







McKinsey & Company

Productivity drivers in Medical
device and healthcare
software development
Numetrics R&D Analytics

- **Growing importance of SW in medical devices and healthcare**

- Insights into SW R&D productivity for medical and healthcare products
- Insights into SW R&D processes, practices and culture
- Introduction to Numetrics R&D analytics
- Numetrics offering and engagement models
- Appendix

There are several trends that increase the importance of software development and quality in Med Tech

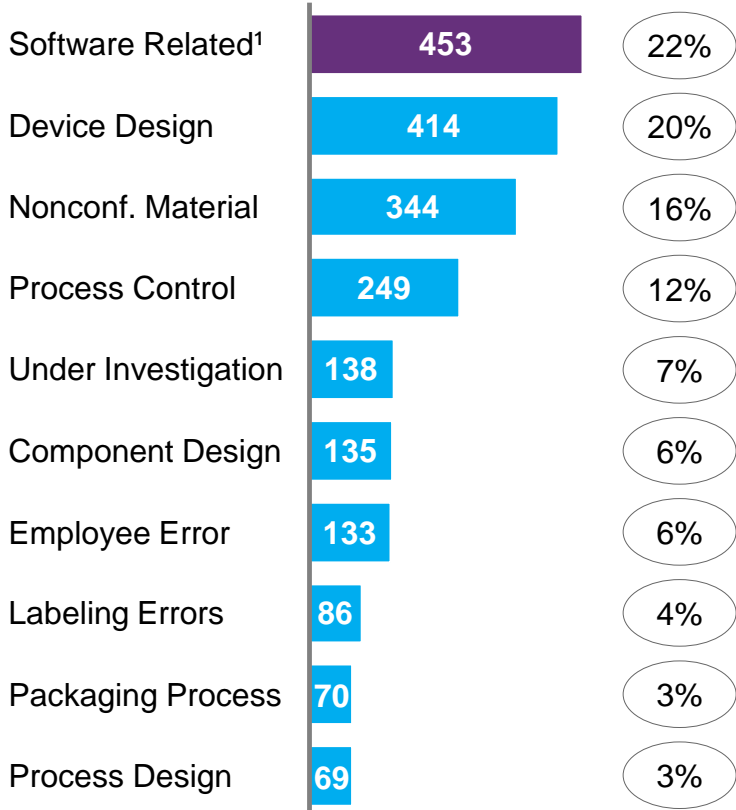
Trend	Description	Impact on SW in Med Tech
 <p data-bbox="46 463 352 495">Integrated solutions</p>	<p data-bbox="422 312 958 495">Integrated medical ecosystems with shared information across medical devices and electronic health record (EHR) systems to allow for continuous care and remote management</p>	<ul data-bbox="984 312 1806 459" style="list-style-type: none"><li data-bbox="984 312 1806 459">▪ Interoperability, SW quality and cyber security become a major concern as connected medical devices are vulnerable to integration issues as well as cyber security and hacking concerns
 <p data-bbox="108 691 292 723">Regulations</p>	<p data-bbox="422 543 958 726">Regulatory bodies continue to implement stricter guidelines for medical device SW, development processes, design control, and quality standards required prior to release</p>	<ul data-bbox="984 543 1806 652" style="list-style-type: none"><li data-bbox="984 543 1806 652">▪ Developers must adopt modular architectures that allow for faster validation, collaborative development, easier integration and improved quality
 <p data-bbox="76 949 324 981">Smarter devices</p>	<p data-bbox="422 792 958 975">Multifunctional devices, combining multiple sensors, processing capabilities with customizable setup and preferences and a personalized user interface</p>	<ul data-bbox="984 792 1806 939" style="list-style-type: none"><li data-bbox="984 792 1806 939">▪ Software is becoming the differentiator for medical device manufacturers, with increased focus on quality as products become more complex with inter-related features and new functions
 <p data-bbox="58 1187 345 1219">Real-time analytics</p>	<p data-bbox="422 1030 958 1213">Software systems that perform real time, predictive analytics and machine learning to determine trends and risks, and to enable immediate and personalized medicine</p>	<ul data-bbox="984 1030 1806 1275" style="list-style-type: none"><li data-bbox="984 1030 1806 1139">▪ Increased product complexity that requires new and different skill sets such as advanced analytics and algorithms, patient care operations, cloud, etc.<li data-bbox="984 1163 1806 1275">▪ More rigorous verification and validation process is needed as device level analytics may determine the selected course of action

Software has become the biggest cause of medical device recalls, indicating to an issue with software development and quality in the industry

Software is the leading cause of medical device recalls

Identified cause of medical devices recall FY10-FY12

Total recalls (cumulative over FY10 – FY12), Percent



Examples of medical devices recalls due to SW issues



Reduced battery run times in a power supply unit due to a software defect



CT systems had faulty software that inverted the data on the longitudinal position



COVIDIEN

Software error in a neonatal ventilator caused the amount of air being delivered to the patient to be less than specified



SW issue caused an infusion pump module to not properly execute a “delayed infusion” setting



A “Rheumatology Calculator” app used to assess patients’ disease status, was giving the wrong results due to a SW bug



An Anesthesia Care monitoring system was displaying the wrong patient’s data when a case was retrieved from records

¹ Software-Related includes software change control, software design (process), and software design (device)

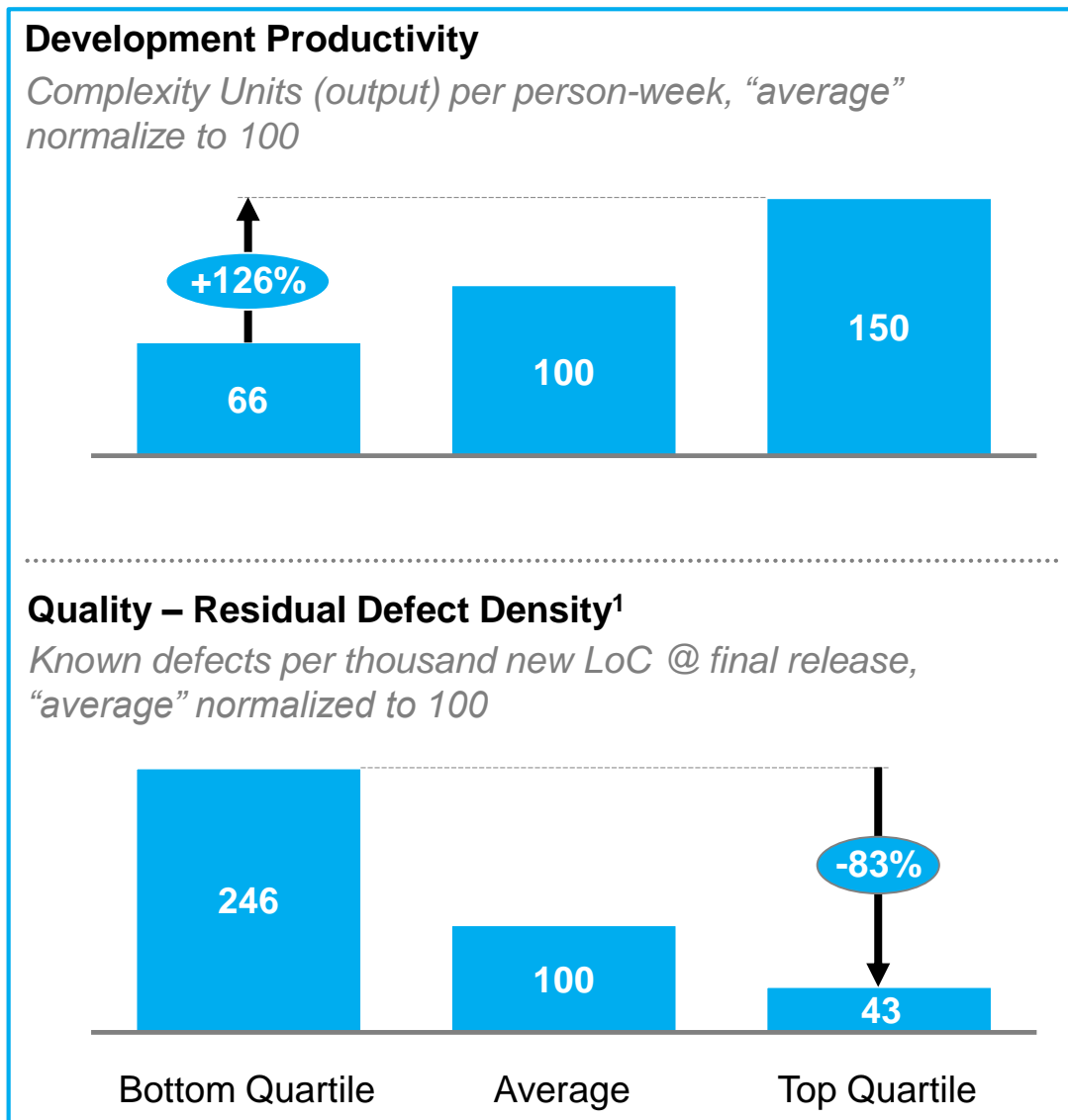
SOURCE: CDRH recall analysis, FDA RES database, various news outlets

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Analysis of productivity drivers and trends, revealing several insights into Medical software development

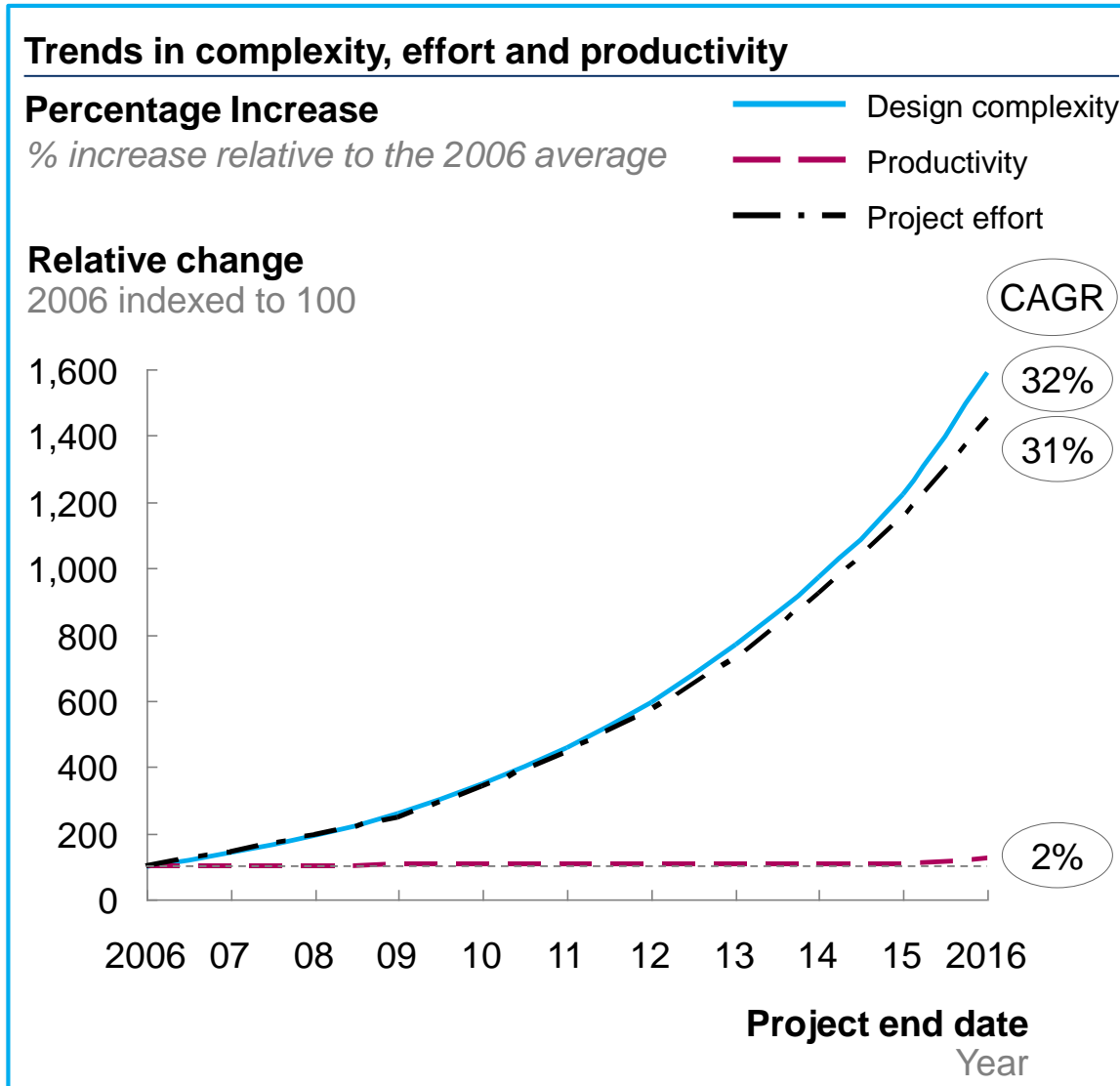
- 1 There is a wide variation in performance between the top & bottom quartiles. The top performers have a significant advantage
- 2 Complexity (and therefore effort) to develop medical SW has been increasing since 2006, but productivity has remained flat
- 3 ~70% of projects experience delays and SW deliveries have been taking longer over the past decade, but product quality continues to improve
- 4 R&D footprint needs to be carefully managed as increases in team size and number of R&D sites negatively affects productivity
- 5 Software quality, measured by known defect density at release, achieved by medical device companies exceed others by ~17%
- 6 Medical product requirements are increasingly hard to nail down. Time to define requirements has increased 29% and unplanned requirements churn has increased 81%
- 7 Reuse significantly improves the quality of software developed for medical applications
- 8 ~70% of medical products are delivered late. Those delivered “on-time” reuse 22% more code & focus more on new rather than legacy tests
- 9 Adding 3rd party SW suppliers increases schedule slip, lowers product quality, and offers only minimal improvement in productivity

1 There is a wide variation in performance between the top & bottom quartiles. The top performers have a significant advantage



- R&D performance between medical software teams varies greatly in terms of productivity and quality
- » Compared to the bottom quartile, the top 25% of medical R&D teams exhibit:
 - 126% higher productivity
 - 83% fewer known defects

2 Complexity (and therefore effort) to develop medical SW has been increasing since 2006, but productivity has remained flat



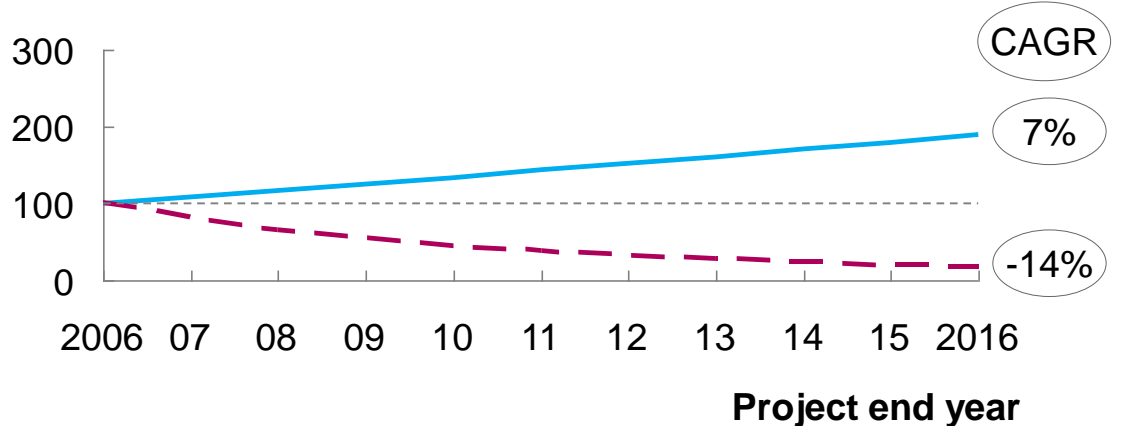
- Both the complexity of the average medical SW project and the average total effort required have increased ~30% CAGR in the last decade
- Productivity over the same period has been relatively flat, rising only ~2% CAGR
- This trend is driven by product differentiation being increasingly in software as well as the introduction of cloud-based, holistic solutions

3 ~70% of projects experience delays and SW deliveries have been taking longer over the past decade, but product quality continues to improve

Trends in Project Duration and SW Quality

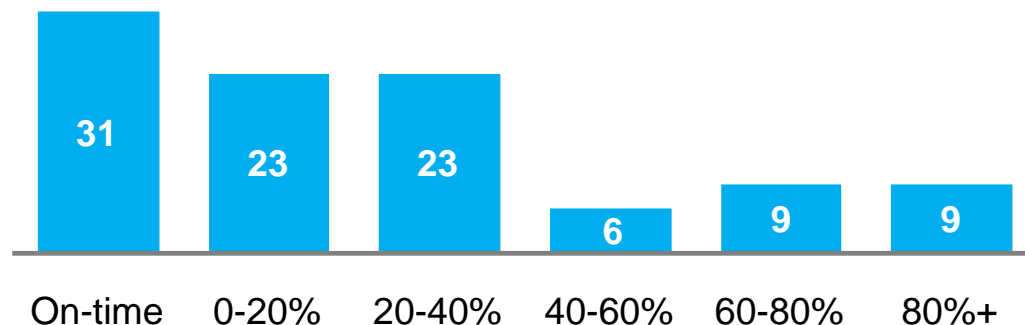
Relative project duration

% increase, 2006 indexed to 100



Schedule Slip Distribution for Medical Products

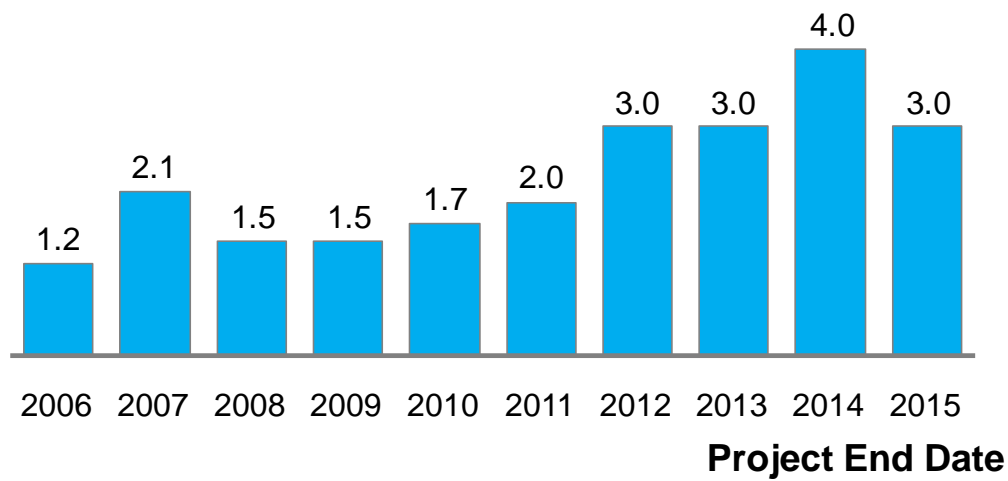
% Overrun of original schedule



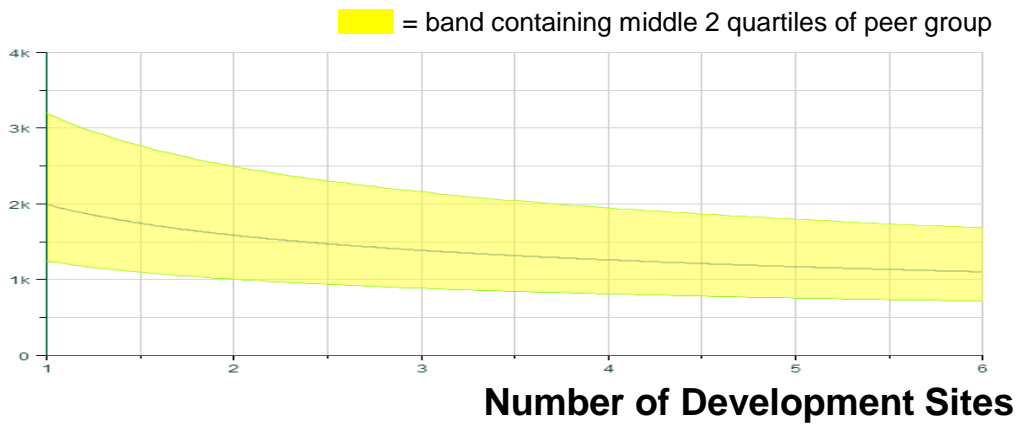
- 69% of medical products are late to market.
- The average schedule overrun for medical products is 25%.
- Project durations have been increasing ~7% CAGR
- Release quality (measured as “known residual defects per thousand lines of new code”) has been improving over time. Residual defect density has been dropping at ~14% CAGR

4 R&D footprint needs to be carefully managed as increases in team size and number of R&D sites negatively affects productivity

Average number of design sites by year



Development productivity
Complexity Units per Person-week

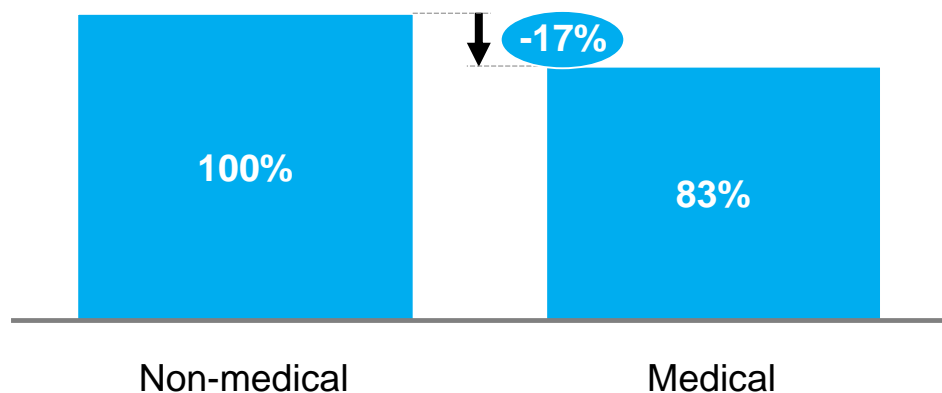


- Distributing development across more R&D sites (~11% per year increase in sites) is a reflection of increased complexity and larger teams
- Fragmenting development across multiple locations introduces inefficiencies associated with (for example) time zones, cultures, communication & collaboration issues, etc.
- The result is a drop of ~11% per site in productivity of medical software teams

5 Software quality, measured by known defect density at release, achieved by medical device companies exceed others by ~17%

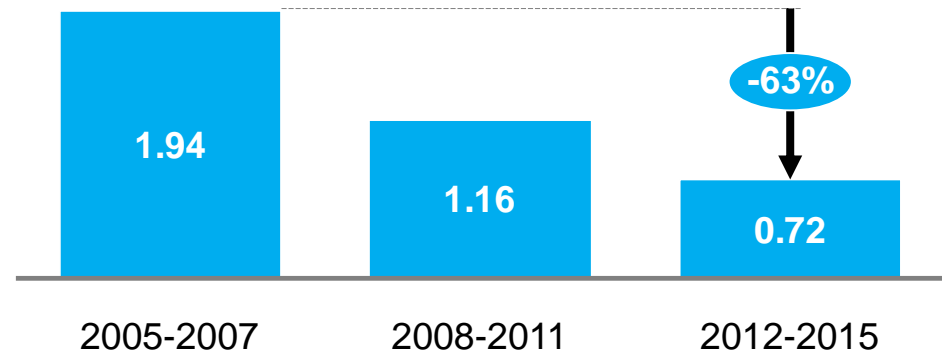
Known Residual Defect Density – Medical vs Non-medical

Average known defects per thousand new LoC (10% trim mean)



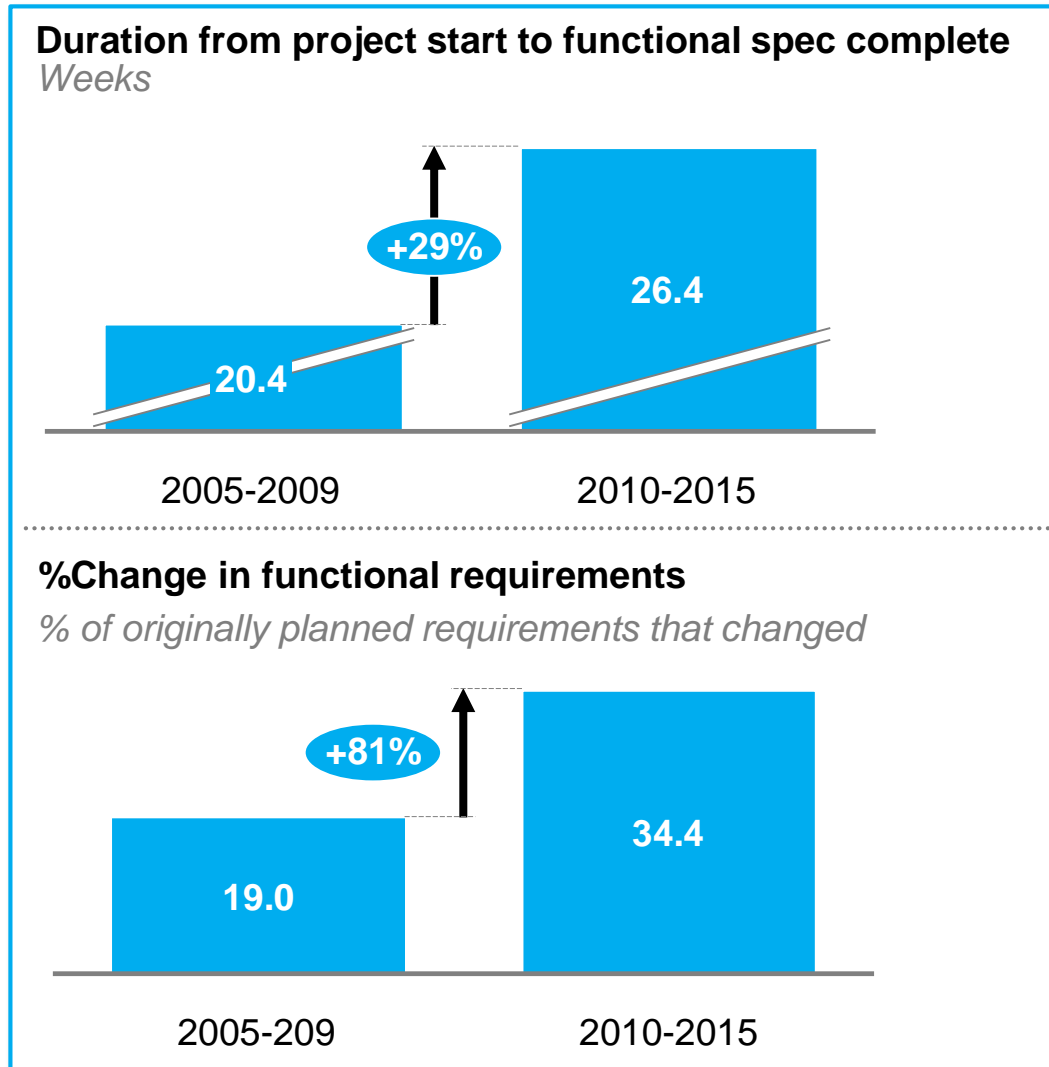
Known Residual Defect Density (trend)

Average known defects per thousand new LoC at final release



- Medical products are delivered with 17% fewer known residual defects (vs. non-medical software)
- Moreover, the outgoing SW quality levels in the health care industry have been steadily improving over the past decade

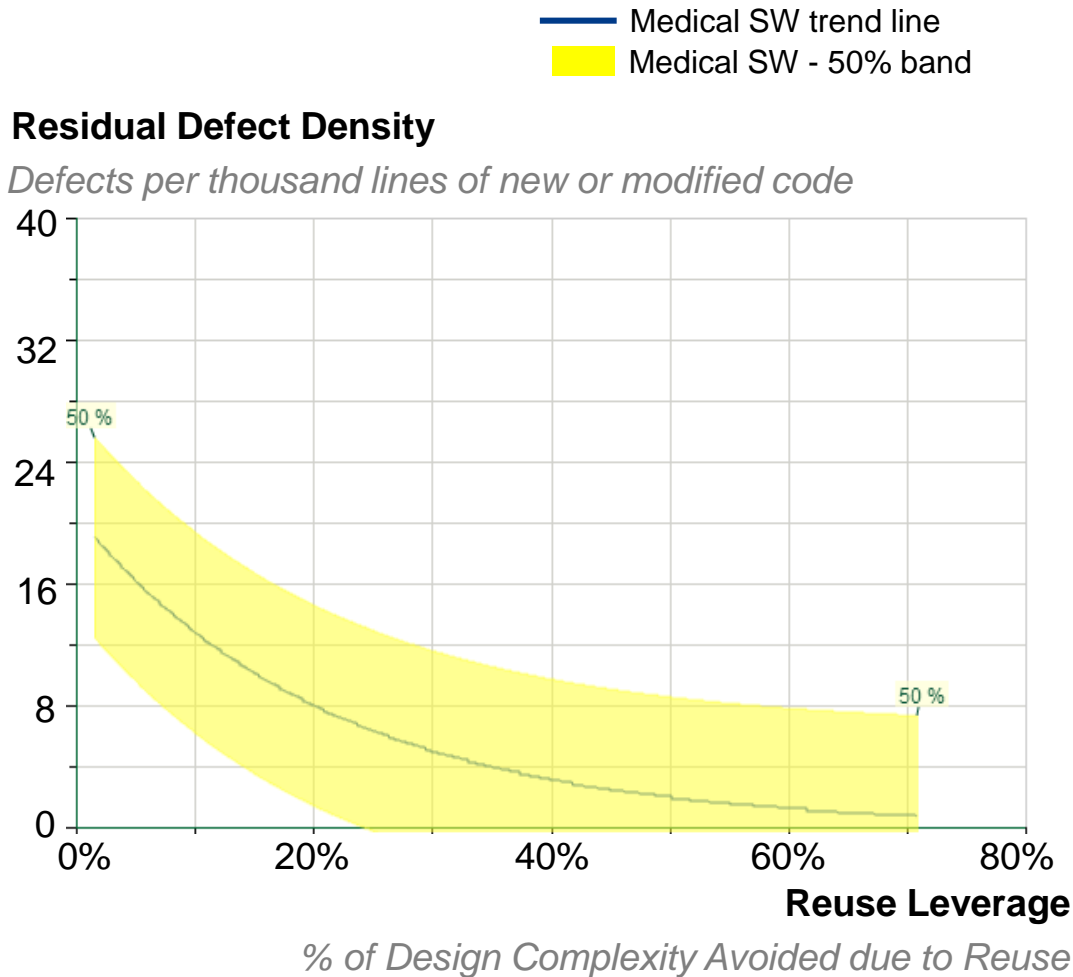
6 Medical product requirements are increasingly hard to nail down. The time to define requirements has increased 29% and the unplanned churn in requirements has increased 81%



- Prior to 2010, the average length of time to finalize medical SW requirements was 20 weeks. Since then, duration of this phase has increased by 29%
- 34% of medical requirements experience some kind of churn during development; i.e. they are added, modified or deleted after the 1st release of the functional requirements
- Requirements volatility partly explains the increase in development duration and highlights the need for medical solution providers to invest in managing market and regulatory requirements

7 Reuse significantly improves the quality of software developed for medical applications

What is the impact on SW quality due to reuse?

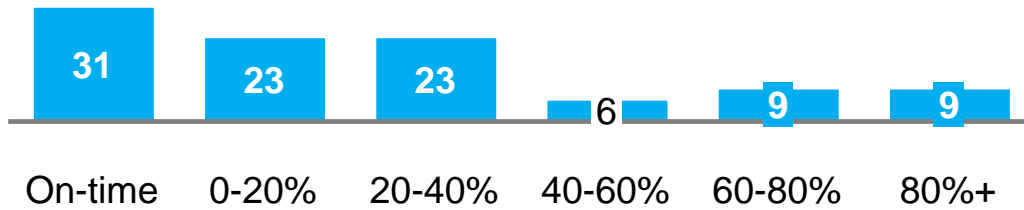


- Increasing reuse leverage is one of the most powerful ways to improve the quality of the software released
- For example, increasing reuse leverage from 10% to 20% is associated with a 37% reduction in average residual defect density
- Reuse leverage is a normalized metric that measures the % of software complexity that is avoided due to reuse of requirements, code and test cases

8 ~70% of medical products are delivered late. Those delivered “on-time” reuse 22% more code & focus more on new rather than legacy tests

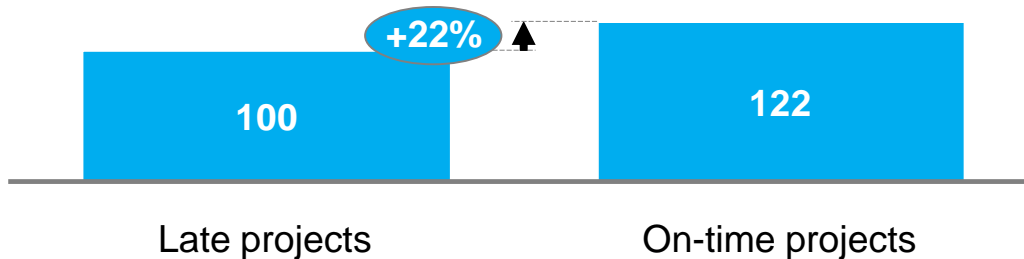
Schedule Slip Distribution for Medical Products

% Overrun of original schedule



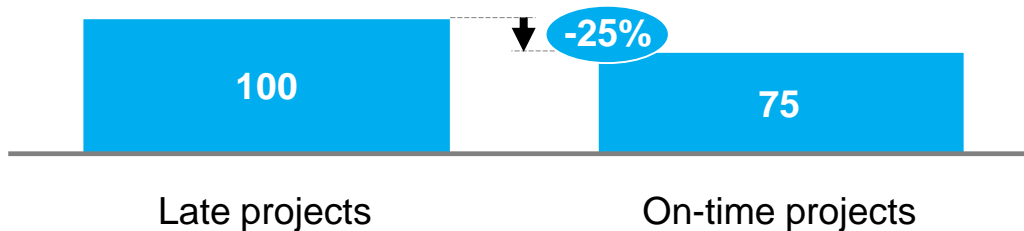
Proportion of reused lines of code

% of “new features” code reused as is; “Late” normalized to 100%



Proportion of reused test cases

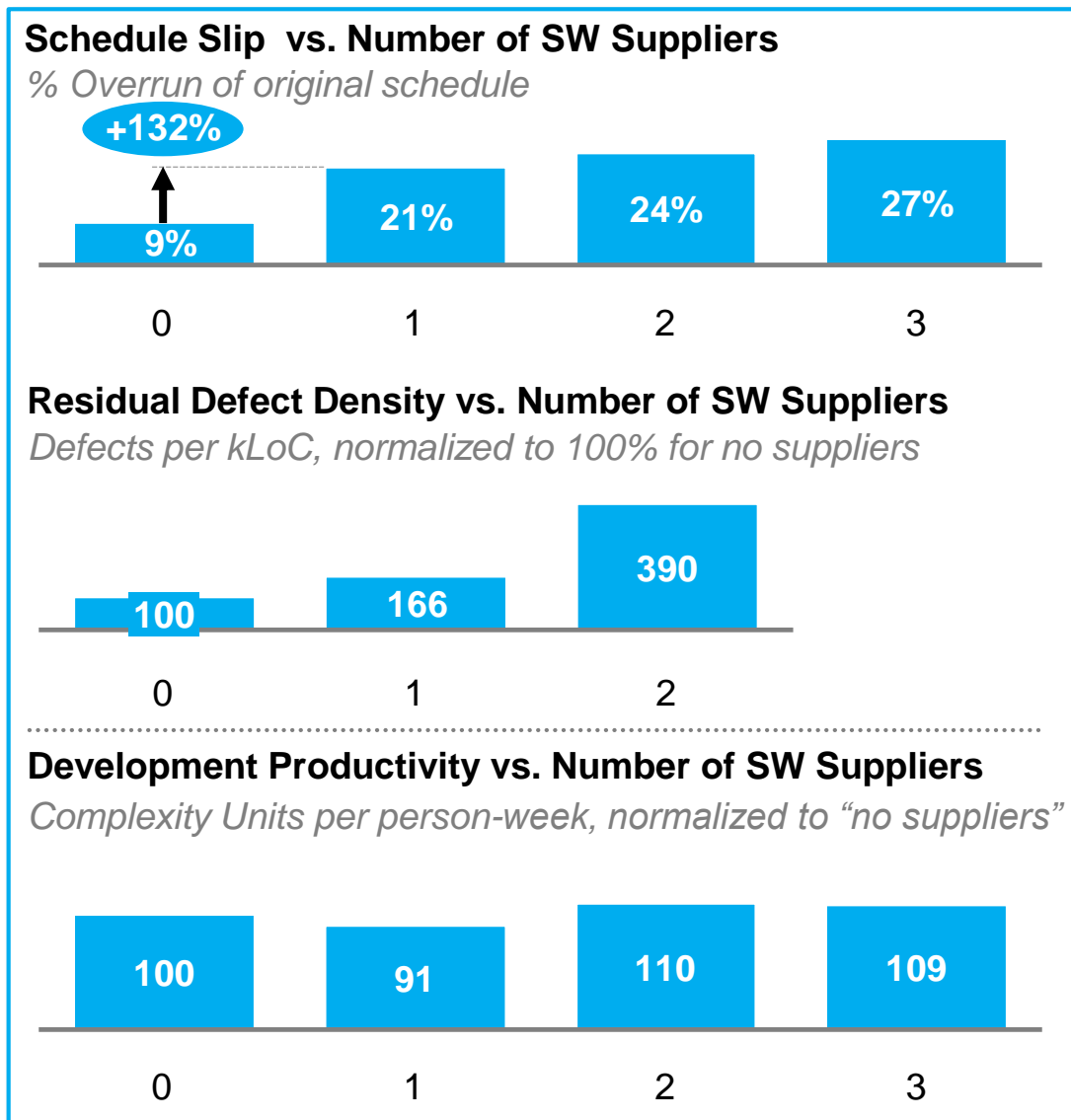
% of reused “new features” test cases; “Late” normalized to 100%



- 69% of medical products are late to market.
- The average schedule overrun for medical products is 25%.
- The 31% of medical products delivered on-time implement new features using 22% more reused code, minimizing the introduction of new defects
- The “on-time” projects focus on developing new tests rather than depending on legacy tests (regression) to validate new features. “On-time” projects use 25% fewer reused tests in their test plans



9 Adding 3rd party SW suppliers increases schedule slip, lowers product quality, and offers only minimal improvement in productivity



- Working with external SW providers can be a way to accelerate deliveries of new features, or reduce internal R&D overhead
- However, when medical companies work with software suppliers, unplanned schedule slip more than doubles and average residual defect density grows substantially
- Average development productivity remains relatively flat, independent of the number of suppliers



Contents

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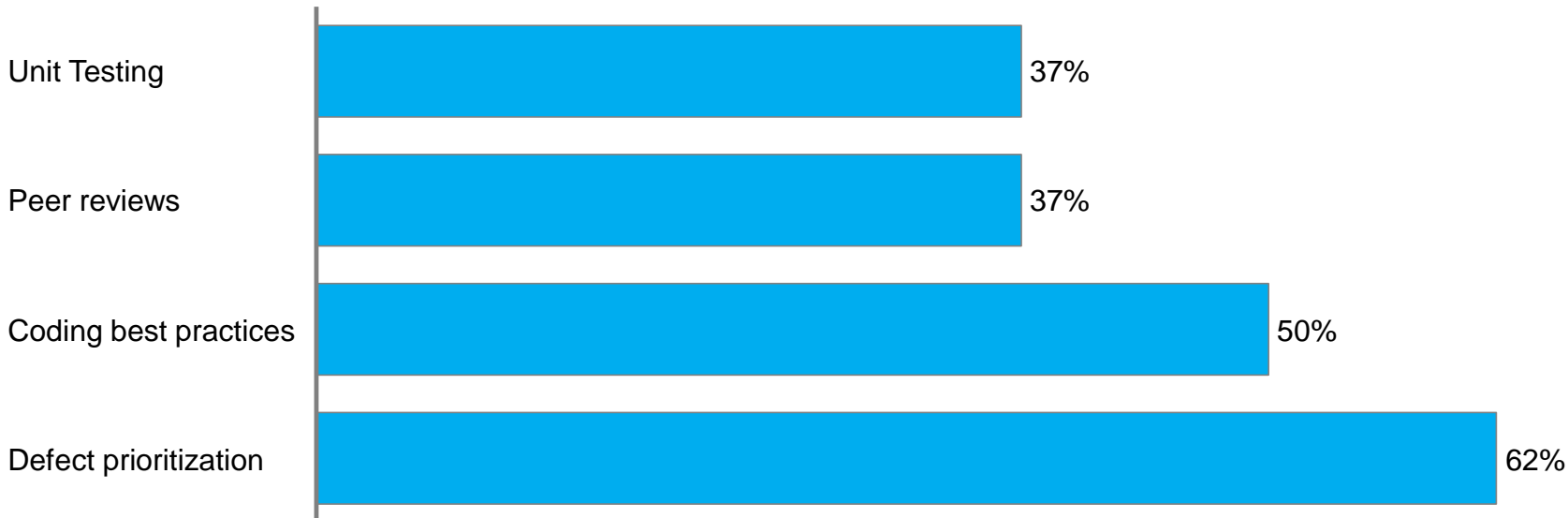
There is a significant opportunity to improve SW development performance by addressing some process, practices and culture related issues

- 1 While some development & QA processes successfully comply with strict regulatory guidelines, many are not properly or consistently implemented
- 2 ~70% of SW related recalls are caused by programming and design faults that can be avoided by using a more rigorous development and validation processes
- 3 Medical-device companies seem to be lagging other segments in adopting, understanding and following proper development processes
- 4 Medical-device companies are also more hesitant to adopt innovative tools such as test automation, code analyzers and advanced analytics
- 5 Adoption rates of Agile processes and methodologies also lag the high tech segment
- 6 Medical-device companies underinvest in developing software expertise, capabilities and tools versus other SW-intensive industries

1 While some development & QA processes successfully comply with strict regulatory guidelines, many are not properly or consistently implemented

Respondents who “did not agree” that the following are consistently implemented

Percent (N=60)



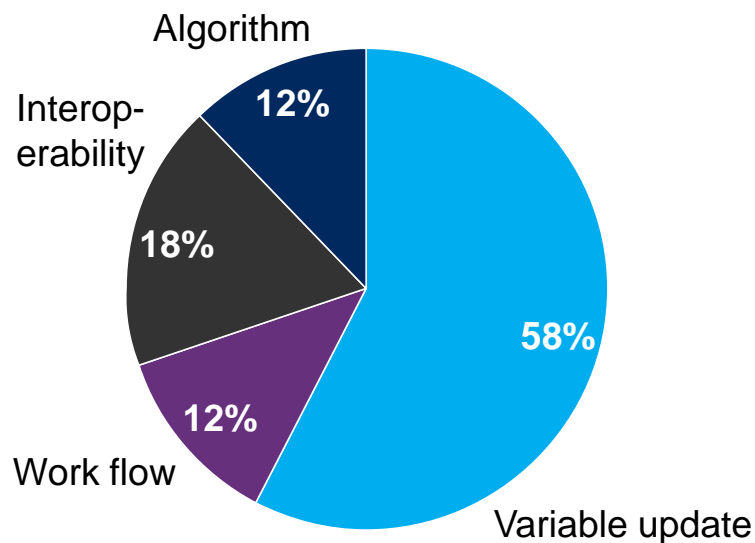
“Rigor is the most important thing in ensuring quality. I see defects leaking through to system test that should have been caught in peer reviews. The level of rigor we need is a big step up from where we are right now”

– Lead software developer, leading medical devices company

2 ~70% of SW related recalls are caused by programming and design faults that can be avoided by using more rigorous development and validation processes

Programming faults such as variables updates and algorithm errors cause 70% of software recalls

Percent (N=33)



“The biggest problem we have is that we don’t write the right tests – people don’t try to understand the actual subject matter and figure out the right test cases. If you don’t do that then you are not going to find bugs no matter how fast you run the tests or how many times you run them”

– Former principal software engineer, leading medical devices company (ICD devices)

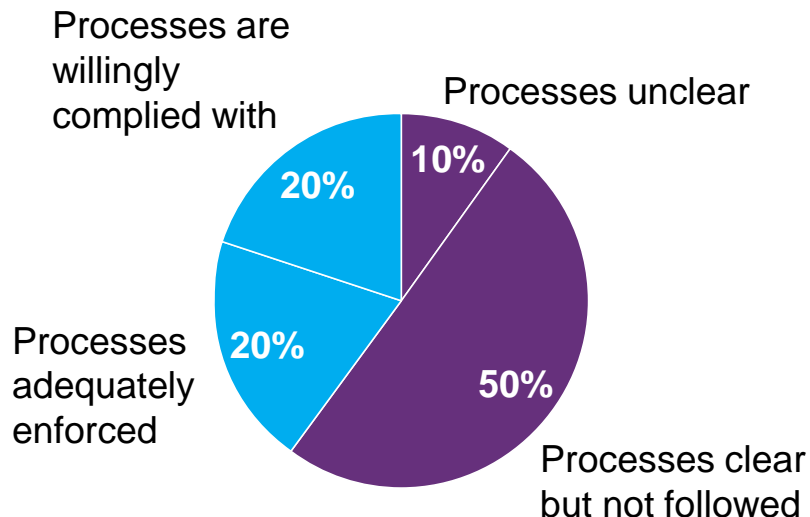
“Too often developers write the tests based on what the code does as opposed to what it is supposed to do. If you don’t define test inputs based on what the real system parameters should be, then you can even get 100% MCDC without actually testing your software”

– Director of software, leading cardiac medical devices company

3 Medical devices companies seem to be lagging other segments in adopting, understanding and following proper development processes...

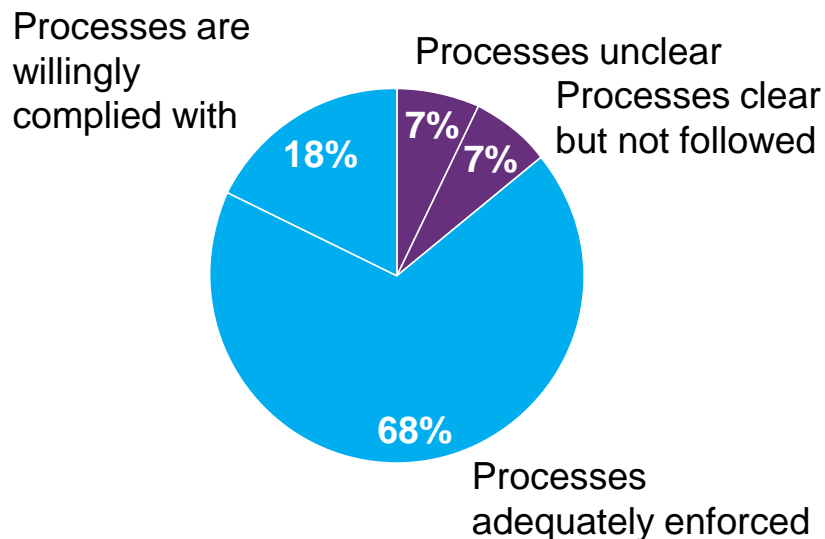
We have a clear understanding of, alignment on, and commitment to, following processes

Medical Device (N = 10)



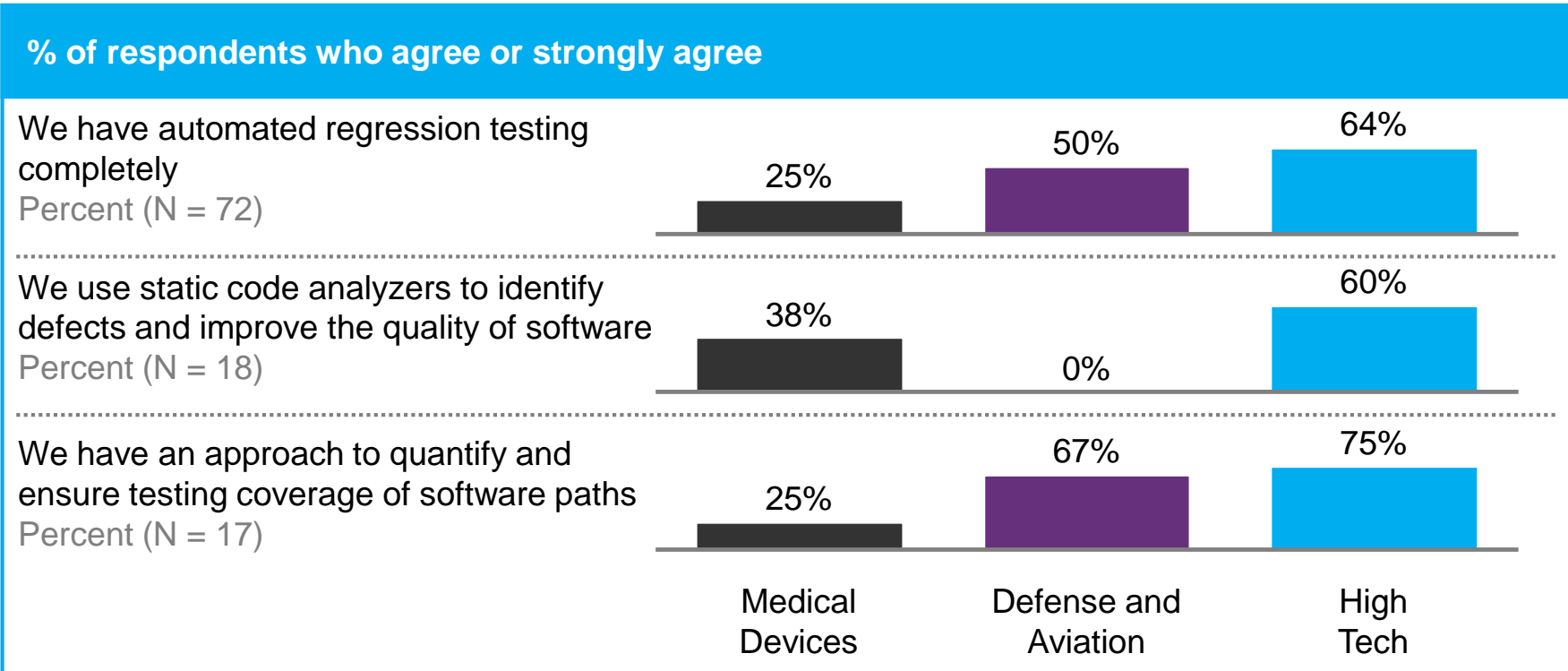
“Lots of engineers have the ‘trust me, I am a good engineer’ attitude and don’t like to follow processes. They believe that they don’t go to school to learn to create documentation, they go to school to invent things”
 – VP of QRA, large medical device manufacturer

High Tech (N = 28)



“Our people take pride in writing good code. We have a culture of peer review and earning the respect of your peers is a big deal. The company put these practices in early during its history and now it’s a habit for developers”
 – Product manager, large software company

4 ... and are also more hesitant to adopt innovative tools such as test automation, code analyzers and advanced analytics



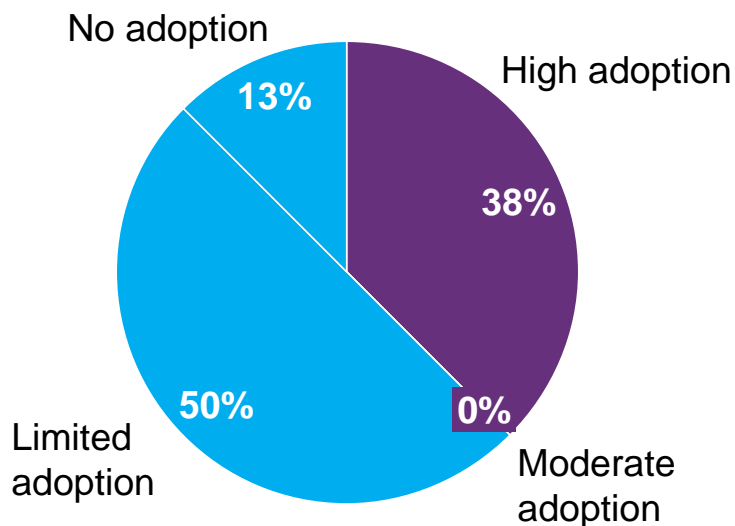
“A lot of people here believe that automated testing is a scam. They think that automated test scripts will constantly need to be updated and don’t see the benefits of this ‘overhead’”
 – Former CIO, large medical device company

“Many people think of automation testing in the context of the user interface. We understand that it is much more than that – 80% of the code written is to implement business logic and we focus automated testing on that code. Anytime changes are made, our nightly tests can tell us if anything broke the core business logic”
 – Principal software test engineer, large software development company

5 Adoption rates of Agile processes and methodologies also lag the high tech segment

Extent of adoption of Agile development practices

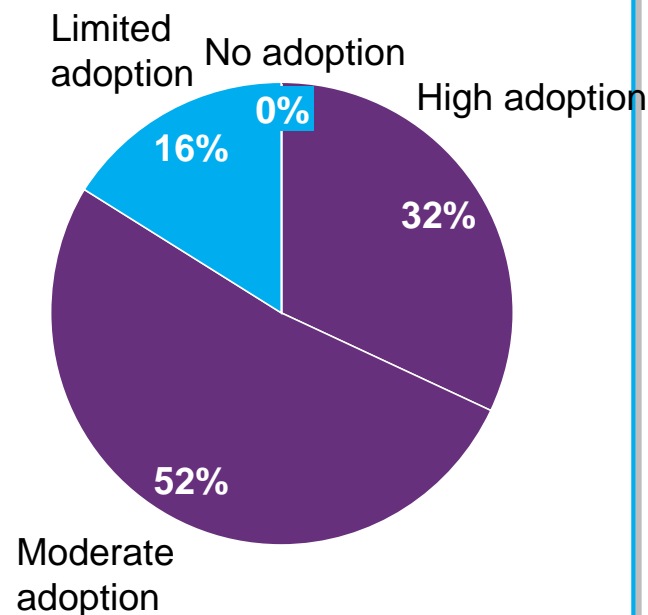
Medical Device (N = 8)



“Our general process aligns with IEC 62304 and that fits well with FDA requirements. With the kind of regulations we have to comply with, our environment is just not well-suited to adopting agile”

– VP of new product development, large medical device company

High Tech (N = 25)



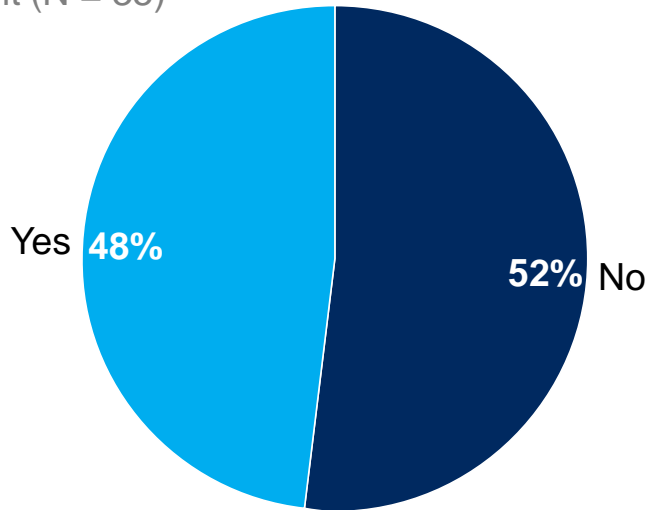
“Agile allows us to be more nimble. Product managers are under constant pressure to add and change functionality based on customer trends. Feature driven development and scrums allow us to build quickly and deploy fast. It’s almost necessary to be agile”

– Product manager, large software maker

6 Medical device companies underinvest in developing software expertise, capabilities and tools versus other SW-intensive industries

Less than half of medical device companies explicitly develop capabilities in software management, architecting and development

Percent (N = 35)

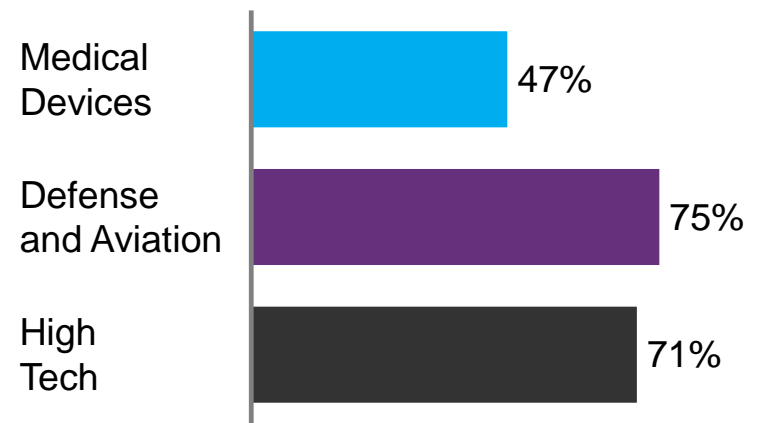


“A lot of the people I worked with are traditional hardware experts with limited skills in software. While they were excellent engineers, they just didn’t understand the nuances of working with software. They think that since software can be changed quickly to add new features, developers and testers should be able to add new functionality even in the middle of a release!”

– Former senior product engineer, large medical device company

Other industries have a higher organizational focus on development of deep knowledge and expertise

Percent (N = 73)



“We have a sophisticated program that helps us categorize people into levels of expertise and then provides a systematic method for them to develop expert level skills. We use a combination of trainings, external certifications and project experience to help software developers build these skills”

– Project manager, large software development company

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Numetrics is a McKinsey SaaS-based analytics solution that enables rapid improvements in embedded and application SW development



Proven complexity measurement method

Large industry database of peer projects

Established analytics platform

Proprietary complexity algorithm successfully applied in **>400** companies

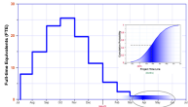


- 1,700+** software projects
- 40+** vertical industry segments
- 140+** Health care and medical related projects
- 50+** operating systems
- 20+** programming languages

Industry Benchmarking



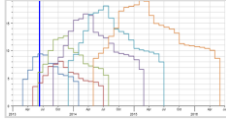
Project Planning & Estimation



Root Cause Analysis / Productivity Diagnosis



Portfolio & Resource Planning



Numetrics offers performance benchmarking, root cause analysis and project planning (predictive analytics) for SW and IC development

What is Numetrics?

SaaS-based R&D predictive analytics platform based on a **patented complexity algorithm** to provide:



Performance
benchmarking



Root cause
analysis



Project
planning

Where can Numetrics be applied?

- **Software (Embedded and application):**
 - **Verticals:** Telecom, Financial, Medical devices, Industrial controls, Aerospace & Defense, etc.
 - **Operating systems:** Android, IOS, Linux, Microsoft, Wind River, TI, etc.
 - **Platforms:** ARM, MIPS, Broadcom, Freescale, IBM, Microchip, Renesas, Samsung
- **Semiconductors (ICs):** Across segments, including Analog, Mixed signal, Memory, SOC, FPGA, IP, RF

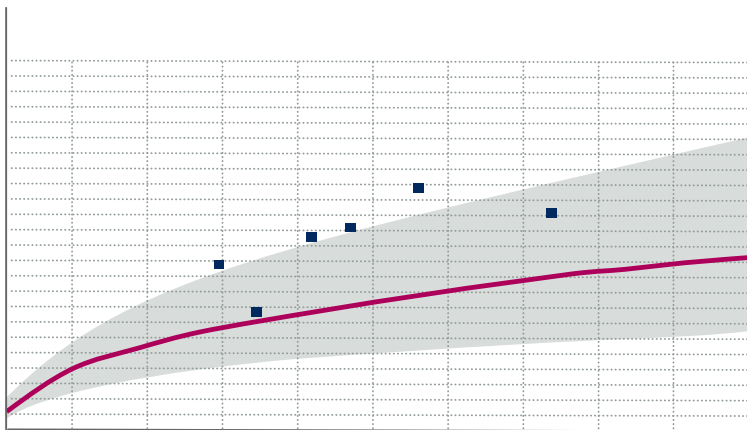
Performance benchmarking – Creates a productivity baseline to enable internal and industry benchmarking

Performance benchmarking

Create a project-level productivity baseline based on recent projects, and benchmark across multiple dimensions against a database of ~2,000 IC and 1,700+ SW projects

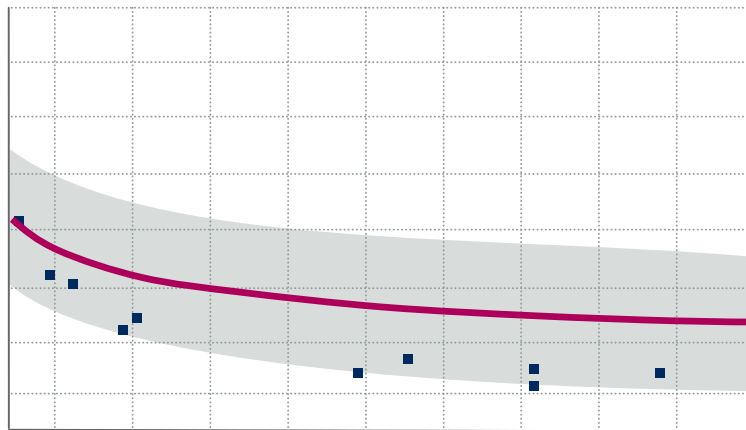
Sample outputs

Project duration Vs. Design complexity



■ Industry peers ■ Client projects

Productivity Vs. Team size

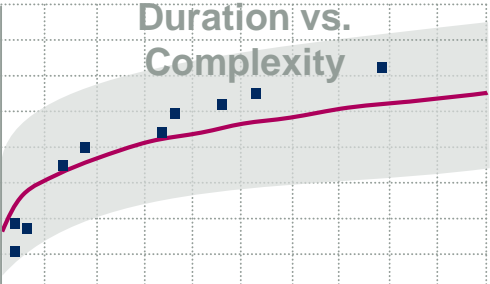


Performance benchmarking – A wide range of metrics can be benchmarked against industry peers

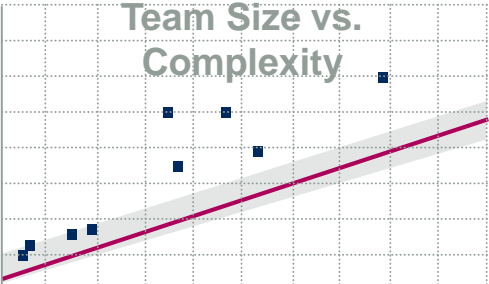
NOT EXHAUSTIVE

■ Client Software Projects ■ Band containing 50% of industry peers

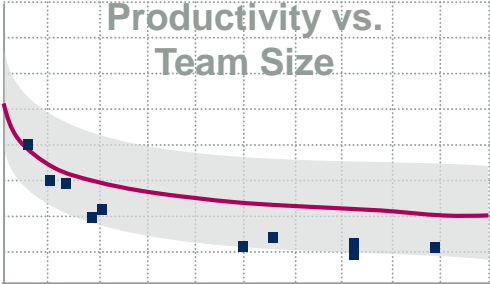
How fast can we deliver SW?



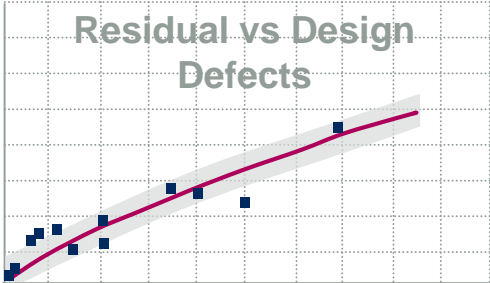
How many people do we need?



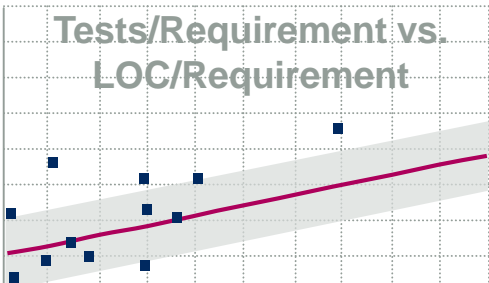
How efficient are we?



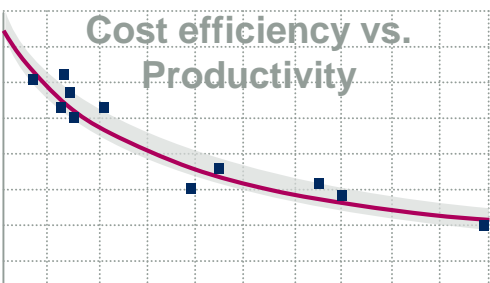
Is our verification strategy effective?



How granular are our requirements?



How cost competitive are we?



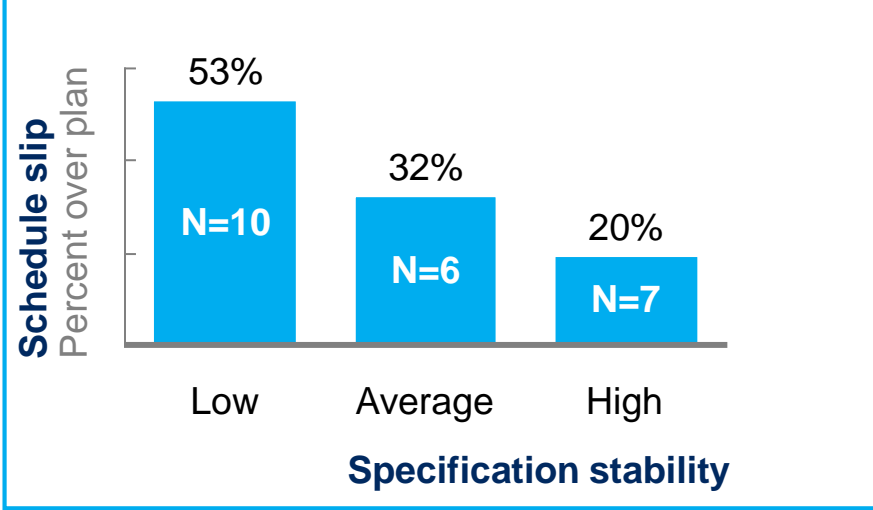
Root cause analysis – Analyzes industry database (best practices) to identify likely causes of low productivity

Root cause analysis

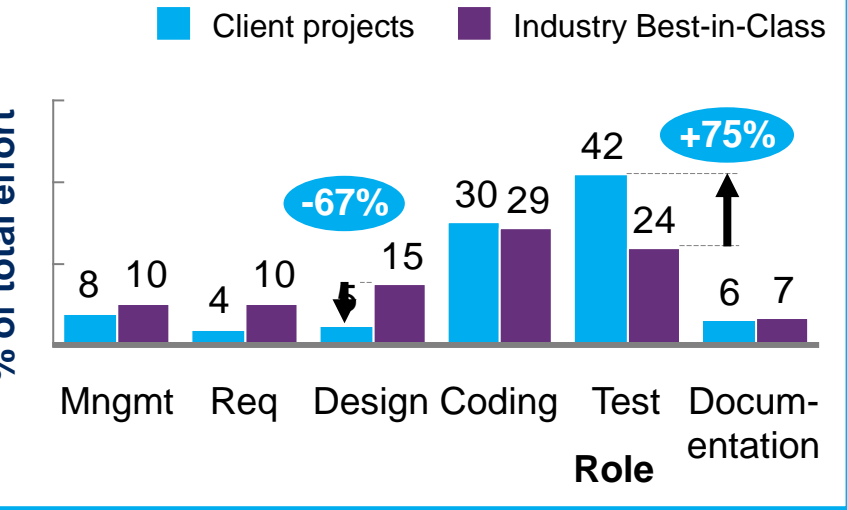
Use analytic tools to find root causes and drivers of low performance, and compare to industry best practices to determine recommended course of action

Sample outputs

Poor spec stability caused significant schedule slip



Insufficient effort during design phase caused higher test effort



Project planning – Predictive analytics generates robust project plans (resources, schedule) to identify time-to-market risks

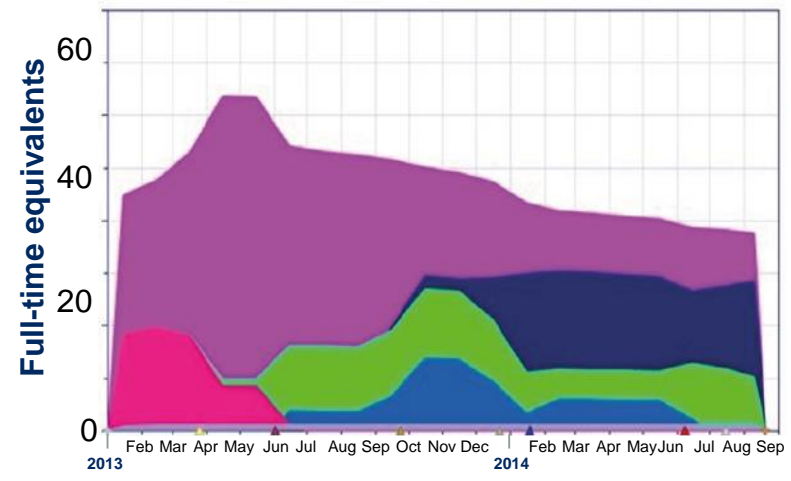


Project planning and risk assessment

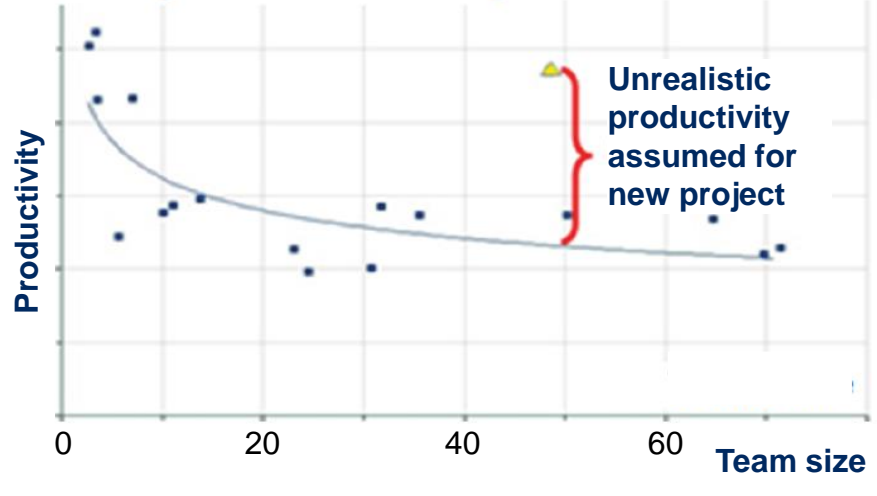
Use predictive analytics to provide better transparency to schedule and required resources at the project's outset and assess schedule risk due to unrealistic productivity assumptions

Sample outputs

Predicted staffing requirements by role and project phase

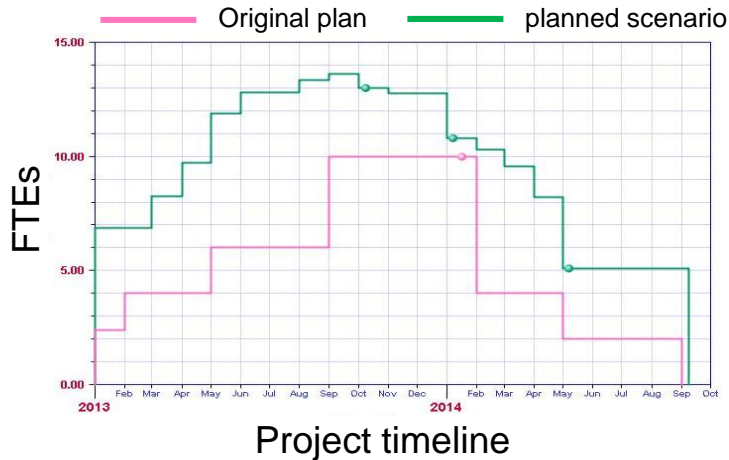


Schedule risk due to unrealistic productivity assumption



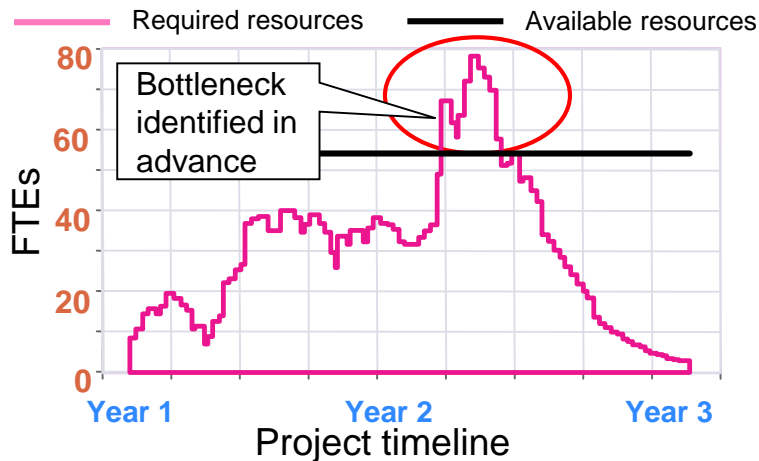
Project planning – predictive analytics is used to optimize schedule and staffing at the project and portfolio levels

“What-if” scenarios to determine tradeoffs and optimize the plan



- Planned staffing plan is plotted against the predicted resource requirements to identify gaps
- “What-if” scenarios can be run to better understand tradeoffs between specifications, resources, budget and timeline, and to determine the optimal plan for the project

Analytics on required staffing and available resources across multiple projects



- Estimated staffing requirements by role and project phase across multiple projects is compared to available resources
- Resource gaps and bottlenecks are identified early on with plenty of time to adjust staffing levels, modify scope or reprioritize projects

Contents

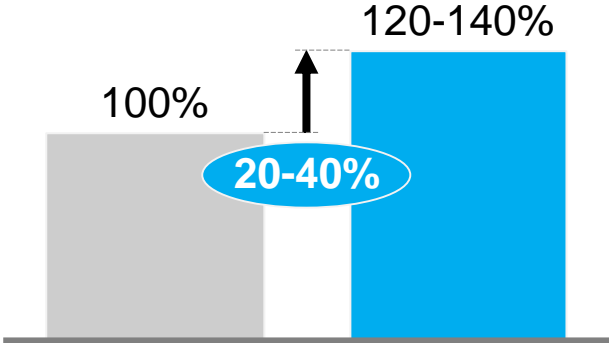
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- **Numetrics offering and engagement models**
- Appendix

Numetrics analytics enables step-function improvement in R&D productivity and time-to-market performance

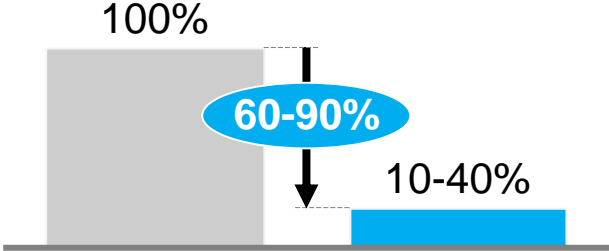


■ Before analytics ■ After analytics

R&D capacity¹



Reduction in schedule slip² (TTM)

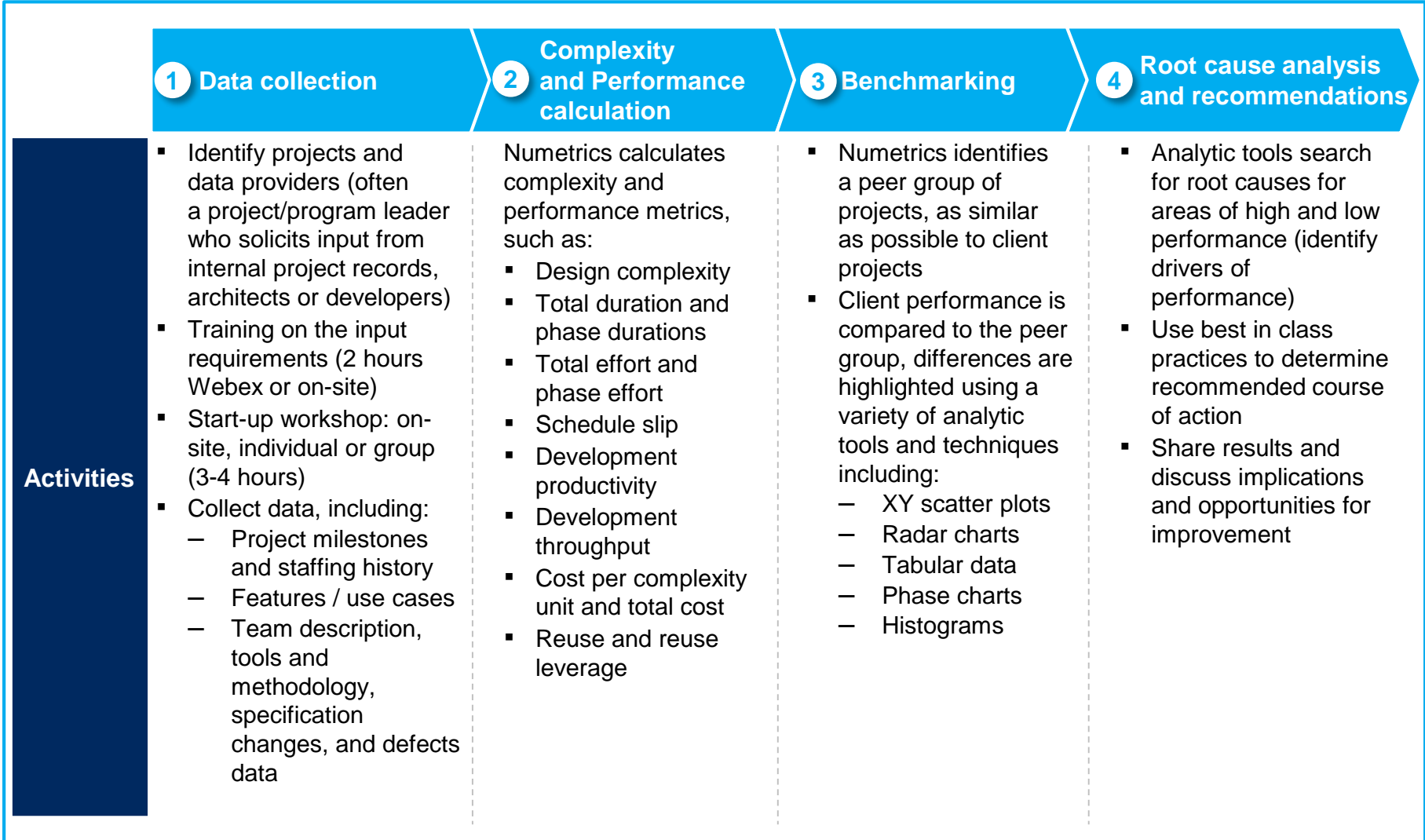


¹ R&D Capacity is measured as “complexity units per person-week”
² Schedule Slip is the amount of schedule overrun, expressed as a % of the original schedule.
 (e.g. if a 100-week project slips 12 weeks, then schedule slip = 12%)

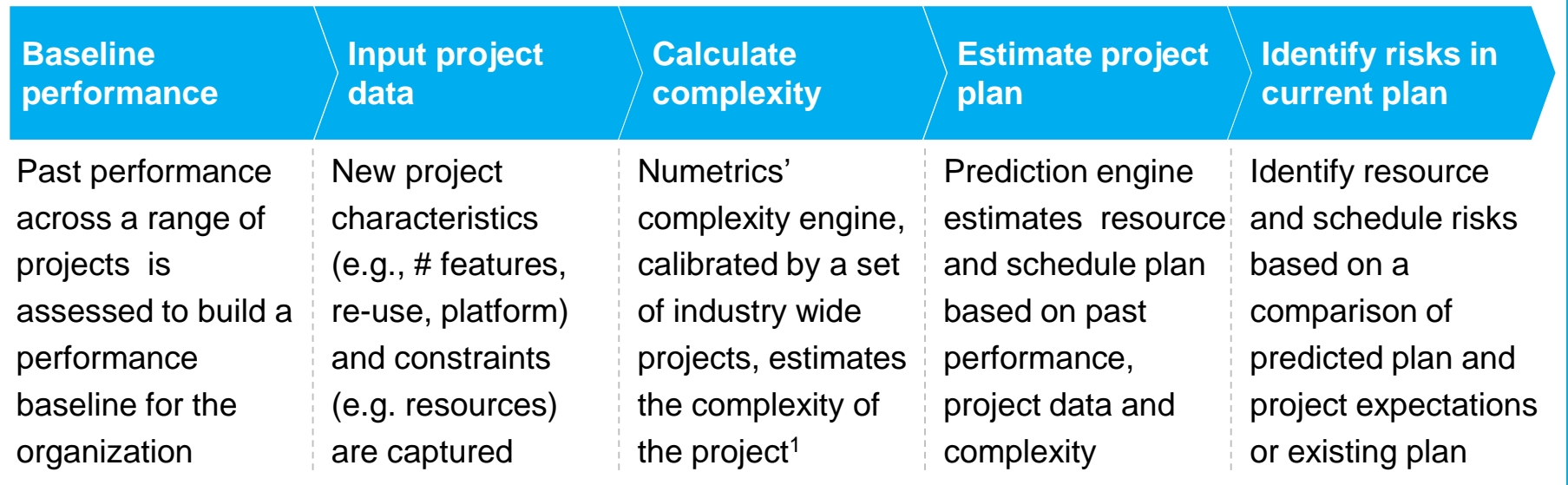
There are several ways to engage Numetrics

	Scope	Engagement model
Analytics focused diagnostic	<ul style="list-style-type: none"> 4-6 week (depending on data availability), Numetrics led diagnostic Standalone analytic assessment of 5-7 completed projects Provides a productivity baseline, industry benchmarks and analytic root cause analysis 	<ul style="list-style-type: none"> Numetrics team handles data entry, validation, analyses, and reports Client collects required project data under Numetrics' guidance and support
Deep R&D diagnostic	<ul style="list-style-type: none"> 8-10 weeks deep diagnostic, combining analytic and qualitative analyses Includes analytics focused diagnostic, complemented by qualitative tools such as surveys, project deconstruction, process mapping, interviews and workshops to provide a complete view of productivity and performance drivers May include planning of a new project to determine required resources and schedule risk 	<ul style="list-style-type: none"> Numetrics team handles data entries, validation, analyses, tailored benchmarking and reports Client collects required project data with Numetrics' guidance
Subscription	<ul style="list-style-type: none"> Embed Numetrics planning tool in the standard PD process to continuously track performance Use predictive analytics to increase TTM transparency and optimize resource allocation Includes initial benchmark and baseline creation and access to the planning tool 	<ul style="list-style-type: none"> Client trained to input project data and run reports directly using the web interface Numetrics team runs the analyses and provides insights

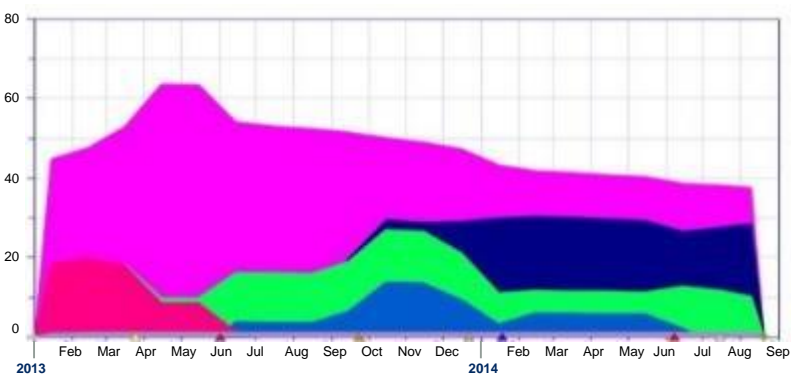
Benchmarking and root cause analysis require project data and timelines of several completed projects



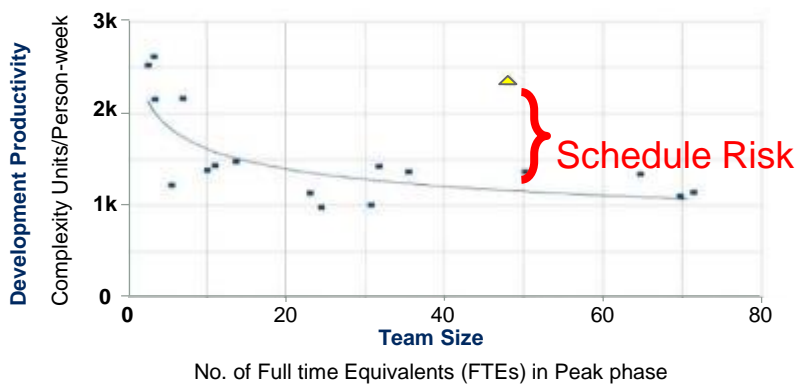
Numerics' predictive analytics can help optimize project planning and timely execution



Schedule & Resource Estimation



Schedule Risk Analysis

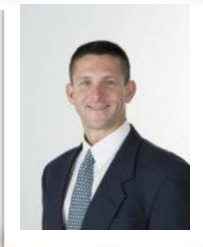


¹ Measured in Complexity Units - A metric reflecting the amount of effort the average development team will spend on the project

Who to contact to get started?



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Contents

- Growing importance of SW in medical devices and healthcare
- Insights into SW R&D productivity for medical and healthcare products
- Insights into SW R&D processes, practices and culture
- Introduction to Numetrics R&D analytics
- Numetrics offering and engagement models
- **Appendix**

Numetrics is a well-established company with a field proven sets of solutions

1998

Launch of semiconductor benchmarking solution

2001

Launch of semiconductor predictive planning solutions

2004

First embedded SW complexity model

2006

Launch of embedded SW predictive planning solution

2010

First 1,000 SW projects released in industry database

2013

Numetrics acquired by McKinsey

- Extensive database of ~2000 IC and ~1700 SW projects
- Field proven complexity estimation and predictive analytics algorithms
- Wide industry coverage including automotive, aerospace & defense, high tech, financial services, medical, etc.

The Numetrics database includes more than 140 MedTech SW projects...

Numetrics database - MedTech

- More than 140+ medical SW projects
- Applications include:
 - Anesthesia
 - BioSurgery
 - Patient bio-system monitoring
 - Medical imaging
 - Blood/body fluid management
 - Patient information management
 - Doctor diagnostic assistance tools
 - Patient bio-system monitoring
 - Medical imaging analysis
 - Remote equipment monitoring & information dashboards
- Spans drivers + operating system/
middleware + UI/application layer
- Team sizes from 2 to >75 FTEs
- Recent data (<3-4 years)



Sample Project Descriptions

- “Medical Neurodiagnostic product”
- “Embedded control and GUI for dialysis machine”
- “Patient Respiratory Monitoring System”
- “Cardioverter defibrillator”
- “ECG monitor”
- “Blood cell count monitor”
- “Controls; samples and displays fresh gas flow for medical anesthesia equipment.”
- “SW for operation of an ophthalmic surgical instrument”
- “Medical ultrasound imaging & associated equipment”
- “Infusion pump software including drug library; user interface; sensor monitoring and fluid propulsion control”
- “firmware and software for an IVD instrument.”
- “SW for analysis, comparison, and visualization of genomic sequencing data”
- “Patient Respiratory Monitoring System”
- “Remote medical equipment monitoring, control and alarm notification system”

Numetrics' analytics engine is based on a proprietary "design complexity" model that normalizes productivity across projects

Design/development complexity:

- A metric representing the total amount of project effort the average design/development team in the industry would expend on the project – quantifies the true, normalized output of the design team
- The complexity model fully takes into account the stochastic nature of product development, which enables the predictive analytics engines to reliably estimate schedule & resource requirements and perform meaningful comparisons of performance metrics across different projects/designs

Complexity inputs

Software Complexity Measures

- Customer requirements
- Functional requirements
- Test cases
- Use cases
- Test types
- Lines of Code
- Architectural layers
- Number/type of components
- Reuse
- Programming language(s)
- Number of variants
- Real-time content
- Available storage space
- Number of platforms
- Platform maturity

