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## iDataFax Technical Deployment Scenarios and Their Implications for Support

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### Deploying Electronic Data Capture Applications in A Regulated Environment

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- How do we deploy, manage and support eDC applications in the “Client” environment when:
  - Computing Hardware is Variable:
    - Computer Hardware Manufacturers Are Many
      - Processors, boards, Drives, peripherals, BIOS, etc
  - Operating systems and Versions
    - Windows 2000, XP, Vista and their Patch Levels
    - Mac OS Flavors (on Power PC, Intel Architectures)
    - Linux (Open Source or Commercial Deployments)
  - Browsers, Versions and the multitude of add-ons
    - Microsoft Internet Explorer 5.5, 6, 7, what’s next?
    - Mozilla Firefox, Opera
    - Safari
    - “Whatever”

## Distributed Application Environments

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- JAVA, AJAX, Active X?
  - Which Version, Client or Server Side?
  - Our programmers feel Java Script and AJAX makes Visual Basic look really efficient...Like programming with your wrists duct-taped to your ankles.
- .NET, SOAP, XML
  - self-describing software modules, semantically encapsulating discrete functionality, wrapped and accessible via standard Internet communication protocols .. *Well.. what the heck does that mean? How do we manage, validate and support all this complexity?*

## Executable Applications versus Web Applications

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- A well written executable application is far more stable, faster, and is less likely to be rendered useless by a third party pop-up blocker or Internet security application.
- It doesn't care what Browser, version or what add-ins and JAVA VM are running.
- It uses the native power of the local processor directly.
- But It must be "*installed*"..
  - *And therein lies the issue in the minds of many IT and system auditors. Especially if it's a custom application and not a common off-the-shelf software product or "COTSS" like Internet Explorer or Mozilla Firefox or even Safari*

## Executable Applications versus Web Applications Cont.

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- Web Applications, Not as efficient but...
  - Nothing is installed... well...*sort of*
    - Have to have a supported Internet Browser Installed
    - Browser Settings, Security, Cookies, crumbs, images and html code may be cached to the local hard drive *and are under control by the remote user*
  - Application is accessible from anywhere there is a internet connection. *However:*
    - Mainly dependant on the speed of internet connection for performance.
    - Dependant on the Browser, version and settings, program language used (Active X is Internet Explorer only)
    - May be interfered with by third party add-ins
    - Application display may be different dependant on remote PC or device display resolutions and settings, fonts.
      - I can access most web based eDC applications from a iPhone
        - » Why would I? Because I can...But that doesn't make them particularly useable.

## How do we Validate the eDC Environment

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- Validation of a eDC System should be a task... not a career
  - As a Contract Research Services Company, ACI does not have the luxury of deciding alone “what is enough”
    - Two different sponsor clients auditing the exact same thing may say:
      - “Wow, this is the best and most detailed validation documentation we have ever seen... Bravo!”
      - “From our interpretation of the regulations, this documentation is clearly not enough. What were you thinking!?”

## Validation Religions

- (The Conservative Orthodox Dogma)
  - a reading from the book of conservative system auditors
    - The System Audit Lord Sayeth unto us:
      - “A custom remote installed client-server executable eDC application that is transmitting original clinical records (*even a application that does not store data locally*) requires documentation of IQ, environment qualification and validation of application functionality, connectivity, and security between the server receiving and holding the original clinical records and the installed client application environment that is acting as the transmittal interface running on the authorized client machine” *uh...sure. Where in the regs does it say that and how would the “Audit Lord” like to pay for that?*
    - “How do you handle application upgrades, patches and potential application conflicts when you are not in physical control of the client machine?”
      - The old, ugly and expensive solution;
        - » Deploy prequalified, validated and identical hardware, OS and installed software to each user location. Lock-out local administration control. \$\$\$\$

## Support Issues

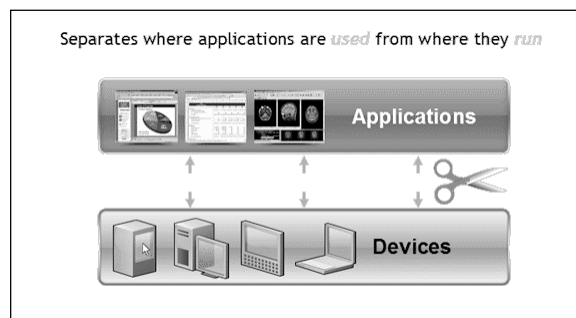
- “OK, so you have a iMac. Garage Band, iTunes, and Safari are all currently running and you also have a active VPN connection to another sponsor’s eDC system using IE and Windows XP running under Parallels and you say you can’t connect to the DataFAX server?
  - “Well... are you running iDataFAX under Apple OS X or under Windows using Parallels?”
  - “What do you mean you have to ask your teenage son?”
- You say the reason you haven’t been entering data for the past few weeks is because the iDataFAX icon on your desktop disappeared when you were issued a new computer by the hospital IT department?
  - “Did I hear you correctly or did I just have a sudden hallucination?”

## Enough Already!

- So how do we create, manage, validate, and support a qualified eDC environment that meets the regulations and will also simplify application deployment and support to the investigation sites... *“oh... and I want to have a life and sleep at night too...”*
- We chose an old idea wrapped in a new package... Citrix Presentation Server

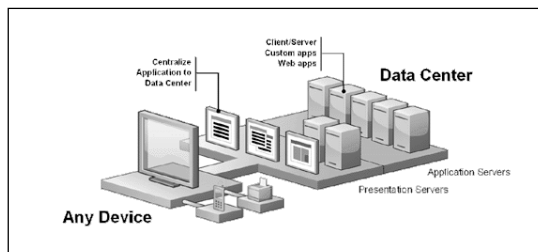
## How does it work

- Presentation Server abstracts the user interface (logical layer) from the application processing (physical layer) that occurs on a centralized, secured server.
- It encrypts and transports an application's interface from the server it is running on to the user's client device for display. It then returns the user's input, mouse-clicks and keystrokes, to the application on the server

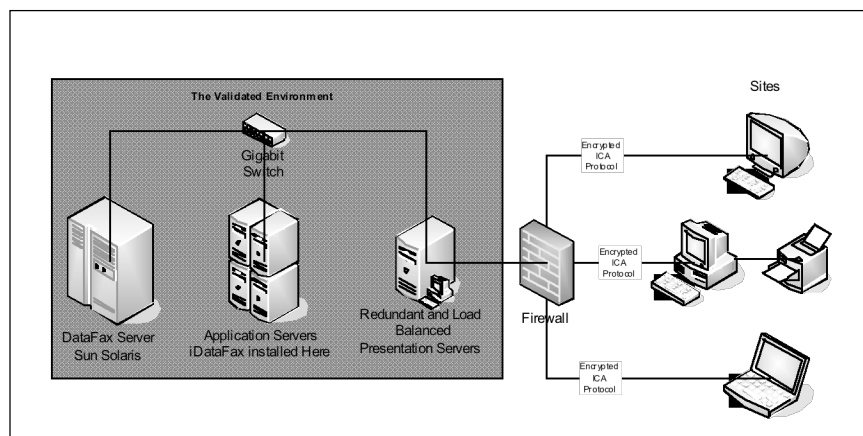


## Citrix Presentation Server

- It eliminates the complexities of deploying, managing, updating and securing a vast array of client software on each individual user's access device. Instead, a single instance of the client application is installed on Presentation Servers within the secure confines of the data center. The application executes entirely on the server while its interface is displayed on the users device. *Application delivery can be enabled for any user, regardless of device, network or location...and without directly exposing the server to the internet*



## AT ACI



## Demo

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- Short Demo
- Questions?