Considerations For Building Your Own Cloud

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CTO

Galen Data

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MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

75
years industry experience

275k
podcast listeners

#1
blog and podcast in the industry

114k
look to us for the latest in quality

FEATURED IN

THE WALL STREET JOURNAL.

THE VERGE

TechCrunch

Forbes

QUALITYDIGEST

MD+DI

Inc.

MedTech Intelligence

MED DEVICE ONLINE

MedicalDesign & OUTSOURCING

TNW THE NEXT WEB

Entrepreneur

MPO

G2 CROWD

LEADER

QMS SOFTWARE

★★★★½

Since Winter 2019

"Best eQMS I have ever used..."

This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry. *It is simple, intuitive and easy to use...* We are successfully implementing a Quality Culture.

- Director of Regulatory Affairs & Quality Assurance

"Modern QMS Software and Outstanding Customer Service."
★★★★★

"Demystifying QMS and Regulatory Requirements"
★★★★★

"Makes your QMS Simple and Effective"
★★★★★

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Benefits for Connected Devices

Remote Monitoring

– Telehealth

– Patient Compliance

New Business Models

– Diagnosis as a Service

– Device as a Service

Device Surveillance

– Device Health

– Remote Device Diagnosis
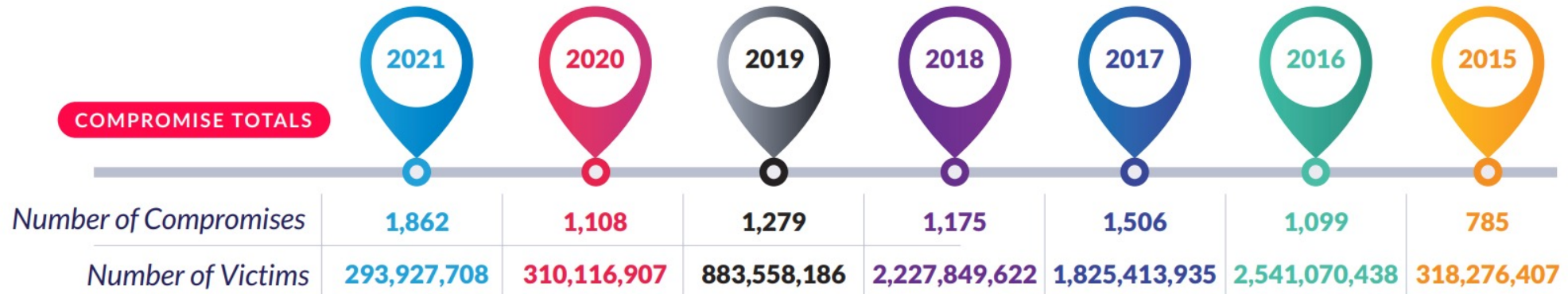
Higher Efficiency

– Error Reduction

– Time Savings

Speed bumps in the path to Cloud Connectivity

- Security and Privacy

- Regulatory

- Build vs Buy

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Compromise Trends

COMPROMISE TOTALS	2021	2020	2019	2018	2017	2016	2015
Number of Compromises	1,862	1,108	1,279	1,175	1,506	1,099	785
Number of Victims	293,927,708	310,116,907	883,558,186	2,227,849,622	1,825,413,935	2,541,070,438	318,276,407

SECTOR TRENDS	2021		2020		2019	
	Compromises	Victims	Compromises	Victims	Compromises	Victims
Education	125	1,680,300	42	978,254	71	5,161,005
Financial Services	279	19,745,846	138	2,687,084	172	103,939,736
Government	66	3,244,455	47	1,100,526	64	1,193,791
Healthcare	330	28,045,658	306	9,700,238	398	9,080,498
Hospitality	33	217,941	17	22,365,384	40	1,459,393
Manufacturing & Utilities	222	49,775,124	70	2,896,627	103	70,265,156
Military	--	--	--	--	1	1,243
Non-Profit/NGO	86	2,309,008	31	37,528	36	248,824
Professional Services	184	22,697,765	144	73,012,132	84	1,694,188
Retail	102	7,186,143	53	10,710,681	86	370,128,202
Technology	79	44,035,156	67	142,028,859	62	107,923,851
Transportation	44	534,280	21	1,208,292	15	211,335
Other	308	79,223,368	172	43,391,302	147	

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Cybersecurity and Privacy Consideration

- Myriad amount of security and privacy laws, regulation and standards

  - Laws/Regulations/Guidance
    - HIPAA/HITECH
    - GDPR
    - CCPA, Mass Data Protection Law etc.
    - COPPA
    - PIPED Act
    - FDA Cybersecurity Guidance

  - Standards
    - ISO/IEC 27001
    - ISO/IEC 27018
    - ISO 278032
    - UL 2900
    - NIST
    - Cloud Security Alliance
    - HITRUST CSF

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Cybersecurity and Privacy Consideration

- Few steps to manage privacy and security
    - Establish a culture of cybersecurity
    - Integrate Cybersecurity as part of your design life cycle
    - Setup appropriate agreements

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Cybersecurity and Privacy Consideration

- Establish a Culture of Cybersecurity
  - Very important and often underappreciated aspect of security protection
  - Regularly train employees and user with access

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Cybersecurity and Privacy Consideration

- Integrate Cybersecurity as part of your design life cycle
    - Risk Planning and Assessment
    - Design with security in mind
    - Develop a cybersecurity surveillance program

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Cybersecurity and Privacy Consideration

- Risk Planning and Assessment
  - Identify all PHI
  - Create a threat model
  - Assess vulnerabilities
  - Assess harm if those vulnerabilities were successfully exploited
  - Assess probability of such an event

Cybersecurity and Privacy Consideration

- Design with security in mind
  - Identity and Access Management
  - Authentication
  - Encryption
  - Audit Trail
  - Software BOM
  - Secure Design and Coding practices
  - Security Testing

Cybersecurity and Privacy Consideration

- Cybersecurity Surveillance Program
  - NIST Cybersecurity Framework
    - Identify
    - Protect
    - Detect
    - Respond
    - Recover
  - Understand all the requisite transnational, national, state and local reporting requirements
  - Use cross functional teams
  - Ensure adequate business protection

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Cybersecurity and Privacy Consideration

- Setup Appropriate Agreements
    - Business Associate Agreement (BAA)
    - Data Processing Agreement
    - Model Contract Languages

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Regulatory Considerations

- How to classify your connected health component?
  - Is it an accessory to your device?
  - Is it a Medical Device Data System?
  - Is it a Clinical Decision Support System?
  - Is it even a medical device?

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Build vs Buy

- Age old question – to build or to buy

Build

- Pros
  - Fully customizable
  - Full control and ownership
- Cons
  - Cost
  - Time
  - Development Risks

Buy

- Pros
  - Cost Effective
  - Quick Time to Market
  - Risk Reduction
- Cons
  - May have to compromise on some functionality
  - Not full control and/or ownership

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Build vs Buy

- Build yourself
  - Start with general purpose cloud infrastructure (like AWS, Azure etc.) for data storage and other functions
  - Ensure development of your solution is done under required compliance
  - Ensure all security configurations are done properly
  - Build an operational team that is skilled in Cloud IT
  - Acquire and operationalize good security monitoring and detection tools
  - Develop a patching and disaster management plan and regularly test it
  - Setup appropriate business safeguards and agreements

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Build vs Buy

- Buy
  - Ensure solution was built with required compliance
  - Ensure solution is fully managed (otherwise you bear the operational burdens and risks)
  - Understand the vendors' track record in terms of security and privacy
  - Ensure solution can scale globally
  - Understand how version controls work and how you can benefit from future improvements
  - Understand what responsibilities and liabilities the vendor takes on and what commitments they are willing to make
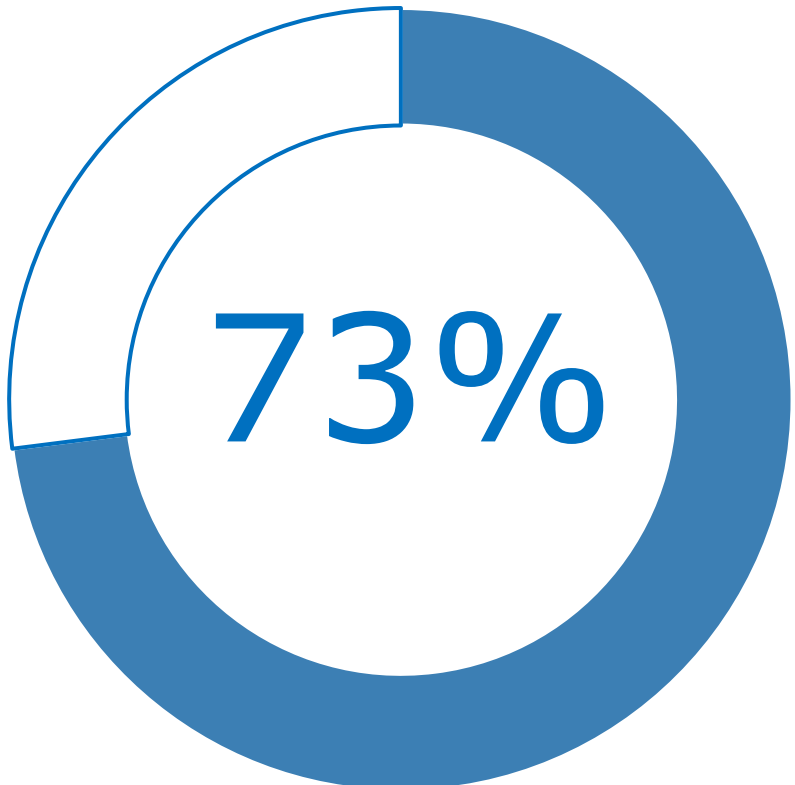
Who are we? And how can we help?

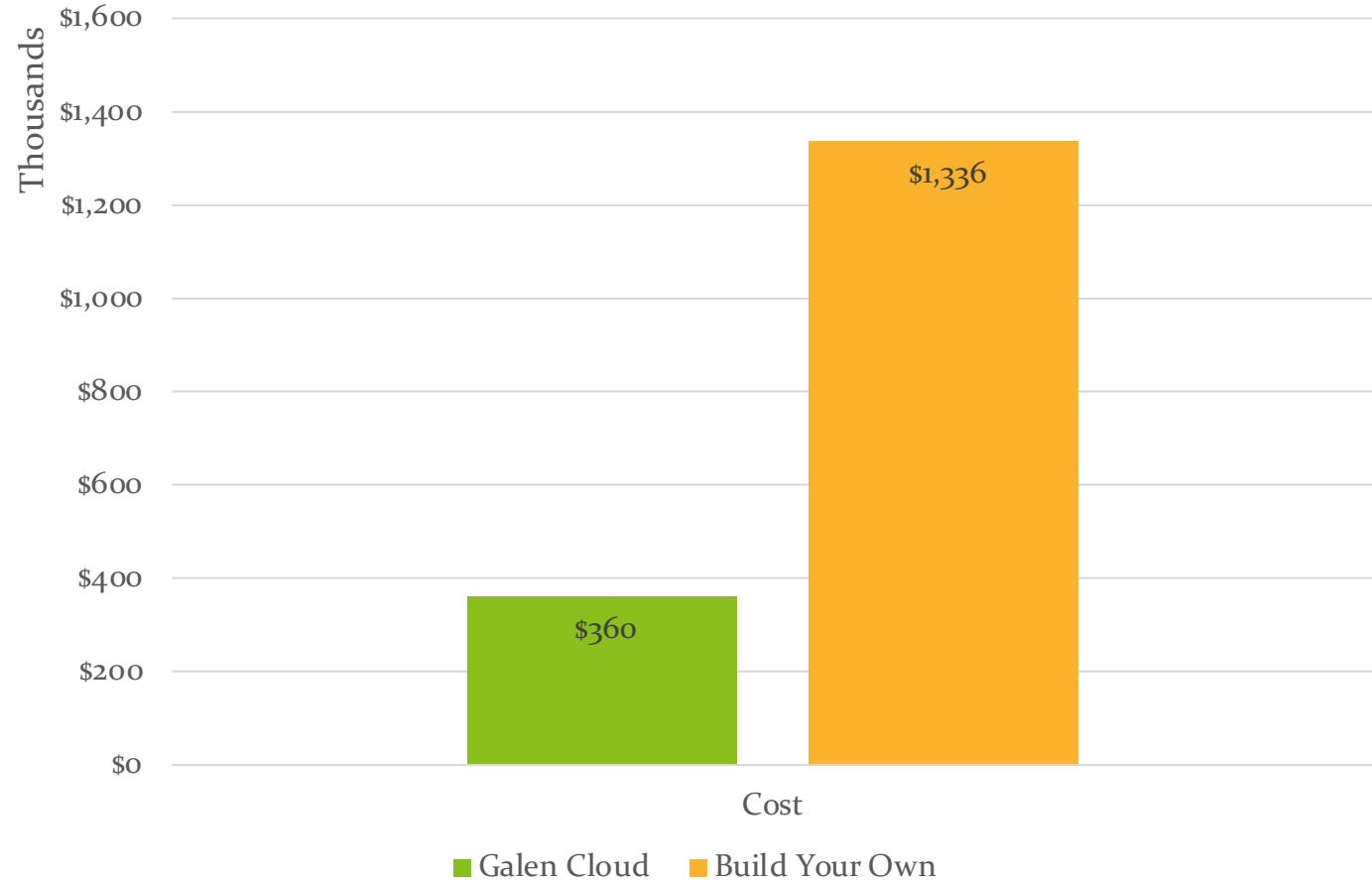- We are cloud platform purpose built for medical devices
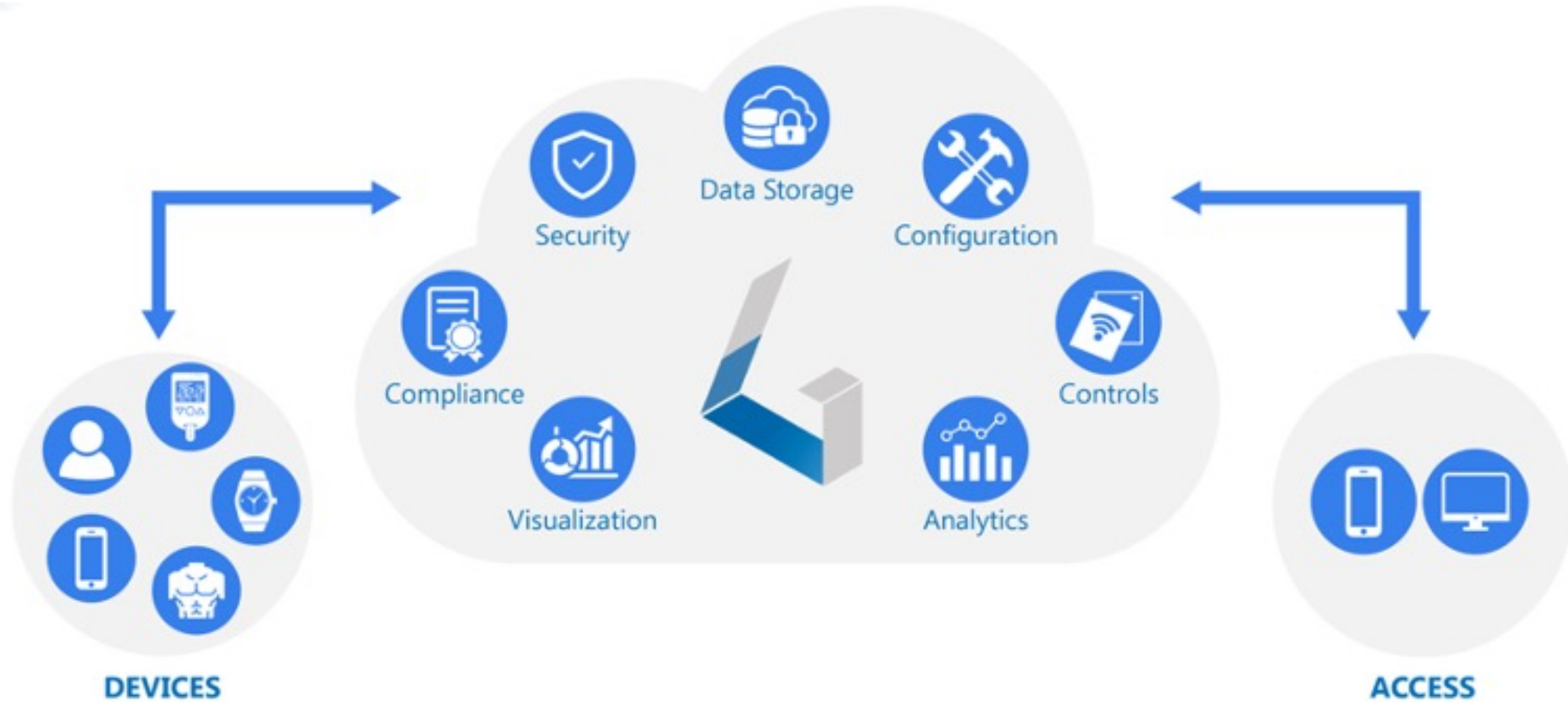
Galen Cloud – Cost Savings

Cost Savings

73%

Average 5 Year Cost

- Galen Cloud
- Build Your Own

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Galen Cloud – Risk Reduction

Reduced Regulatory Risks

Certificate of Compliance

Audit Support

99.9%

Highly Available

Secure Data Backups

Cybersecurity Liabilities

Conclusion

- Connected health is here to stay

- Managed risks
  - Security
  - Privacy
  - Regulatory
  - Cost

- Benefits
  - Greater convenience
  - Easier adherence
  - Improved insights
  - Better health outcomes

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Questions?

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