Update to PRISME –

PhUSE WG – *Lowering the Barriers to the Adoption of Cloud Technology*

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15 Oct 2013

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Welcome & Agenda

My apologies for not being able to be there in person!

- WG Membership
- WG Scope
- WG Activities
  - To date
  - Going forward
- Emerging thinking
- Q&A.

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WG Members & Meetings (to date)

Crystal	Allard	FDA
Dermot	Barrywalsh	Merck
Nancy	Bauer	BI
Seema	Bhat	Bayer
Ocatvian	Boca	Sanofi
Karen	Carr	GSK
Adrian	Cottrell	GSK
Matteo	di Tommaso	Pfizer
Jun	Dong	Sanofi
Luther	Dunlap	FDA
Remy	Evard	Novartis
Susan	Fantoni	Sanofi
Sean	Finnerty	Merck
Janet	Gentry	FDA
Olivier	Gien	Sanofi
Chris	Gile	Amazon
Francis	Gorski	Pfizer
Tony	Hewer	Medidata
Sandeep	Juneja	SAS
Matthew	Laracy	Sanofi

Sebastien	Lefebvre	AZ
Geoff	Low	Medidata
Suresh	Madhaven	Pointcross
Mike	Miller	Pfizer
Mike	Montello	Shire
Barrie	Nelson	Amgen
Louis	Norton	Covance
Simon	Roach	GSK
Donald	Schilp	Sanofi
Ian	Sparks	Medidata
Michael	Stroukoff	GSK
Jason	Swift	AZ
William	Telford	Sanofi
Rocco	Timpano	Pfizer
John	Walker	Novartis
Dan	Weaver	Perkin Elmer
Doug	West	Merck
John	Wise	PRISME Forum contact
Chad	Woolf	Amazon

- So, representation from:
  - 1 Regulator, 5 suppliers, 1 CRO, 10 pharma.
- Meetings so far:
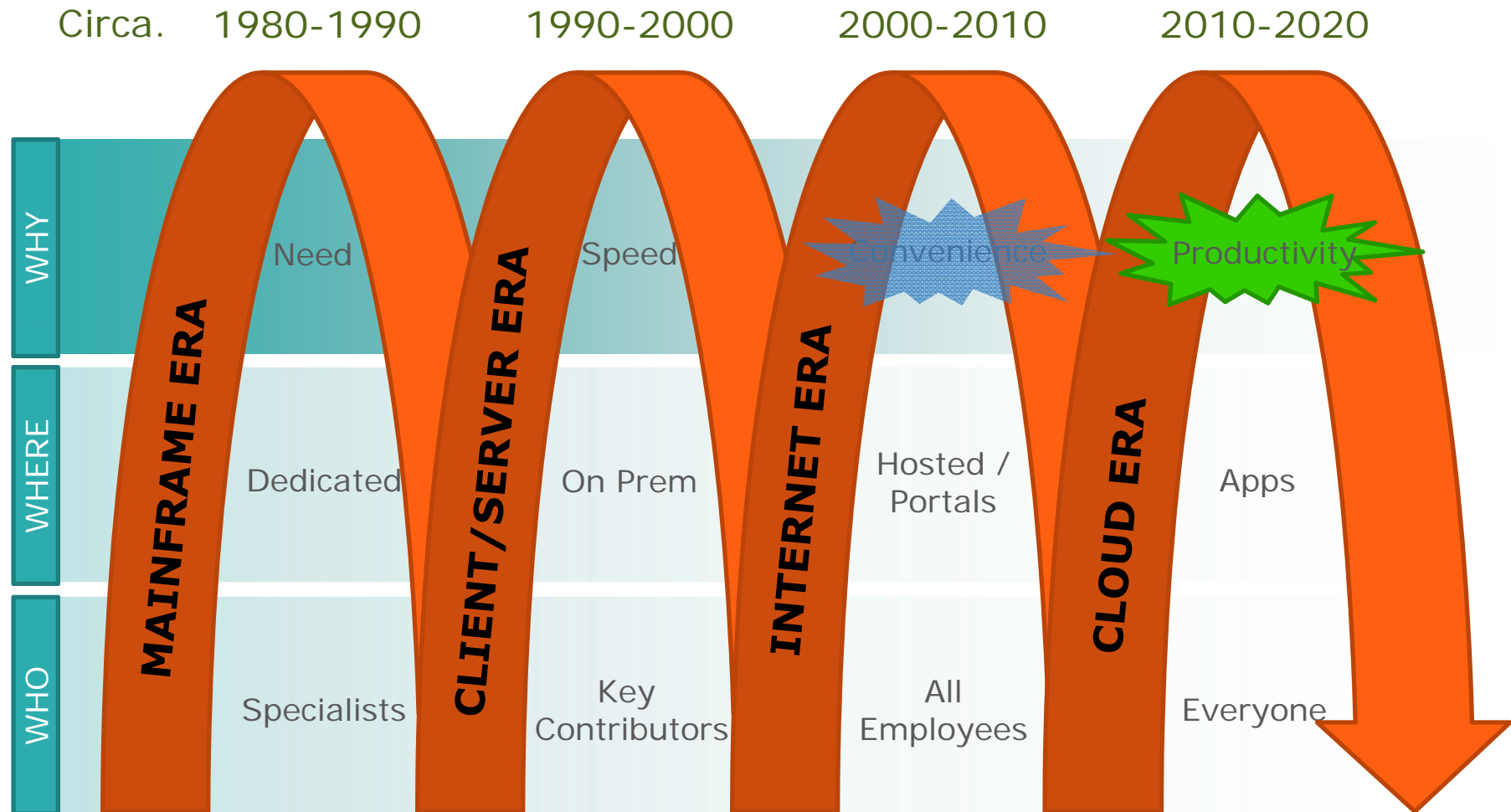 - 23-Jul-13; 01-Aug-13; 08-Aug-13; 23-Sep-13.

WG Scope

- See PhUSE Wiki at: http://www.phusewiki.org/wiki/index.php?title=Cloud_Lowering_Barriers
- In summary:
  - What is *The Cloud*? But, we didn't wish to get hung up on definitions!
  - What are the *perceived* issues/barriers around its adoption/usage?
  - What do we have to do differently:
    - Security, information protection, etc
    - Our approaches to qualification, validation re. apps and data hosted in *The Cloud* – the traditional V-model may have had its day!
    - Our approaches to auditing [suppliers]
    - Our interpretations of regulations.
  - And, importantly...
    - ...sharing experiences, ideas, plans...

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What is *The Cloud?*

- Cloud computing, or The Cloud, is a colloquial expression used to describe a variety of different types of computing concepts that involve a large number of computers connected through a real-time communication network (typically the internet).

- It's jargon – there's no scientific definition. But see footnote.

- In our WG, we have avoided getting into a rehash of definition. Instead, we've solicited use cases to illustrate past, present and planned uses of The Cloud.

- But, the following might be helpful in terms of some lines in the sand...

Footnote: The Pharmaceutical Industry and the Cloud - A PRISM Forum Position Paper, 2011; NIST – "Cloud computing is a model for enabling convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider.

Evolution of Systems and Business Execution

	Circa.	1980-1990	1990-2000	2000-2010	2010-2020
WHY		Need	Speed	Convenience	Productivity
WHERE		Dedicated	On Prem	Hosted / Portals	Apps
WHO		Specialists	Key Contributors	All Employees	Everyone

MAINFRAME ERA   CLIENT/SERVER ERA   INTERNET ERA   CLOUD ERA

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Key *Cloud* service attributes

- Scalability
- Availability
- Resilience [to component failure]
- Reliability
- Security
- Readily facilitates SaaS
- Supported by IaaS and PaaS
- Interoperability
- Configured vs. customized
- Standards-based
- Development and maintenance efficiencies
- User experience
- Service/usage cost structure.

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WG activities to date - 1

- High level of engagement and top-quality discussion
- Use Cases - http://www.phusewiki.org/wiki/index.php?title=Cloud_Lowering _Barriers_Use_Cases

  - Adverse Events and Cloud Computing – authored by GSK
    - Data confidentiality
    - SaaS in the Cloud vs. hosting internally
    - Common solution
    - Procedures, policies and regulatory requirements.

  - Batch Processing – authored by Medidata
    - Large/huge data processing volumes
    - On demand usage
    - Standardized approaches re. development and deployment
    - Data warehousing can be in the cloud too – but consider it separately.

WG activities to date - 2

- EDC in The Cloud – authored by Bayer Healthcare and Medidata
  - Historical perspective – evolution of Medidata services
  - Internal procedures and policies [in Bayer]
  - Performance and service quality
  - Security
  - Who benefits?
  - Roles and responsibilities.

- AWS Case Study – authored by Pfizer
  http://aws.amazon.com/solutions/case-studies/pfizer/
  - Usage of Amazon EC2 for HPC augmentation
  - On demand usage
  - Cost efficiency.

WG activities going forward - 1

- More Use Cases – more sharing of experiences – both good and otherwise.

- Develop some quantification around *perceived* and *real* barriers and recommendations for change w.r.t:
  - Policies, procedures and approaches
  - Regulations and guidances.

- Explore PRISME (Spring 2013) recommendation re. "..should be proactive in the exploitation of the cloud and inter-alia should construct a multi-tenant, reference implementation of SaaS that would provide an exemplar for PRISME Forum members to reference when it came to convincing their key stakeholders of the viability of the cloud as a platform..".

WG activities going forward - 2

- The general "feeling" already within the WG is that:
  - Existing policies, procedures and approaches are likely not be fit-for purpose to deal with *The Cloud*
  - Such environments were created to deal with "in house" solutions - maybe with some external augmentation
  - "Traditional" models of roles and responsibilities, liabilities and "ownership" almost certainly need changing
  - Leverage "[IT] supply chain" concepts and practices
  - Technology (per se) is not an obstacle! In fact, it's a fantastic opportunity – both now and going forward. Embrace it – or get left behind!
  - Security-related matters must be considered strenuously but Cloud Providers can – and do – provide service solutions can be superior to "in house" solution.

- Continue collaboration with the PhUSE/FDA Computational Science Symposium (CSS).

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Q&A