- Better understanding of business
- Quick response to business needs
- Gap identification and optimization

# ACCELERATOR SERVICES

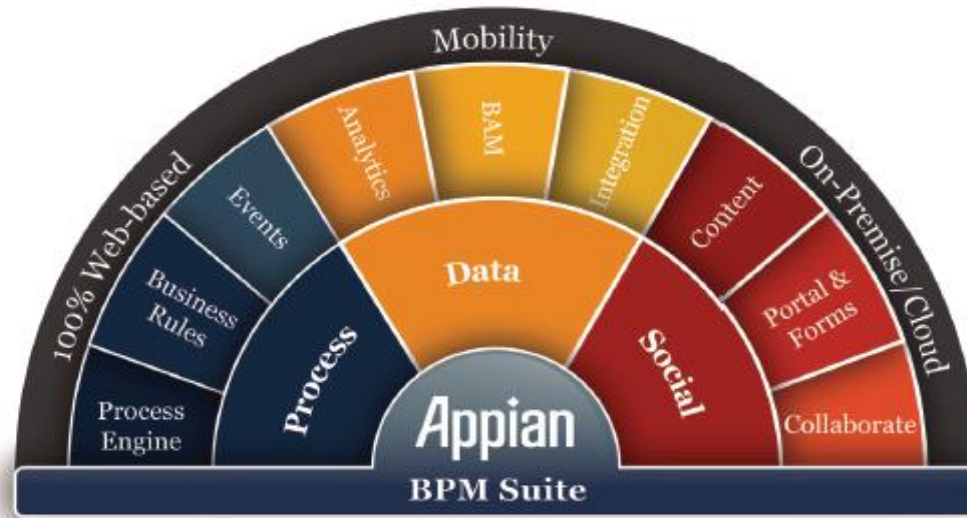
- Reliable and scalable Appian platform
- Appian training, best practices, lessons learned
- Appian process automation (development)
- BPMS integration with legacy and future systems
- Participation in process scoping and requirements analysis
- Streamlined validation practices for frequent process change
- BPMS Enterprise Architecture: enterprise fit and reuse via enterprise business process orchestration (SOA)
- Access management
- User experience: consistency & usability, mobile availability
- BPMS vision & maturity model
- Platform evolution and vendor relationship



# A ROAD TO COE



# WHAT IS THE APPIAN PLATFORM?



## Analyst Comments

*“they [Appian] bake social into the core of their BPM offering.”*

– Clay Richardson, Forrester Analyst

FORRESTER

*“Appian sets the bar for BPM in the cloud.”*

– Gartner Magic Quadrant for Business Process Management Suites, October 2010

Gartner

# APPIAN DESIGNER EXAMPLE: WHAT YOU SEE IS WHAT YOU GET

This Model Allows an Employee To Submit An Expense. If the Expense is greater than \$500 it will be sent to a Manager for approval. If the manager rejects the expense, the Employee will be tasked with Re-entering

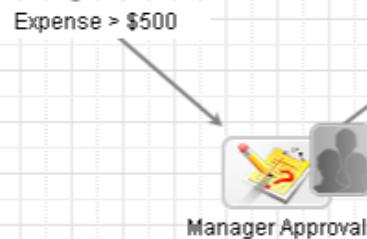
Employee



System

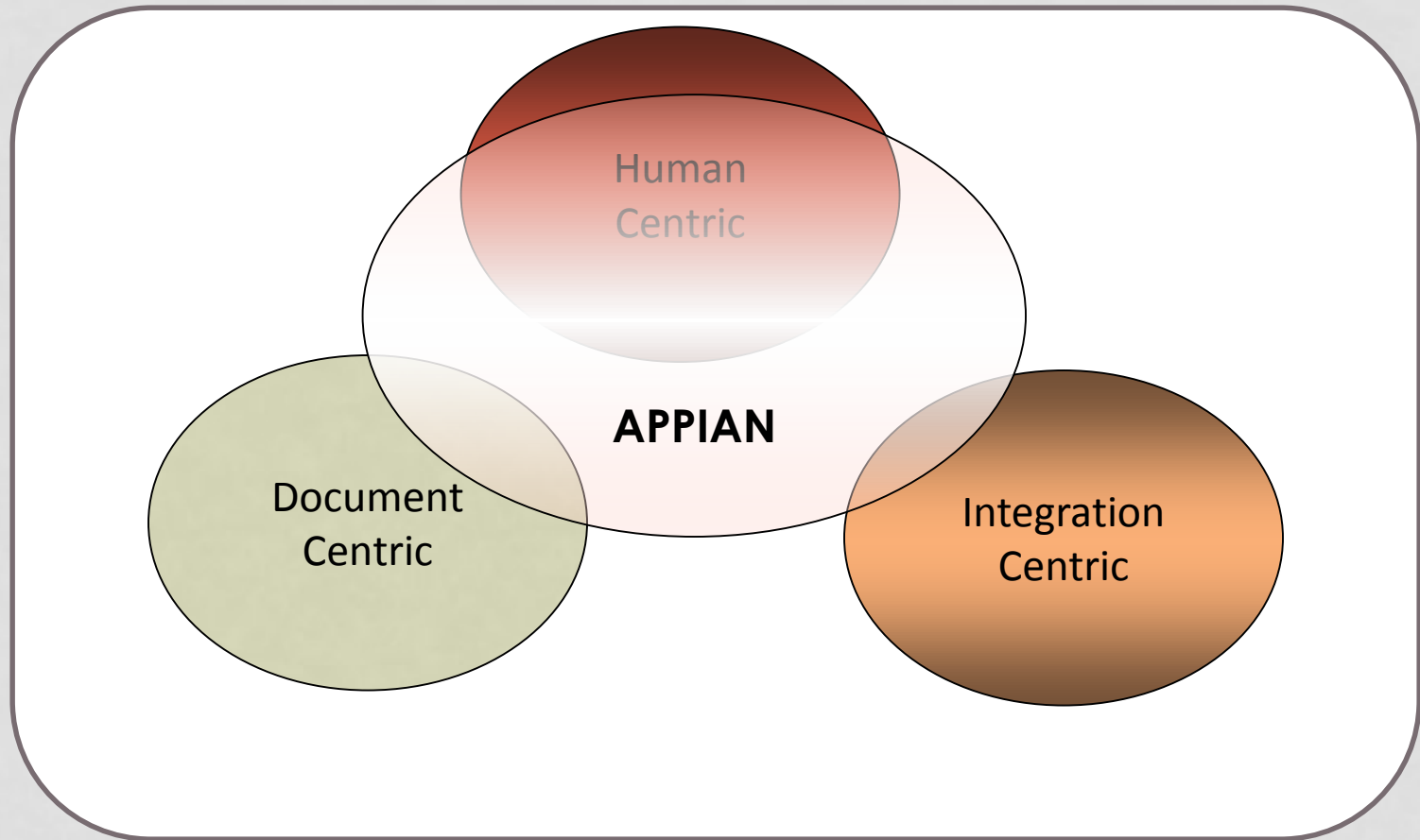


Manager

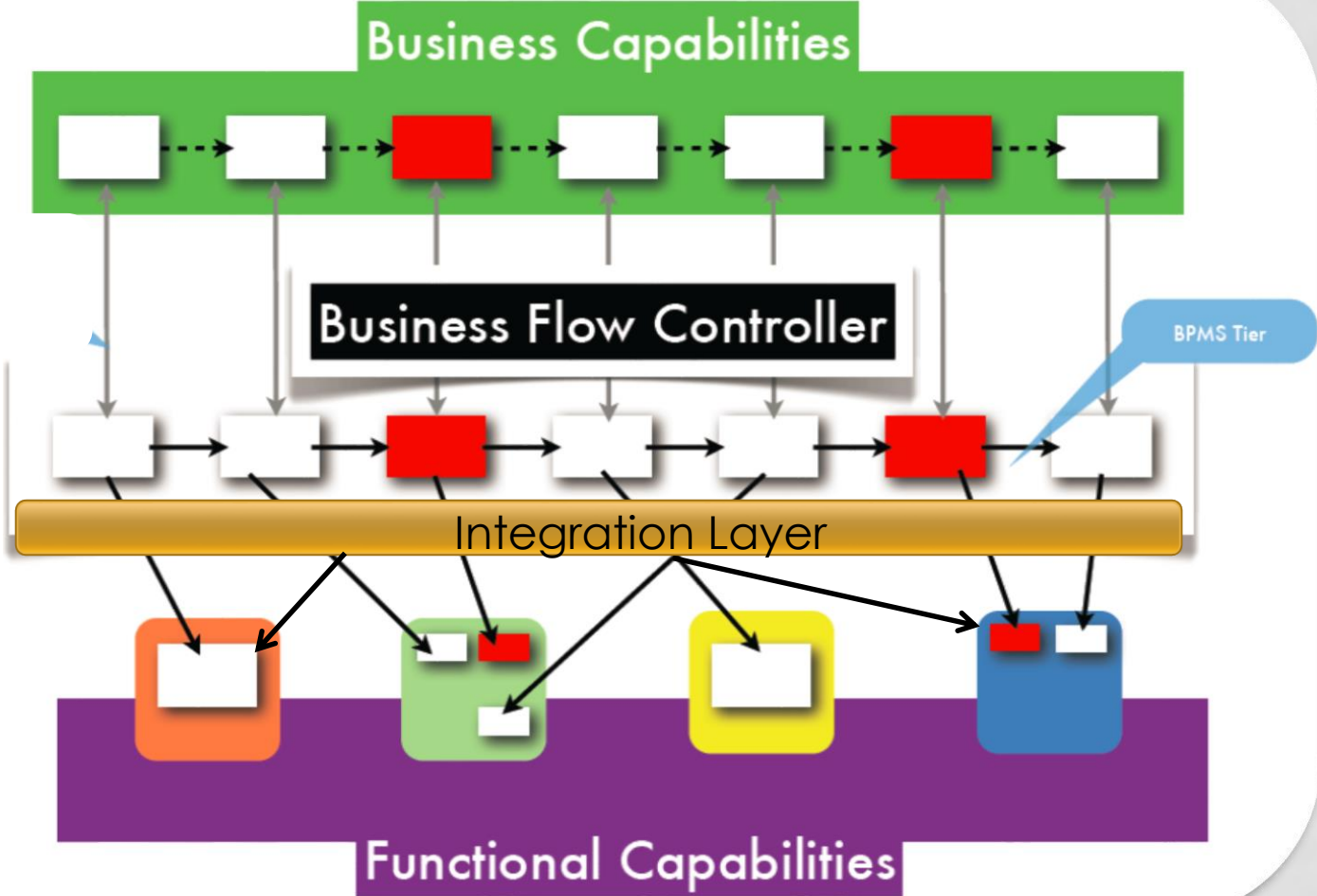


Rejected

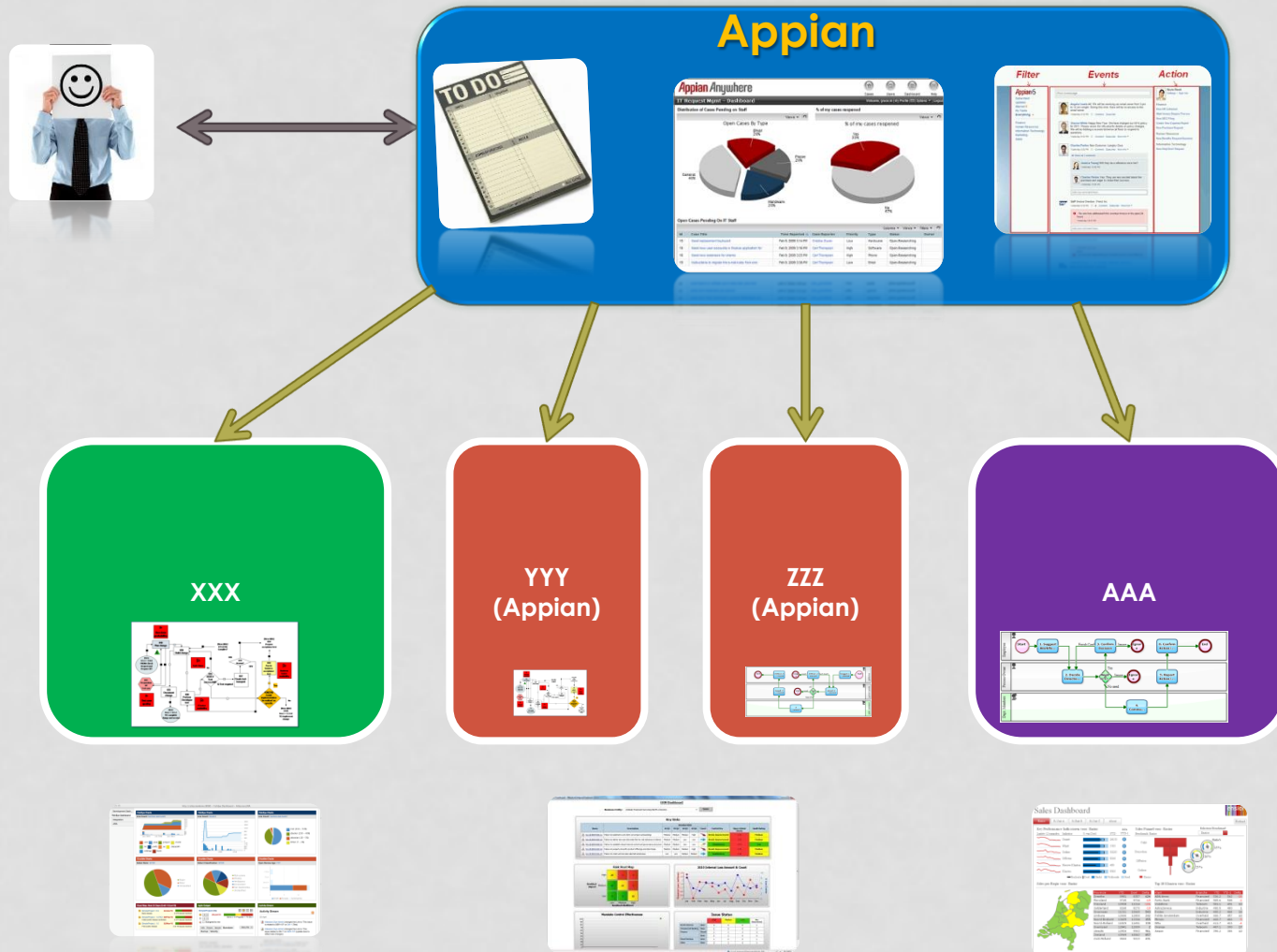
# ARE ALL BPMS' THE SAME?



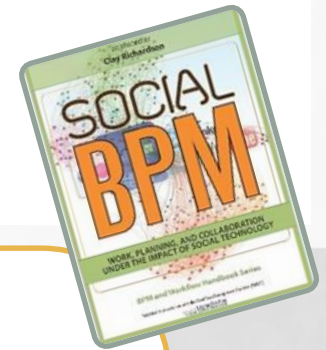
# BUSINESS SOA



# SINGLE PROCESS ORCHESTRATOR SINGLE USER EXPERIENCE NAVIGATOR



# SOCIAL BPM



- 2010 - a new fad emerged called “Social BPM.” In theory, this concept advocated that business should have the ability to leverage on popular social network tools in order to allow both customers and staff across the enterprise to collaborate on process improvement activities
- Since 2010, the concept has generated little more than a lot of discussion – ambitious, time consuming, embedded social collaboration features rarely used
- Social BPM may become a focus for discussion again in the future.

“The Ultimate Guide to BPM” by Theodore Panagacos



# APPIAN'S TEMPO

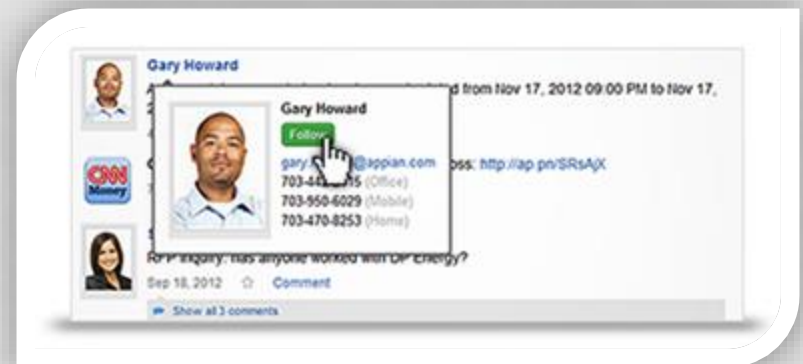
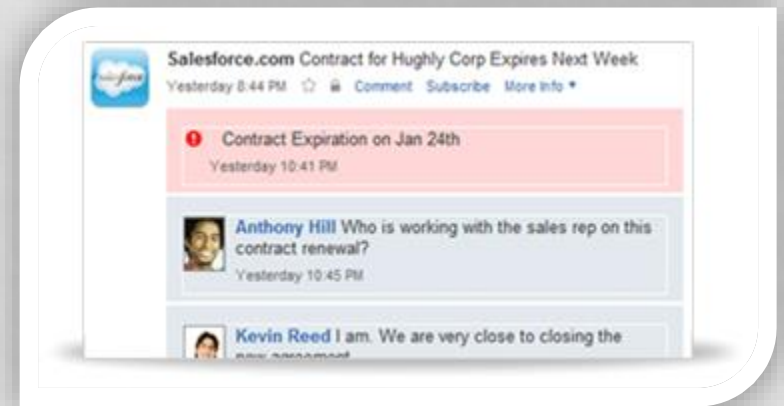
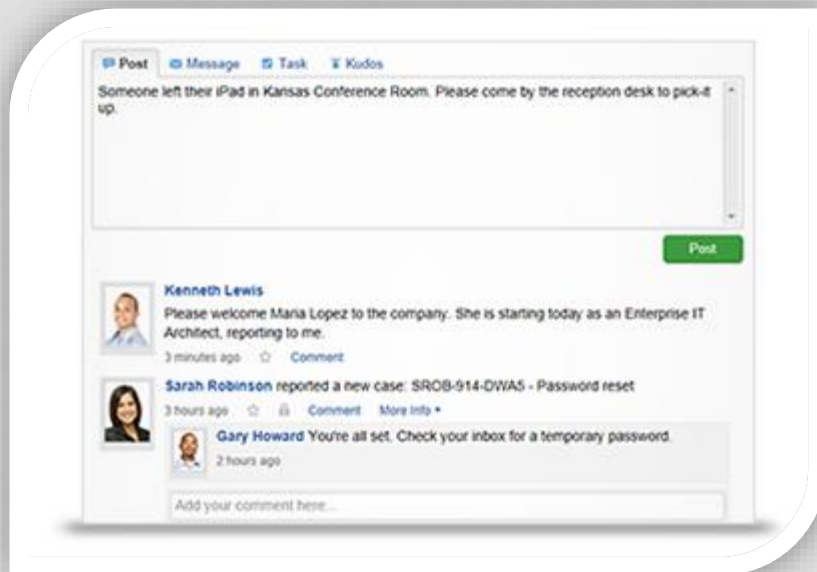
- Familiar and more consistent customer experience
- Improved real-time decision making
- Faster business action
  
- Process social network
- Peer process support system
- PDC/PDS



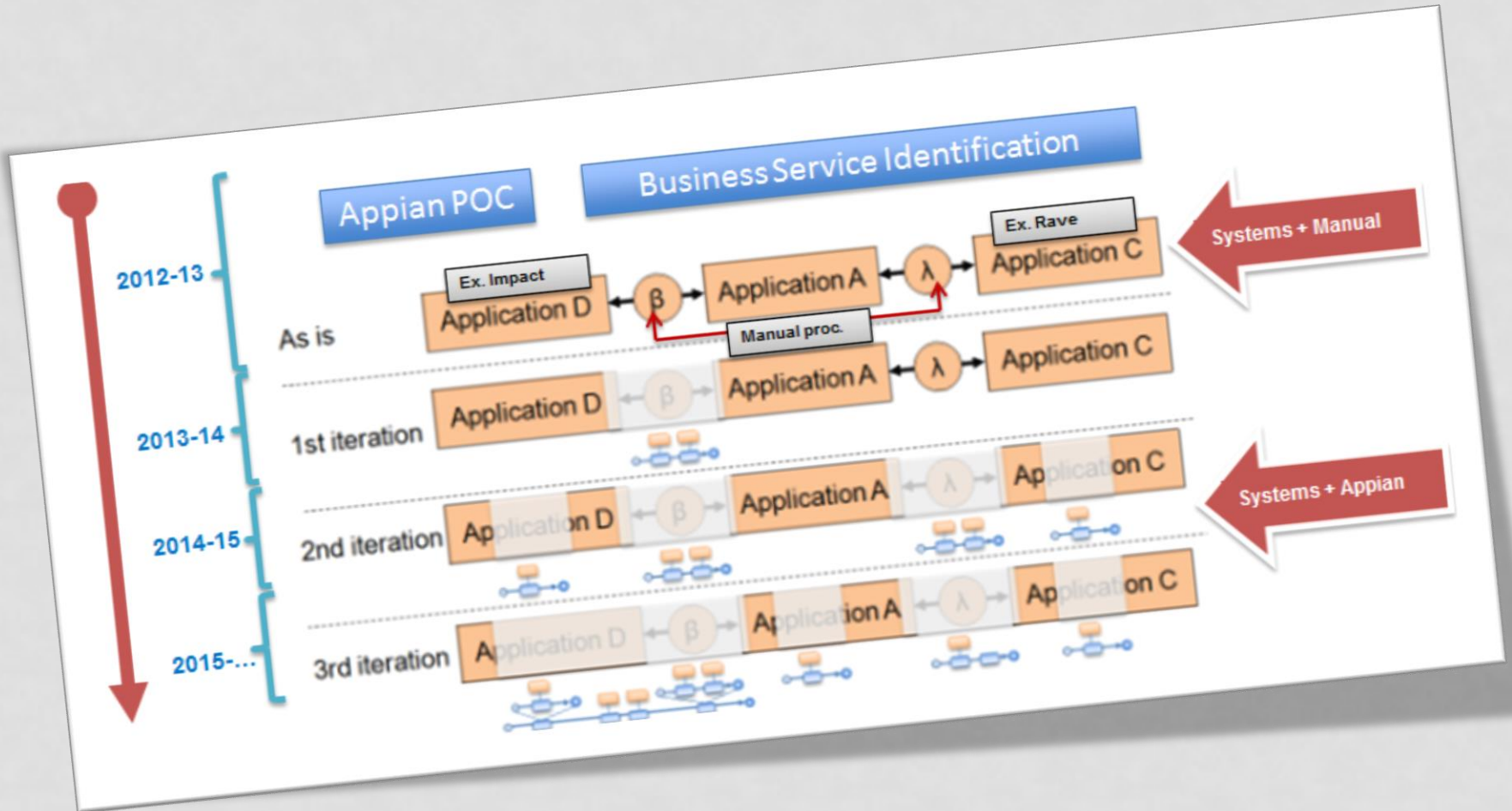


# TEMPO KEY BENEFITS

- Real-time collaboration
- Key event monitoring & feed
- Status updates
- Following



# PATH TO PROCESS-CENTRIC ENTERPRISE

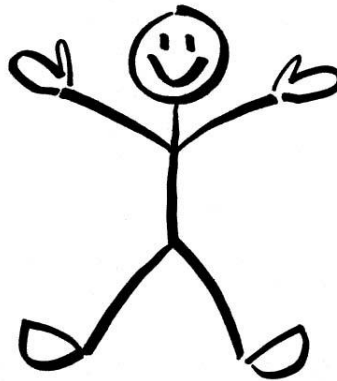
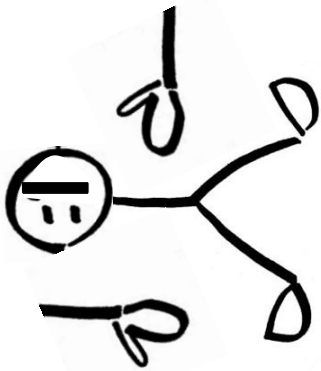


# ROAD MAP SIMPLIFIED

2012-13

2013-2014

2014-...



# PEOPLE CHANGE MANAGEMENT

- Research has indicated that human change management can occupy anywhere from 25% to 35% of project time, cost, and effort
- Magnified with BPM(S)
- Active executive endorsement
- Strong process owners a must



QUESTIONS?

# WHY BPM?

- Efficiency
- Effectiveness
- Agility

*“a management discipline focused on improving corporate performance by managing a company's business processes”*

– Paul Harmon