Disclosure of Clinical Trial Payments

Preparing to Meet the Challenge

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Because health matters

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- Presentation content and comments are the opinions of the presenter and do not necessarily represent the views or position of sanofi-aventis US

Learning the Ropes

- **Becoming familiar with internal lingo**
  - **CTMs, CRUs, CROs, CRAs, SPOOS, NDAs, INDs, protocols, phase I, II, III, IV, post marketing trials, observational trials, registries, health outcomes studies, sponsored trials, ISTs, line extensions, etc., etc., etc.**
- **When it comes to the *types* of trials & research projects, you will need to understand exactly what each one is to**
  - **Assure that you are accounting for all potentially reportable activity, and**
  - **Make a determination of how the law will apply to each.**

Trial Management & Oversight

- For each type of trial or research project your company is involved in, you'll want to determine:
  - Which department is responsible (R&D, Med Affairs, Managed Markets, Global, etc.)
  - Who is involved in the management internally
  - Who monitors the trial sites
  - If any CROs or external vendors are involved
  - Who handles trial registration & results disclosure
  - Who tracks and reports SPOOS & conflicts of interest
  - Who audits for compliance with applicable laws

- Regulatory Compliance or Quality Assurance has traditionally been responsible for GCP/ICH/FDA compliance for R&D –
  - Where does 'Corporate Compliance' fit in?

Entering Someone Else's Turf

- As the focus of OIG scrutiny shifts from sales & marketing activities to R&D, and
- With physician payment disclosure requirements spreading from marketing activities to research,

- How will your Quality Assurance & Corporate Compliance departments work together to manage these new requirements?

- Communication & Teamwork; establishing clear roles & responsibilities, documented by Policies & SOPs, will be critical to a successful disclosure process

But, Back to Learning the Ropes…
Trial Related Payments

- **Who is making the payments?**
  - **Internally paid (AP)**
    - US or Global?
  - **CRO or JV Partner**
- **Who is receiving payments**
  - **Institutions, Foundations, LLCs, Investigators**
- **Understanding types & structure of payments**
  - **Study subject payments**
  - **Administrative fees**
  - **Screen failure payments**
  - **IRB fees**
  - **Advertising fees, etc.**
  - **Overhead**

Payments to Institutions

- If you or your CRO pay an institution, are they:
  - hiring and paying primary and sub investigators & other research staff,
  - hiring & paying primary investigators only, who then employ their own subs or research staff, or
  - are some or all investigators and research staff *employees* of the institution?
- Your company (legal) will be making decisions about
  - what payments
  - for what purposes
  - to what types of recipients

  will be reportable under their interpretation of each state or federal law.

Trial management SYSTEMS

- How many systems?
  - Do all groups involved in trials & research use the same CTMS (Clinical Trial Management System)?
  - Do all groups us the same KOL database with a unique identifier across all units & affiliates (globally)?
- Are some systems housed/managed outside your company (either globally or by a partner company)
- Are some trials managed by the US, but payments are made by systems you do not have access to?

- IT & Finance colleagues will help you identify the myriad of arrangements & systems that may exist

Tracking Payments

- **Which internal systems talk to each other**
  - **Clinical Trial Management system &**
    - KOL Database
    - Vendor Master
    - AP
- **Where payments are made by CROs, Global, or a Partner,**
  - **What is the level of detail your internal management teams get now regarding payments made?**

Beginning to Create a Plan of Action

- Initial meetings with QA, IT, Finance, R&D, Med Affairs, Affiliates, Global
- Get your arms around the basics & the lingo
- Set up a Task Force to Manage the Processes
  - Short term – Assessing gaps, gathering data for current or near term reporting requirements
  - Longer term solutions – Systems & Processes
- Determine what types of trials & research projects will be subject to near term reporting & which will qualify for delayed reporting
- Do some dry runs
  - Request payment data from a CRO
  - Prepare for the Vermont disclosure

Questions / Comments ?

Thank you!

& Good Luck!!