

NRDS Policy and Governance Working Group

Monday June 1, 2015

Meeting Minutes

Action Item	Who	By When
Send out the guiding principles to the working group	Neesha Desai	6/4/15
Send out meeting minutes	Neesha Desai	6/05/15

Agenda Topics

Introduction of members on the call – Neesha Desai welcomed the callers to the meeting and provided a recap of the last meeting.

Policy Challenges – Mike Montello discussed the focus of this group and what would be out of scope. This group is not focusing on the content but the policy and governance of the content, while keeping the big picture in mind. We want to take an approach that allows us to take other working groups (WGs) in consideration and something that does not lock us into anything too early. We need to ensure there is a balance of powers between these WGs so that each group can accomplish their goals, but ensure they work together to do so. If we say at the beginning of the initiative that we will only provide policy around 4 or 5 components it will be harder to move forward. To be able to make a stronger argument, we will need to make a reasonable attempt to standardize as much as possible and provide a reason for what items we cannot standardize. It would be in our best interest to start with a broader scope and focus in as we continue.

- Angela: I understand what we do not want to say at day one, but what do we want to say at day one of the initiative?
 - Mike: It will important to look at what makes sense to standardize – content that provides value to the oncology community (i.e. integration, science, safety, regulatory, efficiency, and general oncology elements). It will be important to start with some definition and scope down as the Content WG provide their content.

Policy Components/Guidelines – Mike Montello reminded the WG members that is it important to keep the macro level (integration, science, safety, regulatory, efficiency, and oncology elements) a little more vague to start with and work to the micro components (modules of CRFs, CRF, etc.) and guidelines.

- Angela: Do you think it is premature to start talking about this until we have more content?
 - Mike: It may be better to wait until we have more Content WG meetings prior to moving forward.
 - Angela: The two groups go hand in hand. It is hard to standardize content until you know the policy availability. It may be hard to discuss policy enforcements until we have a better idea of the content.
 - Dianne: The content working has made some higher-level decisions and we should be ready within the next week or two with the first set.

Open Forum

- Dianne: How would recommendations from the Policy WG change based on the Content WG? How and what recommendations would we make?
 - At first, none, but over time we may be able to make recommendations based on what value makes sense.

- Judi: Policy and Governance are two different things, the policy is the philosophy for standardization and governance is how we will make people do it. So for the policy, it makes sense to make philosophical parameters the Content WG could work with – i.e. not harmonizing the coded values unless there is a program that requires it. If the Content WG is going to change the coding for harmonization, we would need a good reason. The goal is to keep it simple.
- Shauna: I keep hearing that we want to keep the integration to a smaller subset to control it but I hear you saying that NCI wants us to have a broader scope.
 - Mike: The recommended approach is to go through this incrementally and note the items we decided not to do, instead of just saying we will not look at the other items.
- Shauna: Why can't we start small?
 - Mike: I agree, I am not looking to start with everything; we should start small and broaden as available.
- ****Guiding Principles:**
 - Minimal Necessary
 - Rationale: There should be a core set of elements that we think are universally important. We recognize the DCP approach - they identified a core set of elements that were important on all studies.
 - Don't standardize codes unless necessary
 - Rationale: Depending on the application, the codes can be mapped downstream. There will be no universally acceptable set of codes that will avoid the need for re-mapping, so harmonizing codes may not be the highest priority.
 - Don't change data elements unless necessary
 - Rationale: Changes will have impact (and associated cost) on existing systems if there are changes that do not justify the associated cost
 - Keep it simple
 - Rationale: Makes sense
 - Start small
 - Rationale: We can test the impact of the most important changes before expanding.
 - Dianne: Should we share this with the Content WG?
 - Mike: We can share this with the Content WG but these are guiding principles, not requirements. We do not want any other groups waiting until we have hammered out our guidelines.

Next Steps

- Finalize NRDS Content 'Guidance' – Working group members look at the current guiding principles and add/change as needed
- Identify Additional Policies/Procedures – We need policies, pick lists, waivers, location of stored content, roles/responsibilities, and content review cycle.
- Develop Simple and Effective Governance Process (short and long term)

Attendance:

Name	Affiliation
Katie Allen Ziegler	Alliance
Shauna Hillman	Alliance
Steven Jong	COG
Judi Manola	Eastern Cooperative Oncology Group-American College of Radiology's Imaging Network (ECOG-ACRIN)
Dianne Reeves	NCI
Janice Chilli	NCI
Mike Montello	NCI
Christina Warmington	NCI - Essex Management
Neesha Desai	NCI - Essex Management
Jennifer Thomas	NRG
Angela Smith	SWOG
Rodney Sutter	SWOG
Diana Vulih	Theradex