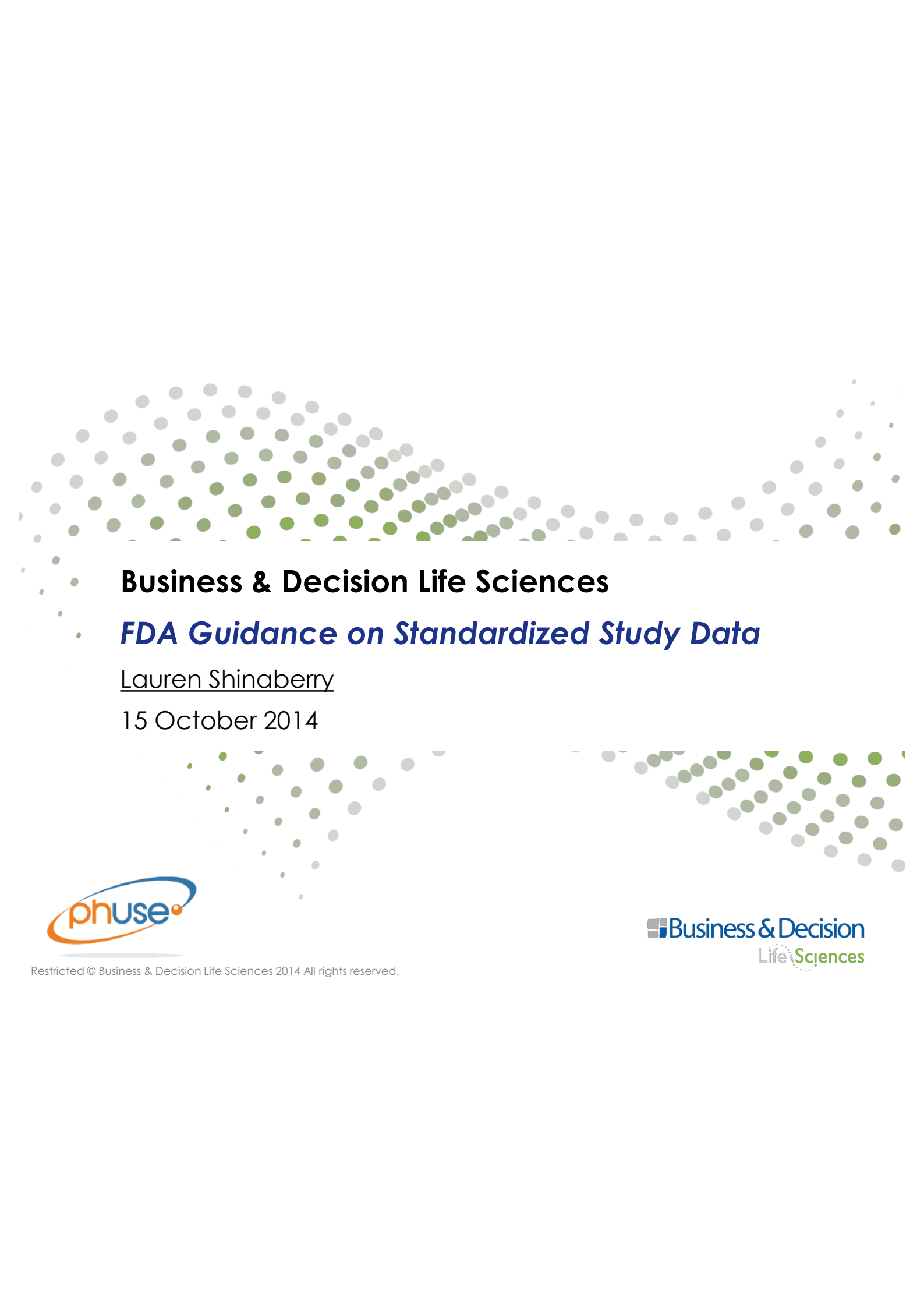




Business & Decision Life Sciences

FDA Guidance on Standardized Study Data

Lauren Shinaberry

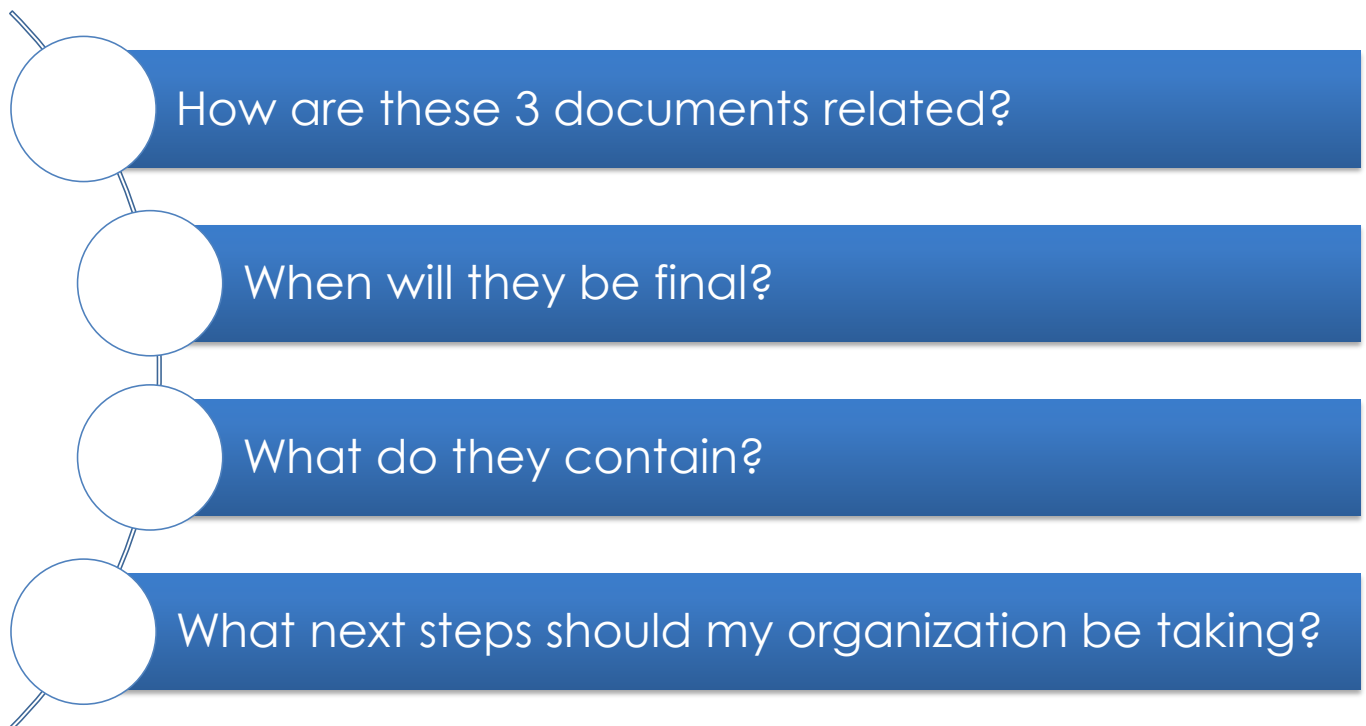
15 October 2014



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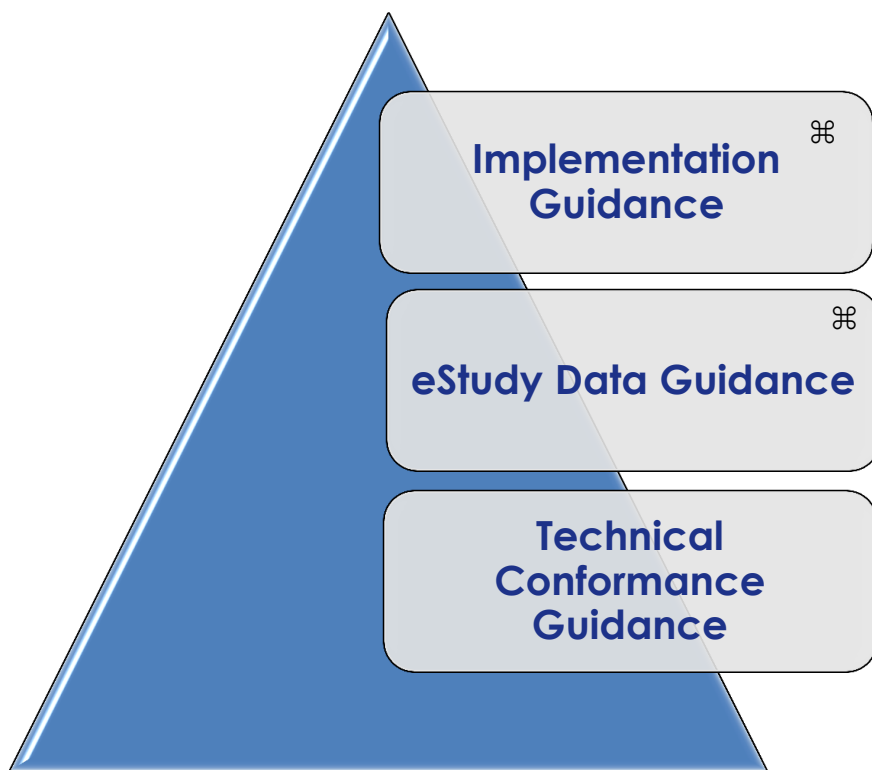


Today's Agenda



Relationship between documents

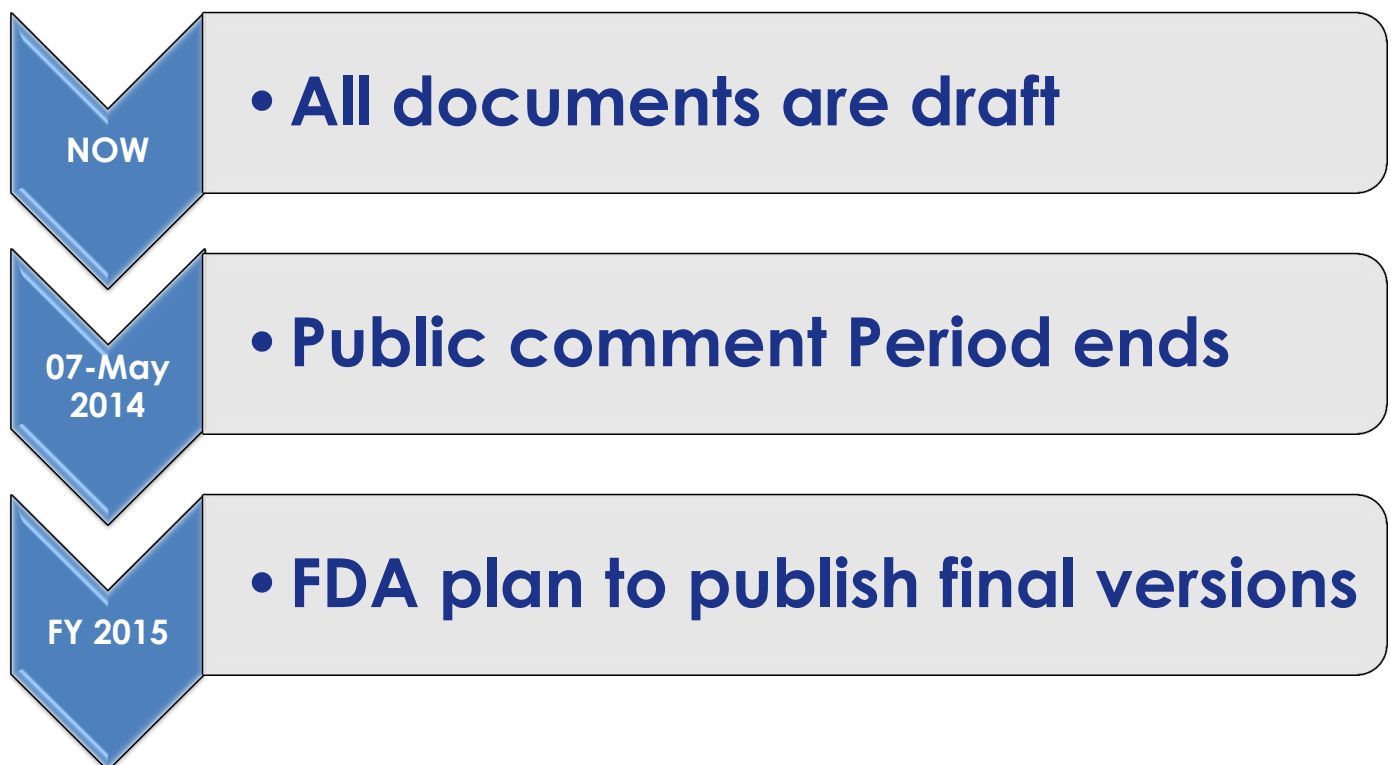
Food and Drug Administration Safety and Innovation Act (FDASIA)



⌘: Binding Document



What is the timeframe?



The documents



Guidance for Industry Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Division of Drug Information at 301-796-3400 or (CDER) Office of Communication, Outreach, and Development at 800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

February 2014
Electronic Submissions

Guidance for Industry Providing Regulatory Submissions in Electronic Format — Standardized Study Data

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

February 2014
Electronic Submissions
Revision 1

STUDY DATA TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This Document is incorporated by reference into the following Guidance Document(s):

Guidance for Industry Providing Regulatory Submissions in Electronic Format — Standardized Study Data

For questions regarding this technical specifications document, contact CDER at cdcr-cdata@fda.hhs.gov or CBER at cber.cdsc@fda.hhs.gov

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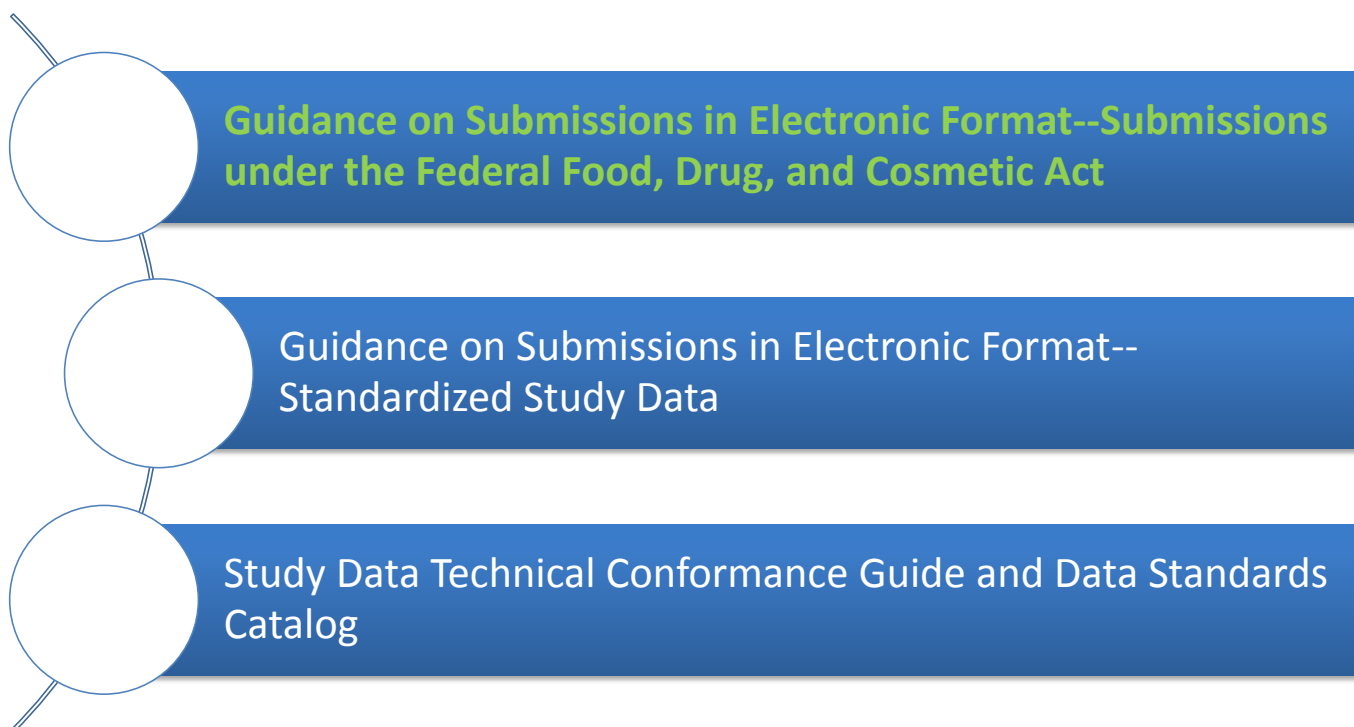
February 2014

BINDING DOCUMENTS

Business & Decision
Life Sciences

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What do they contain?



Guidance for Industry

Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

**February 2014
Electronic Submissions**

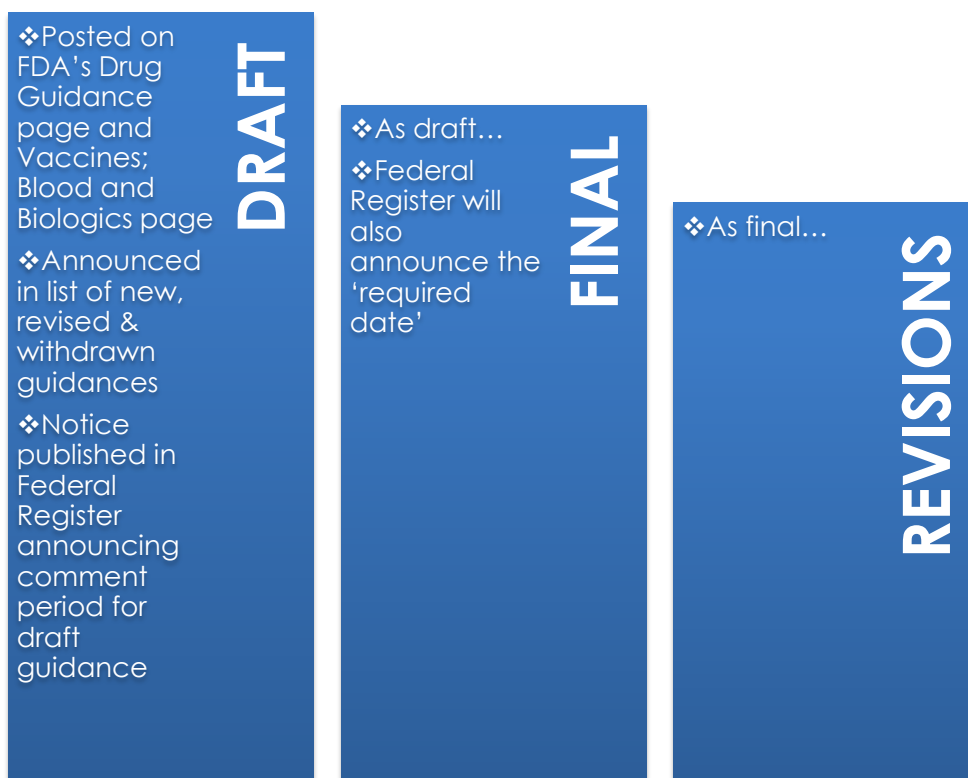
What does (and does not) require eSubmission?



- ❖ Certain INDs
- ❖ NDAs
- ❖ ANDAs
- ❖ Certain BLAs
- ❖ All subsequent amendments, supplements and reports to the above *(even if original submission was not electronic)*

- ❖ Those described in section 561 of FD&C Act
- ❖ Devices regulated by CBER as biological
- ❖ *Other exemptions & waivers will be described in the applicable individual guidance*

How will requirements be implemented?



When will electronic submissions be required?



Sponsors will have at least 24 months notice

Each guidance will specify the exact timetable for specific submissions

Revisions to existing formats, timetable may be less than 24 months

Minor changes may have immediate effect

Example 1: New Format (with 24-Month Implementation Period)



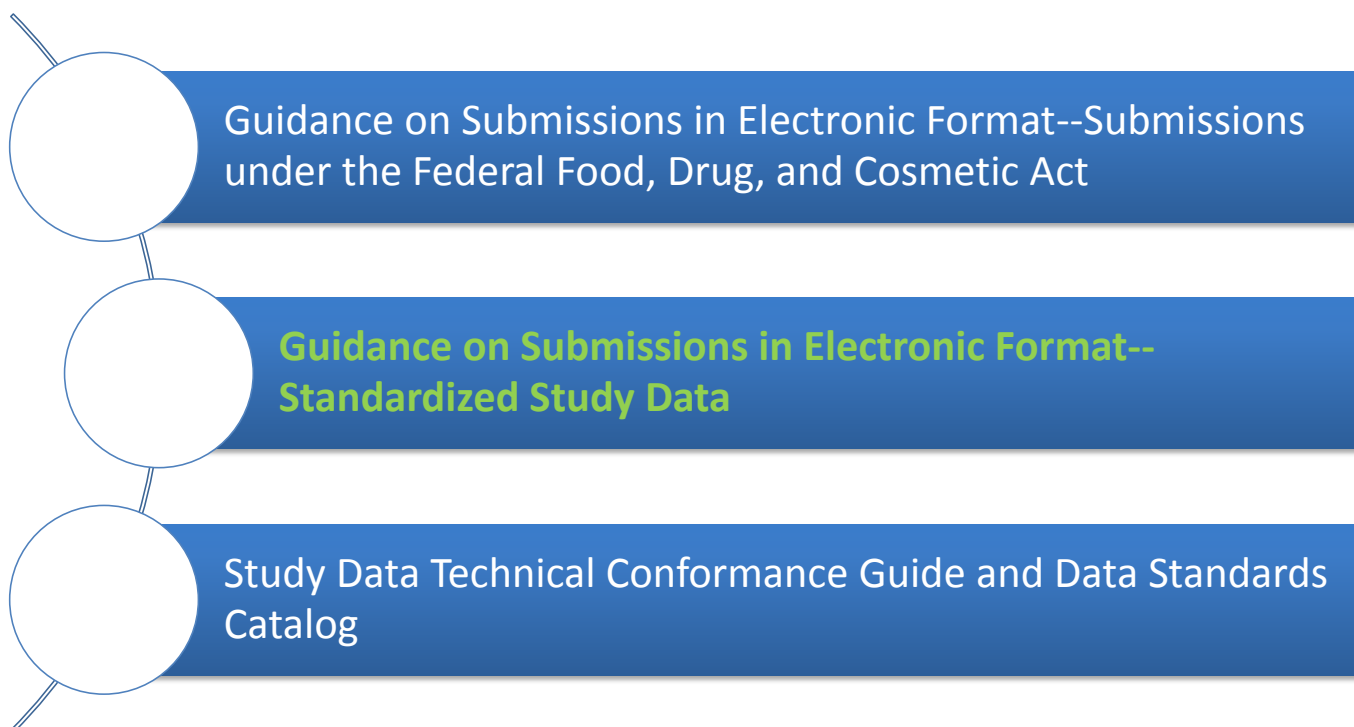
FDA issues a draft individual guidance specifying new format(s) for electronic submission of data contained in certain NDAs, ANDAs, BLAs, and INDs, and publishes a *Federal Register* notice announcing availability of the draft guidance. Following the comment period, FDA finalizes the guidance and publishes another *Federal Register* notice announcing availability of the final guidance. The *Federal Register* notice also provides that the specified format(s) will be required 24 months after the date of publication of the notice. After the 24-month implementation period has passed, the guidance will have binding effect and the electronic formats specified in the guidance must be used for the submission types identified in the guidance document.

Example 4: Correction to Required Format



FDA finalizes an individual guidance specifying new format(s) for electronic submission of data contained in certain NDAs, ANDAs, BLAs, and INDs, and the implementation timetable specified in the guidance has passed. The guidance has binding effect and the electronic formats specified in the guidance must be used for the submission types identified in the guidance document. Some time later, FDA announces a correction to one or more of the formats specified in the final guidance. The announcement also provides that the corrected format must be used 2 weeks after the date of the announcement.

What do they contain?



Guidance for Industry

Providing Regulatory Submissions in Electronic Format — Standardized Study Data

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

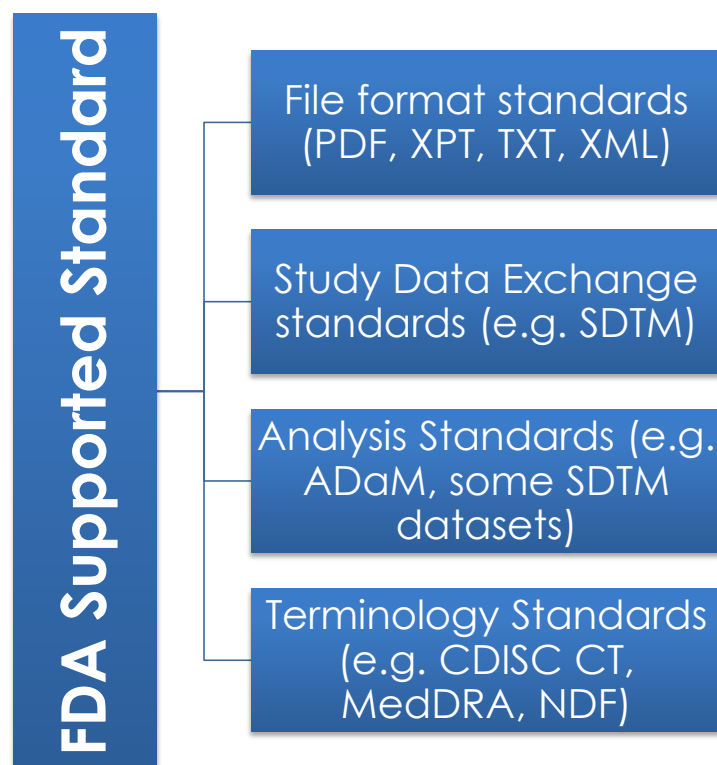
Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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February 2014
Electronic Submissions
Revision 1

What are the requirements?



eStudy Guidance: Waivers



No waivers will be granted for submission of data in non-FDA supported study data standard



Can request waiver to allow a use of a non-current version of a supported standard



FDA will notify in writing if waiver has been granted

eStudy Guidance: Timetable



NDA, ANDA and certain BLAs

Must follow details in the Data Standards Catalogue for all studies with earliest informed consent date 24 months after Federal Register notice of final guidance availability

24

Certain INDs

Must use specified formats in studies with earliest informed consent date 36 months after Federal Register notice of availability



eStudy Guidance: Support



Established Meetings

- Pre-IND and end-of-Phase II
- Premarketing application meeting is considered too late for these discussions

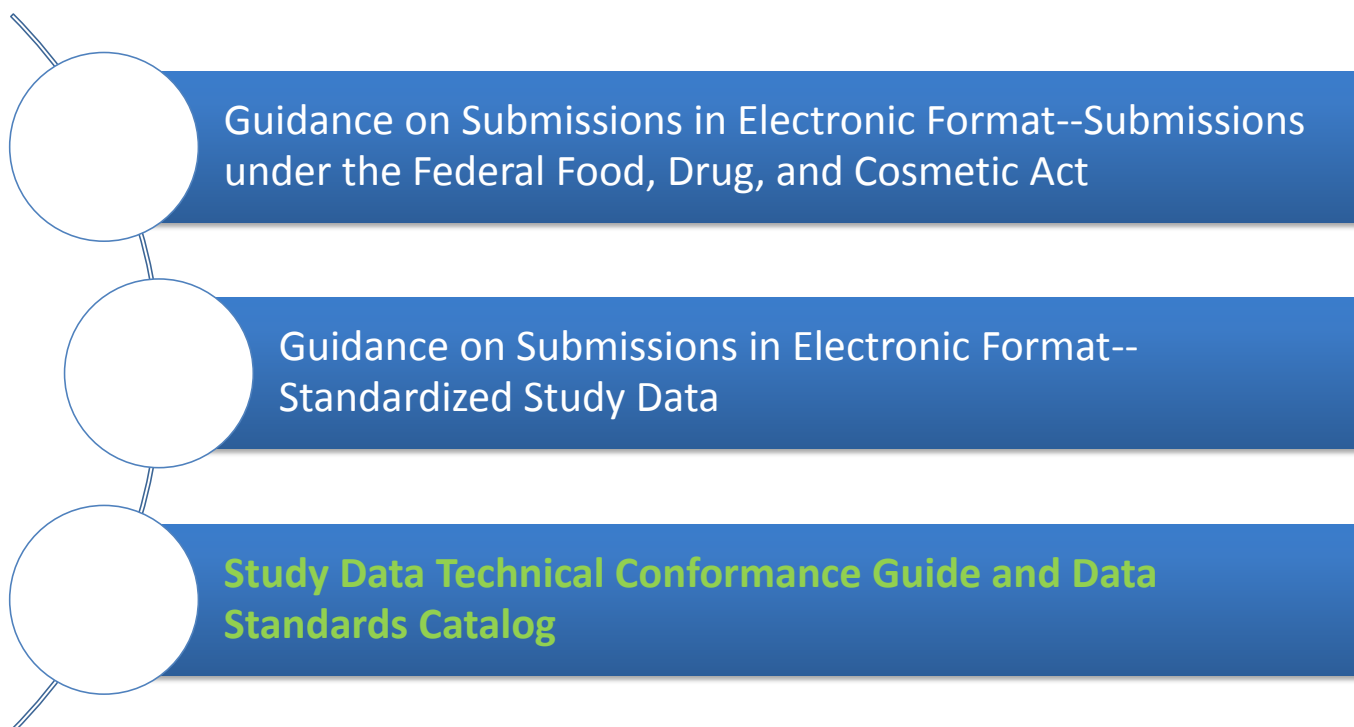
e-mail lists

- Technical questions may be submitted to the appropriate FDA e-mail list

Conformance Guide

- Refer to the Draft Study Data Technical Conformance Guide for non-binding details on submitting standardized study data

What do they contain?



STUDY DATA TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This Document is incorporated by reference into the following
Guidance Document(s):

Guidance for Industry *Providing Regulatory Submissions in Electronic Format – Standardized Study Data*

For questions regarding this technical specifications document, contact CDER at
cdcr-edata@fda.hhs.gov or CBER at cber.cdisc@fda.hhs.gov

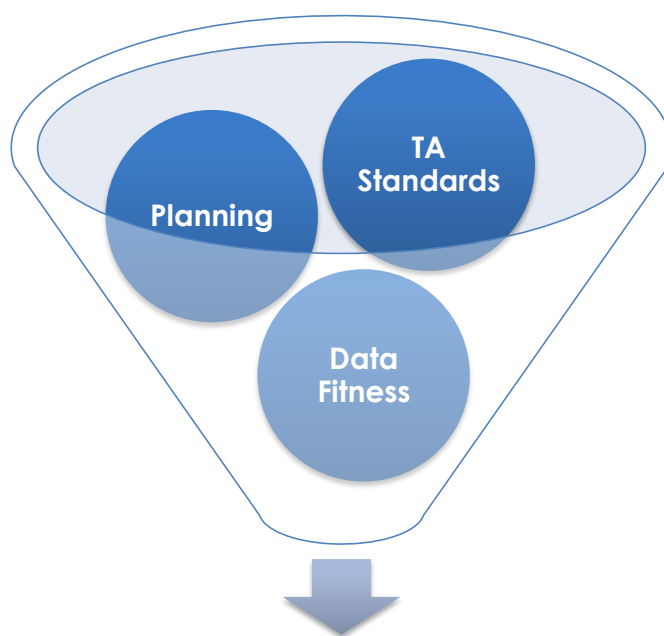
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February 2014

The document is a mix between the CDER common data issues and new information



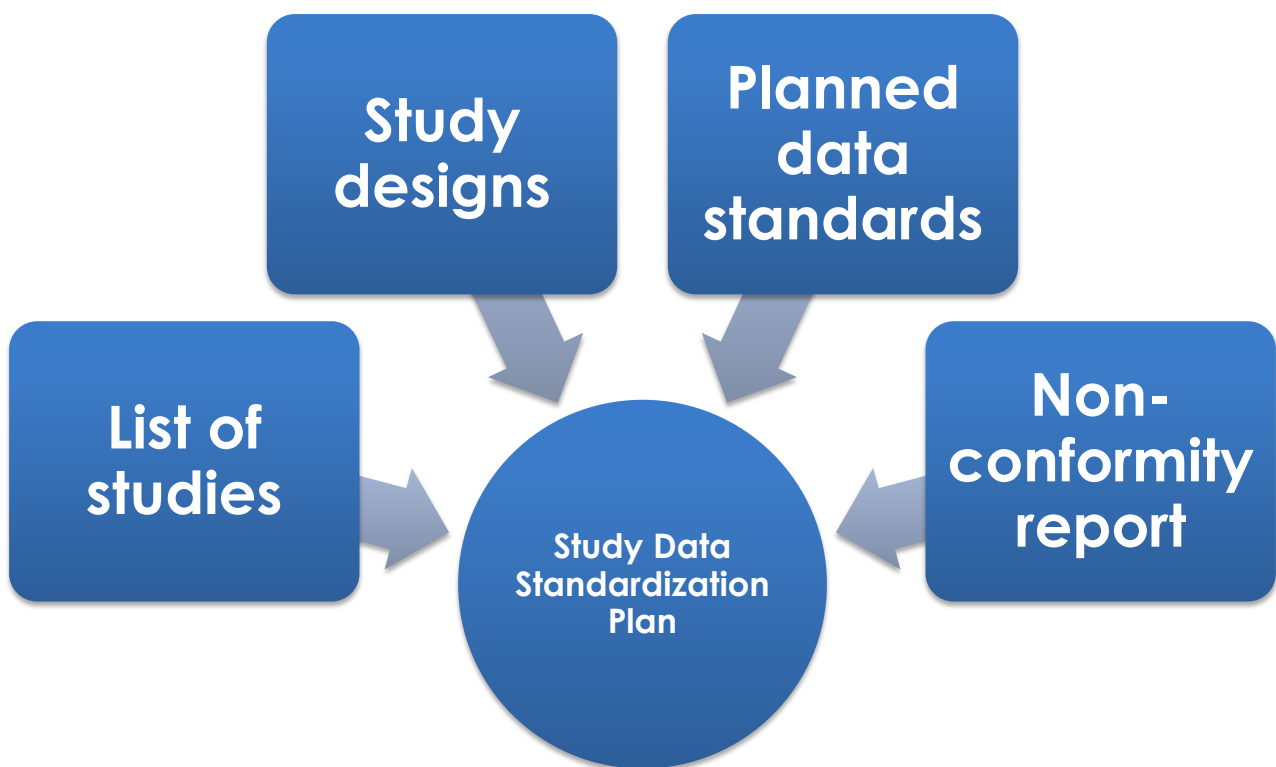
What are the new sections?



A complete data guide

Assist FDA in identifying

potential data standardization issues early in the development program



Read documents in detail looking for:

- Requests that contradict SDTM or ADaM
- Processes that will cause your organization difficulties
- Anything that is unclear

Provide Comments

- Important opportunity to comment on the Common Data Standards Issues content



Participate Today!

Submit your comments on proposed regulations and related documents published by the U.S. Federal government. You can also use this site to search and review original regulatory documents as well as comments submitted by others.

Help improve Federal regulations by **submitting your comments**.

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Next 30 Days (807)
Next 90 Days (1,178)

Newly Posted

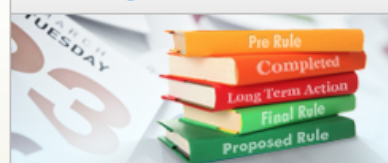
Today (107)
Last 3 Days (341)
Last 7 Days (651)
Last 15 Days (1,333)
Last 30 Days (2,374)
Last 90 Days (6,005)

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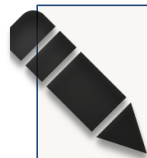
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Contact FDA (email)
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One well-supported
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Be concise but
support your claims



Refer to specific
sections or lines in the
document



Thank you for your attention.

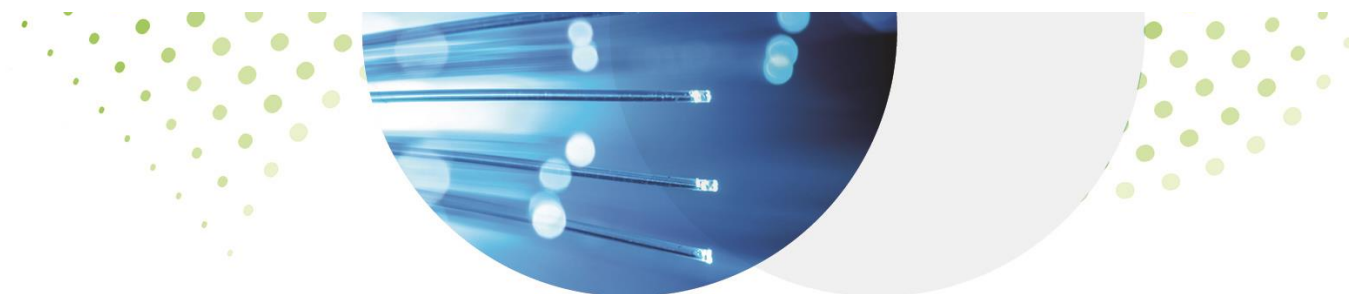
Join us for a coffee at our stand.

London, United Kingdom, 13 OCT 2014



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