



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

SAFETY AND PERFORMANCE – DEVELOPING “THE” COMPREHENSIVE STANDARD CASE STUDY: CLOUD SERVICES

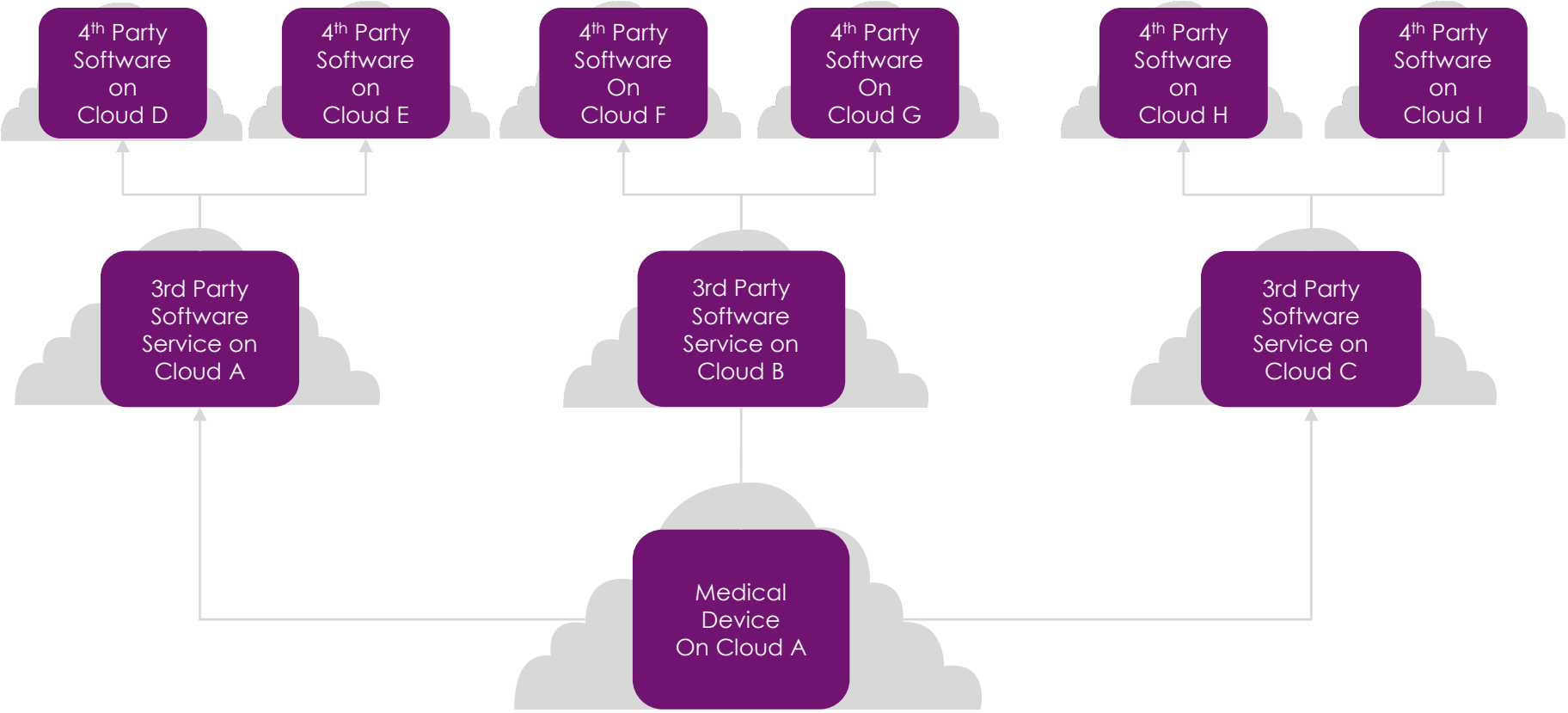
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Emerging Technology & Standards: Case Study

- A regulatory contact called me a few years ago; he was seeing that medical device companies want to use cloud services in their medical devices.
- We are used to a world where the medical device manufacturer will validate 3rd party software that is used in our medical devices (e.g. COTS/SOUP validation.)
- But when we use 3rd party cloud vendors, they control when the software is updated (and they might not even tell us that it was updated), which means our product would no longer be validated.
- Because of this, the regulator saw that medical device companies are writing their own clouds.
- The problem with this is that the software quality and security is much higher when using a vendor such as Microsoft, AWS, or Google, vs. having medical device people write their own cloud software.
- One could argue that our legacy approach to this situation is leading to a lower-quality product.

Note that a single device might use multiple clouds..



“6 Key Recommendations for Responsibly Embracing the Cloud for Medical Devices”

Some applications are at such a high risk that cloud probably shouldn't be used – but what about other, lower-risk applications? After consulting with a few experts, we put together a team to develop two whitepapers to explore this topic, see if there is a possible solution, and offer some preliminary advice:

1. Identify the intended function of the cloud computing resources
2. Apply a risk-based approach to evaluating resources for your project or process
3. Identify the typical frequency of updates
4. Assess the vendor and its processes with a level of scrutiny
5. Establish a plan in case an update adversely affects the software
6. Develop a supplier monitoring process

Current Status

The papers were well received, and we've started a project to develop a Technical Information Report (TIR) to provide a more formalized framework for evaluating cloud service providers.

We held a 2-day in-person meeting in August to brainstorm possible solutions and although we started by looking at how we can modify the COTS/SOUP approach, we are investigating if traditional supplier management processes might be more appropriate.

We have also been approached by others NOT working on cloud services, but are facing a similar problem with not having complete control but are interested in "Periodic Validation"



Advantages of Standards & TIRs

There are several advantages to using standards & TIRs to address emerging issues:

1. They can be developed (and updated) faster than legislation
2. Standards development can be a place where regulators, device manufacturers, and vendors can collectively solve problems by sharing their ideas and experiences.
3. There is real-time feedback on the approach used in the draft standard – we don't spend too much time developing content that no one needs.
4. We can supplement standards with informative annexes that provide examples, education, shares best practices, and shares worst practices.

