

RPA and CA in medtech

Increasing efficiency, reducing costs

Automating medtech processes can increase efficiency, reduce costs

A significant number of medical technology (medtech) product development, commercialization, and back-office processes are manual and labor intensive. This typically adds time and cost to the product life cycle and can heighten the potential for human error. By employing digital technologies including robotic process automation (RPA) and cognitive automation (CA), medtech companies can improve quality and efficiency by automating critical functions within sourcing and procurement, product development, and commercial operations.

What's at stake

Manual and labor-intensive processes can add time and expense to medtech product life cycle

Lengthy and expensive R&D cycles, increasingly stringent regulatory requirements, persistent pricing pressure, and intensifying global competition are driving medtech companies to identify ways to develop and launch innovative new products as quickly and cost-effectively as possible.

Yet, even as companies look to the future, they are often constrained by the past. A significant number of medtech product development, commercialization, and back-office processes are manual and labor intensive. This typically adds time and cost to the product life cycle and can heighten the potential for human error. Fortunately, many of these processes are relatively straightforward and can be automated cost-effectively and within a short time frame. By employing digital technologies including robotic process automation (RPA) and cognitive automation (CA), medtech companies can improve product life cycle efficiency and quality, and generate savings of 40 percent to 75 percent in labor hours, depending on the operation being automated.¹

This paper explores RPA and CA technologies' potential to streamline medtech clinical and business operations; describes how RPA and CA can help solve common product development and commercialization challenges; and provides a suggested approach and key success factors for automation deployment.

Our take

Now is the time to use RPA and CA to streamline medtech clinical and business operations

Our recent findings from engagements at top medical device companies suggest that medtech interest and investment in automation are on the rise; still, some organizations may not fully understand or appreciate the scope of automation's potential clinical and business value. Among our observations:

- Many medtech product development cycle times are long and often depend on legacy/manual methods for approvals, risk assessments, and defect tracking and resolution.
- Writing a clinical protocol typically uses no form of automation, adding lead time and operating cost to the process.
- Identifying the right clinical study population, sites, and physician champions generally involves no back-end automation and analysis, creating process delays.
- Many medtech companies remain highly dependent on insourcing (versus outsourcing) their product development capabilities, even if doing so falls outside their core competencies. This typically adds costs and moves production away from lean methodology.
- Many medtech companies use many repetitive, rule-based tasks for back-office operations such as sourcing and procurement, purchase order (PO) creation and dispatch, invoicing, accounts payable, and information technology (IT) services.
- Persistent, widespread use of manual processes for commercial operations activities, such as responding to requests for proposals, contracting, tendering, and field communications, typically results in decreased efficiency and greater lead time.
- Lack of intelligent solutions for analyzing customer complaints, publications, electronic health records (EHRs), claims data, and private payer data often results in inaccurate risk assessments and safety analyses.

With the medtech industry facing new and expanding clinical and business challenges, now is the time for leadership to incorporate innovative approaches to streamline operations. Cognitive technologies including RPA and CA (see sidebar) can help companies improve quality and efficiency by automating critical functions within sourcing and procurement, product development, and commercial operations.

Cognitive technologies defined

RPA, CA, and other cognitive technologies enable machines to replicate human actions and judgment to improve speed, efficiency, accuracy, and quality; and to reduce variability, risk, rework, and cost. Cognitive technologies perform and/or augment tasks and accomplish objectives that have traditionally required human intelligence, such as planning, reasoning, and learning.² Currently, four major categories of cognitive technologies seem to be expanding exponentially (see table 1).³



Table 1. Cognitive technology categories and select application examples

Categories	Descriptions	Application examples
Robotic process automation (RPA)	“A combination of artificial intelligence and automation” that’s able to “sense and synthesize vast amounts of information and can automate entire processes or workflows, learning and adapting as it goes.” ⁴	<ul style="list-style-type: none"> • Process automation and configuration • Graphical user interface (GUI) automation • Advanced decision systems
Cognitive—language technologies	A set of statistical techniques that enable the analysis, understanding, and generation of human languages to facilitate interfacing with machines in written and spoken contexts—that is, to convert human (natural) languages into machine languages and vice versa.	<ul style="list-style-type: none"> • Natural language processing and generation • Semantic computing • Speech recognition • Speech synthesis • Sentiment and text analytics
Cognitive—machine learning (ML)	A set of statistical techniques that automate analytical model-building using algorithms that iteratively learn from data without the need for explicit programming.	<ul style="list-style-type: none"> • Supervised learning • Unsupervised learning • Deep learning
Cognitive—computer vision	Automatic extraction, analysis, and understanding of useful information from a single image or a sequence of images, thereby modeling, replicating, and, more importantly, exceeding human vision using computer software and hardware. ⁵	<ul style="list-style-type: none"> • Image recognition • Video analysis • Handwriting recognition • Voice recognition • Optical character recognition

Source: David Schatsky, Craig Muraskin, and Ragu Gurumurthy, *Demystifying artificial intelligence*, Deloitte University Press, November 4, 2014; William D. Eggers, Tiffany Fisherman, and Pankaj Kishnani, *AI-augmented human services*, Deloitte Development LLC, October 18, 2017; and Deloitte analysis.

Automation opportunity areas

With application opportunities across the medtech value chain (see figure 1), RPA and CA can increase organizational efficiency and quality by automating decision-making, approval routing, and task and document management. So why are companies waiting to automate their clinical and commercial operations? Among common hurdles are the perceived high cost of integrating multiple systems, departmental process variations, and entrenched production and commercialization methodologies. However, increasing numbers of medtech organizations are discovering that RPA and CA technologies are relatively easy to implement, integrate, and scale, as they reside in the cloud. Areas with considerable potential for automation efficiency gains include sourcing and procurement, product development, and commercial operations.

Sourcing and procurement







Executing back-office operations such as order processing, invoicing, returns management, procurement, inventory management, and customer service can consume significant time and resources. Seeking relief, some medtech companies have moved these and

other sourcing and procurement tasks offsite to business process outsourcers (BPOs). However, by using RPA and CA enablers, some activities can be automated by the BPOs, leading to lower clinical trial costs, and some activities currently performed by BPOs can be brought back in-house.

In one example, a leading medtech company operating in more than 40 countries wanted to transform its procurement process. Accounts Payable had to manually execute certain rule-based activities—adding accounting details for pre-approved (non-PO) invoices globally, and adding tax code/tax type on invoices in Asia and Europe—which constrained the company in reaching its business goals. The company designed a set of rules by region/country to implement RPA, which was programmed to replicate the tasks. This implementation reduced/eliminated human errors and helped the company achieve significant savings.

Figure 1. Automation targets

There are opportunities for RPA and CA across the medtech value chain:

R&D	Supply chain and manufacturing	Commercial
 <ul style="list-style-type: none"> • Site initiation documentation • Investigator payments • Enrollment tracking • Monitoring visit reporting • Clinical and medical writing • Trial master file • Quality compliance (CAPA, NCR) • Change management • Risk management 	 <ul style="list-style-type: none"> • Order processing • Bill of materials generation • Returns management • Shipping confirmation • Sourcing and procurement • Inventory management • Customer service 	 <ul style="list-style-type: none"> • Charge-backs and rebates • Returns and reimbursements • Contract writing • Benefits verification • Competitor price monitoring
Finance	HR	IT
 <ul style="list-style-type: none"> • Order to cash • Purchase to payment • Reconciliation • Reporting • Accounting entries 	 <ul style="list-style-type: none"> • Payroll • Hiring • Recruitment process • Onboarding and training • Benefits management 	 <ul style="list-style-type: none"> • Help desk • Systems validation • Network/app monitoring • Folder/file management • Documentation QC



Product development

Major countries and economic blocks (e.g., United States, European Union, Japan, China) have distinct regulations around life sciences (pharmaceutical, biopharmaceutical, and medtech) product development, and these are becoming more stringent with every passing year. In response, many medtech companies, in conjunction with partnering contract research organizations (CROs) and medical research organizations (MROs), are exploring advanced automation to achieve improved data accuracy, operational efficiencies, and risk management in upstream research and clinical trials. Among processes suitable for automation are protocol development, site selection and initiation, patient recruitment, study conduct, monitoring, safety, data management, trial management, analysis, reporting, and closeout.

For example, a life sciences company found that getting an agreement in place with an investigational site was a rate-limiting step in study start-up, as the median turnaround time from site selection to an executed CTA was more than 80 days. By reengineering the process to automate key steps the business was able to secure a contract in a day.

Adverse event (AE) reporting is another automation opportunity area. Marketing Authorization Holders (MAHs) are obligated to follow up on AE reports; however, the administrative, repetitive, and

time-consuming nature of this task can lead MAHs to deprioritize it in favor of other activities. By applying RPA to this process, a medtech company improved the speed, timeliness, and quality of AE follow-up—in some instances, by more than 90 percent—simultaneously freeing-up resources to focus on more value-adding activities.

Commercial operations

Medtech commercial operation processes can be numerous and wide-ranging, and include (among other things) charge-backs and rebates, contract writing, benefits verification, patient eligibility, competitor price monitoring, and customer service (e.g., call center operations). Many of these processes are ripe for automation. To illustrate, using robots to reduce the manual work involved in pharmaceutical formulary validation may provide learnings to help medtech companies ease labor shortages and improve commercial operations efficiency. In this pharma-specific example, companies could supplement their employees with robots that use machine learning to search for products in a formulary, compare claims data with a product's formulary position, summarize units and rebates by plans for products to be disputed, and submit the validation report. With the robot improving iteratively while working alongside its human counterpart, it can continually improve the percentage of data checked and help companies reduce revenue leakage at a low cost.

Potential benefits of using RPA and CA

Based on value creation and cost savings achieved in Deloitte client projects across industries (see table 2), the potential benefits of automating medtech development, commercial, and operational processes look to be broad and substantive.

Table 2. Potential process automation benefits

Process type	Potential benefits of automation*
High-volume transactional processes (e.g., requisitions, purchase orders and invoices)	<ul style="list-style-type: none"> • Can reduce the average time and associated costs to execute transactional processes by 60% to 80% on average • Helps enable process to be executed approximately 15 times faster than a human and operates 24x7, leading to high throughput
High-risk processes with multiple handoffs (e.g., non-conformance reports, CAPA documentations)	<ul style="list-style-type: none"> • Can eliminate need for manual intervention, and reduces the number of employees needed to execute tasks by 20% to 60% • Helps increase compliance by reducing errors and time spent on rework and review by 70% to 99%
Data validation processes (e.g., risk assessments)	<ul style="list-style-type: none"> • Helps ensure data consistency and accuracy in reporting by eliminating manual errors by 80% to 99% • Helps improve ability to shift FTE focus from report generation to analysis by 30% to 60%
Dependent or linked processes (e.g., change management)	<ul style="list-style-type: none"> • Helps decrease processing time by up to 300% by enabling processes to be executed outside standard business hours (i.e., overnight and weekends) • Helps enable organizations to build automated system connections/interfaces without investing in IT architecture by 20% to 50%

*Range estimates are representative samples of the value creation and cost savings found in Deloitte RPA client projects.

Automation-aided cost and time savings can be quite significant depending on the specific industry and the characteristics of the functions a company selects to automate. Other potential benefits include:

- **Compliance.** Automation can eliminate the need for error-prone manual intervention and increase compliance, thus reducing the amount of time spent on rework and review.

- **Control.** Automation can enhance management control of processes through improved visibility and expand expertise and insights to deliver greater customer value.
- **Capacity.** Automation can enable transformative change by leveraging technology to complete tasks previously viewed as too costly or time-consuming to consider.

A path forward

Phased implementation approach can deliver time and cost savings

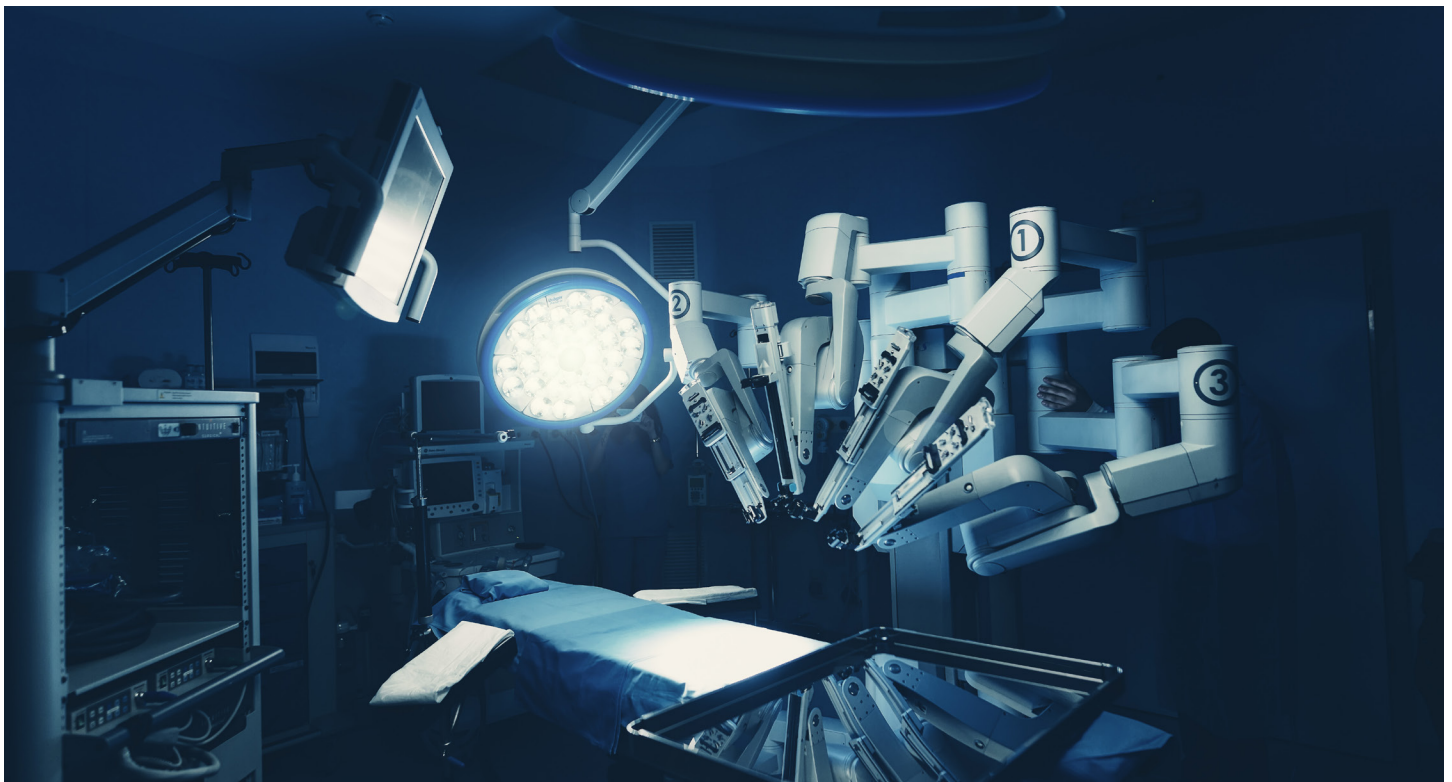
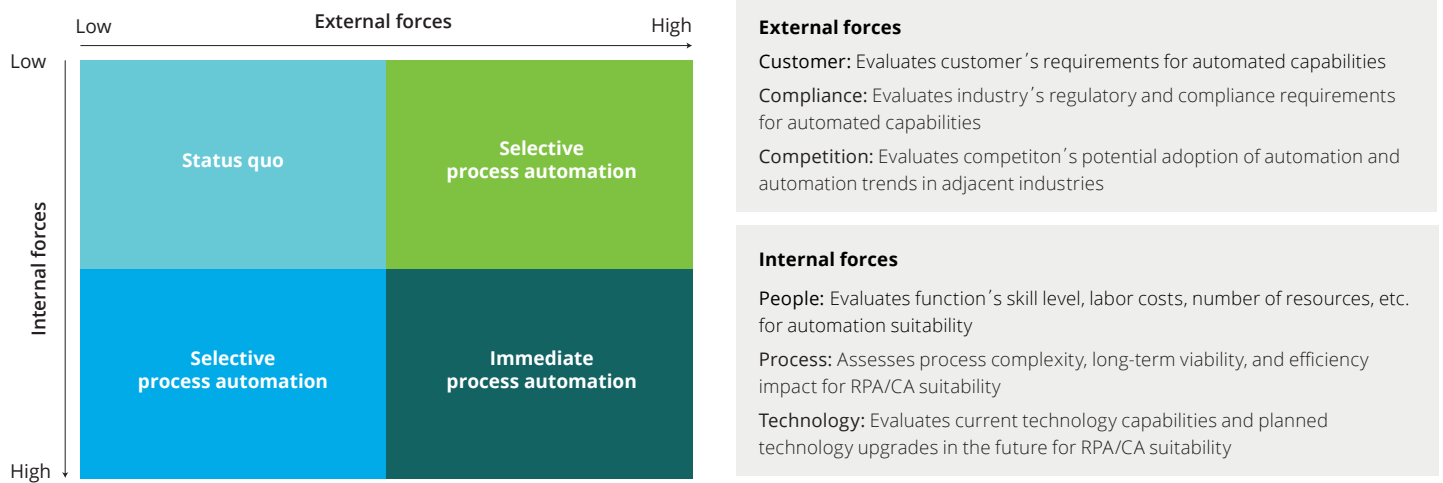
Learnings from numerous client engagements have taught us that successful automation programs evolve from strategy to pilot to production. As a first step, program stakeholders should answer a series of internally and externally focused questions to identify whether or not a function needs and would benefit from RPA or CA (see table 3).

Table 3. Questions to determine whether a function would benefit from RPA or CA

Internal drivers	External drivers
<p>People</p> <ul style="list-style-type: none"> • Does the function require low-to-mid-level critical thinking for performing day-to-day requirements? • Is the function operating with high labor costs compared to other functions while delivering the same or lower value? • Is the ratio of number of transactional workers to number of management employees high? • Does the function have high attrition rate among low-to-mid-level skilled workers? 	<p>Customer</p> <ul style="list-style-type: none"> • Do customers demand faster responses than current benchmarks? • Do customers demand minimum touch points with internal employees for issue resolution? • Is consistent and standardized data valued by top customers? • Do customers prefer regular reporting for the services used?
<p>Process</p> <ul style="list-style-type: none"> • Are the processes required within that function transactional or strategic? • Are the processes required less complex, highly repeatable, labor-intensive, and high-volume? • Do the processes depend on highly skilled labor or thoughtful decision making? • Are the parameters/variables to complete the processes the same or stable in multiple use cases? • Do the processes require a high standard of regulatory compliance or substantial lead time to complete, causing delay in end result realization? 	<p>Compliance</p> <ul style="list-style-type: none"> • Does the industry demand a high standard of regulatory compliance for products, data, or other services provided? • Does the industry demand periodic standards reporting enforced by regulatory bodies? • Does compliance demand high dependency on technological solutions? • Can the compliance bodies demand strict timelines for submissions or issue resolution?
<p>Technology/data</p> <ul style="list-style-type: none"> • Do the systems utilized by the function require multiple manual inputs? • Does the function utilize systems that have the ability to share/centralize data? • Can the systems/data be altered to perform automation without changing architecture or detailed technological requirements? • Does the organization have the capability to maintain/store records from various automated transactions? • Is the base technology not capable of near-term automation? 	<p>Competition</p> <ul style="list-style-type: none"> • Is the competition utilizing new technologies that are enabling it to be more efficient? • Is the competition able to respond to regulatory bodies in a timely manner? • Does the competition have lower labor costs? • Is the competition more strategic- or transaction-focused?

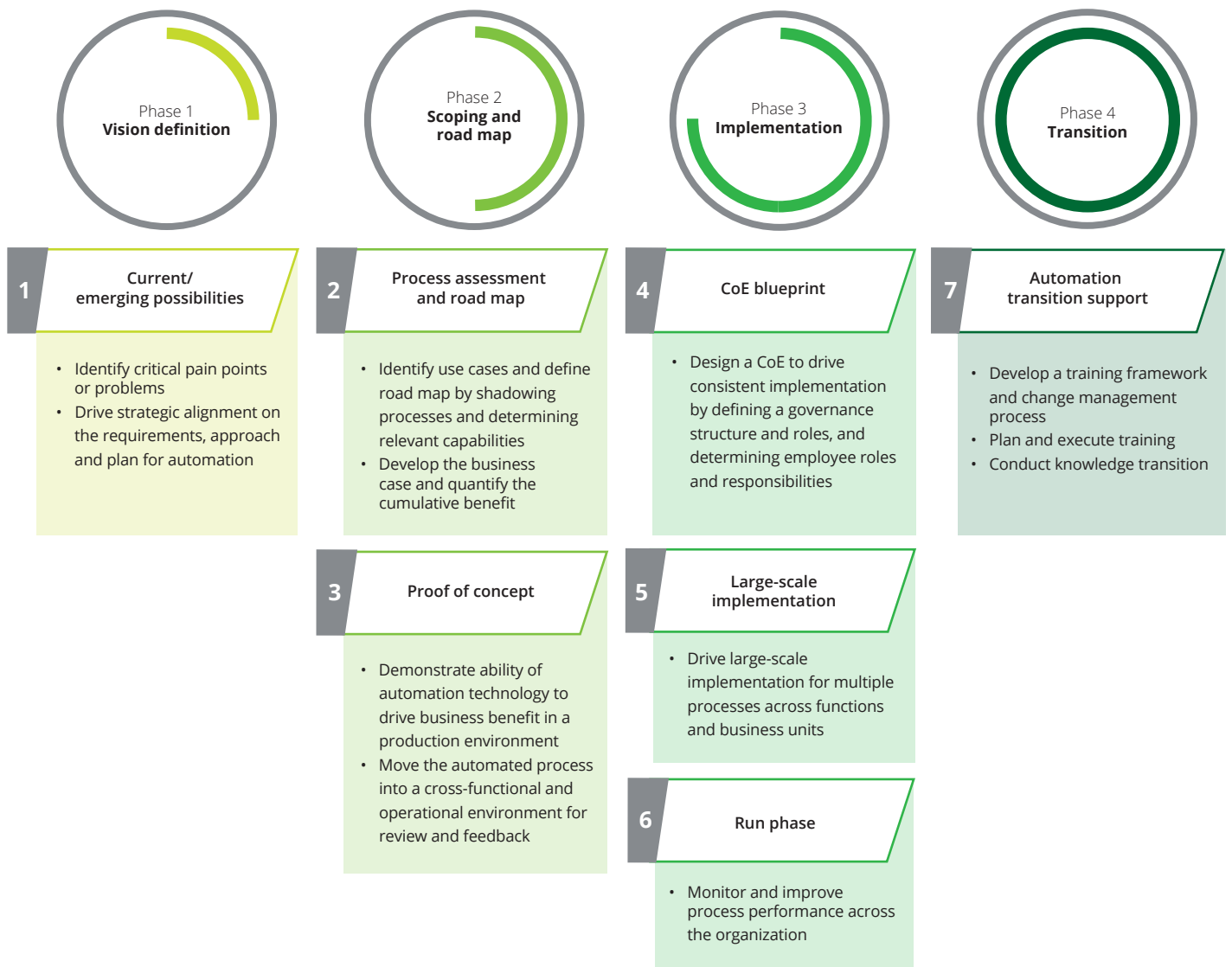
Based on the answers to these questions, stakeholders should use a mutually exclusive and collectively exhaustive (MECE) thought process to evaluate specific functions and processes that would benefit from automation (see figure 2).

Figure 2. MECE process to evaluate functions for potential RPA/CA



RPA and CA implementation will vary by company and selected functions/processes but typically uses a phased approach that can produce a proof of concept within weeks (see figure 3).

Figure 3. Automation implementation approach



Deploying automation technologies typically comes with a range of challenges, such as identifying the appropriate and optimal level of automation; integrating the technologies into existing business and clinical processes; governing and driving transformation so the robotics are deployed consistently; and using the right change management approach for effective workforce integration. We have identified 10 success factors for deploying RPA, CA, and other automation tools.

- 1. Right process or activity.** The business process is well-defined to determine that automation can be implemented.
- 2. Testing.** Business process testing confirms the automated solution's robustness and efficiency.
- 3. Stable processes.** Processes are made as efficient as possible before implementing automation to enable the most desirable outcomes.
- 4. Quality and exceptions management.** The company invests in exception management and continuously monitors automation output quality to confirm that outputs are trustworthy.
- 5. Approach to measure and track benefits.** Automation's benefits are tracked using a detailed measurement approach that is agreed upon prior to implementation.
- 6. Adequate education and user adoption.** Company executives and project leaders explain why automation is needed, make sure it is adopted, and share its results throughout the organization.
- 7. Checklist for requirements.** Project leaders verify that the correct infrastructure is in place and compliance requirements have been met.
- 8. Stakeholder management.** Stakeholders are engaged at the program's start to enable effective buy-in, collaboration, and adoption.
- 9. Vendor and business vision alignment.** The chosen automation vendor supports the company's long-term process automation requirements.
- 10. Wider strategic technology initiatives.** Selected automation investments align with the company's broader technology improvement programs.

Bottom line

Implementing RPA and CA at scale within the right governance and deployment model can deliver substantial cost and time savings—presenting a compelling business case for medtech companies. Depending on the process being automated, a proof-of-concept project can deliver efficiency, quality, and monetary benefits within weeks but typically must be deployed at scale for 12 to 18 months to achieve optimal strategic and operational benefits.

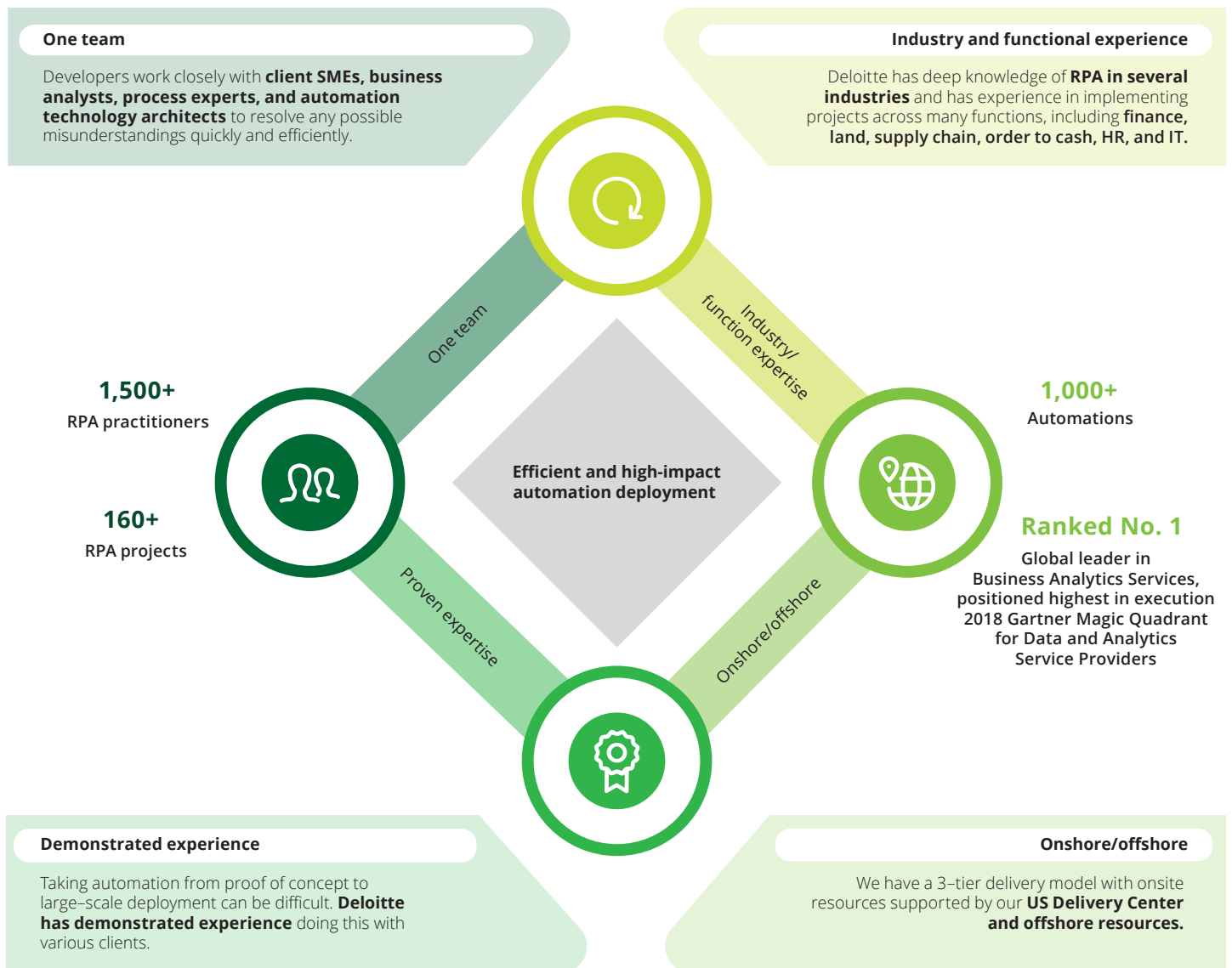
If you are interested in learning more about Deloitte's global RPA and CA capabilities (see sidebar), please contact the individuals listed at the end of this paper.



Deloitte’s global RPA and CA capabilities

Deloitte has a global professional services presence in robotics to deliver large-scale, automation-enabled transformation (see figure 4).

Figure 4. Deloitte’s automation capabilities



Endnotes

1. Based on Deloitte analysis from multiple clients across industries.
2. David Schatsky, Craig Muraskin, and Ragu Gurumurthy, "Cognitive technologies: The real opportunities in business," *Deloitte Review 16 (January 26, 2015)*, <https://www2.deloitte.com/insights/us/en/deloitte-review/issue-16/cognitive-technologies-business-applications.html>.
3. "Cognitive technologies: A technical primer," Deloitte Insights, February 6, 2018, <https://www2.deloitte.com/insights/us/en/focus/cognitive-technologies/technical-primer.html>.
4. David Schatsky and Vikram Mahidhar, "Intelligent automation: A new era of innovation," Deloitte University Press, January 22, 2014. <https://www2.deloitte.com/insights/us/en/focus/signals-for-strategists/intelligent-automation-a-new-era-of-innovation.html>.
5. BMVA, "What is computer vision?" (web page), <http://www.bmva.org/visionoverview>, accessed January 19, 2018.

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