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Moderator: John Burklow
December 9, 2010
11:56 am CT

Coordinator: Good afternoon and thank you all for standing by. This is the conference coordinator. All lines will be placed on listen only until we're ready for the question and answer session of today's call. This call is also being recorded, if you have any objections please disconnect.

I would now like to introduce your speaker, Mr. John Burklow. You may begin, sir. Thank you.

John Burklow: Thanks very much, (Laurie). Good afternoon everyone. I'll be the - I'm John Burklow the Head of Communications at NIH and I'll be the moderator for the call.

Just to go through the format Dr. Collins will make opening remarks and then we will open it up for questions and answers. And I’m sure there'll be many callers in the queue so I'd just ask if you could limit your questions to one apiece for the first round.

And this is certainly a Q&A session. If you have comments - I know Dr. Collins will mention it in his remarks but we will have a Web site up tomorrow for those of you who want to have additional comments.

At this point I will turn it over to Dr. Collins.

Dr. Francis Collins: Thanks, John, and good afternoon to all of you or morning if it happens to be morning where you are because I know we are reaching out to touch many different centers across the country. I understood from the operator that there are at least 40 CTSA phone callers that are represented in this conversation and we do want to leave plenty of time for you a lot pose questions about what this particular topic involves.

I really appreciate you're taking the time on very short notice to join this call. The short notice was basically necessary because of events that just happened yesterday and we wanted to as quickly as possible reach out to all the leaders of the CTSAs to hear from you about the - both concerns that you might have and I expect also some excitement about the potential here for an a new environment for clinical research to find itself into potentially at the NIH.

So basically these changes that I'm going to discuss are exciting and open up, in our view, enormous opportunities for translational medicine and therapeutics. But of course change can also be threatening and as we already learned can provide a rich environment for breeding rumors and anxieties.

So the best anecdote we think for such anxieties and rumors is information. And this effort here this afternoon is the first in what I hope will be many steps to try to be sure we have wide open channels of communication with all of you because you are a critical part of the vision that is now being put forward.

So I realize that today because we have an hour and because there are lots of people on the call we may not be able to answer every question but it is a start. And as John mentioned a minute ago we will have by tomorrow a Web site for feedback and I'll give you more information about that in a little bit.

But let me just paint the picture here of how we've arrived at this juncture. And I think this will resonate with many of you leaders who are very dedicated to seeing clinical research supported by NIH move forward in a way that is going to generate the maximum benefit to the public.

I think we're at a critical juncture. It is clear that scientific advances, many supported by NIH, are providing new insights into the molecular causes of disease at a dizzying rate.

And many of these insights are potentially actionable suggesting new approaches to prevention or treatment that need to be tested. Yet we would all agree the long timelines between such ideas and they're reaching the market are frustrating and sometimes they never get there at all.

The lack of economic incentives for rare and neglected diseases and the uncertain value of many new targets for common diseases have been slowing entry into the pipeline and to getting projects that do get into the pipeline long delay times and high rates of failure are encountered at virtually every step.

It is fair to say that new technologies are being developed to accelerate movement through that pipeline. But that in - that alone will not suffice to achieve what might now be possible.

We have come to the conclusion - and yesterday's meeting of the Scientific Management and Review Board, the SMRB, certainly documented their agreement with this that it is time for a new view and not an incremental tweak.

The perspective the SMRB has now endorsed is that structural changes are needed to ensure that we capitalize on these new opportunities for translation. We need to spend resources wisely; we need to deploy new technologies efficiently, we need to work effectively with the private sector and with regulatory agencies.

We need to be sure that we are capitalizing on our community connections. And most importantly we move with all due speed to improve human health. Training is another critical part of this and certainly something that resonates with the CTSAs.

All of these are our mission and yet the SMRB concluded that our mission could be more effectively accomplished by a structural change. Basically last summer I asked the SMRB to look at this question. And they formed a working group on translational medicine and therapeutics, TMAT, a acronym that I think we stole from Garret Fitzgerald.

And the TMAT group basically was charged to identify attributes and functional capabilities of an effective translational medicine program for advancing therapeutics development. Also they were asked to assess the NIH landscape for programs, networks and centers for inclusion in this network and to recommend their optimal organization.

I asked the SMRB to complete this charge by this month, December, because we wanted to be able to have those board recommendations in time to

formulate the agency's request to Congress for the fiscal year 2012 budget which would begin next October 1. If we miss that deadline we might have to wait another year.

So yesterday the SMRB met here at the NIH, received the recommendation of the TMAT working group and voted 12 to 1 to recommend that NIH create a new center for advancing translational sciences.

Specifically they voted for the creation of that center as recommended by the working group with a variety of components that I'll come to in a moment. They also endorsed and supported the NIH's commitment to undertake a more extensive and detailed analysis to evaluate the impact of a new center on other relevant extant programs at NIH including NCRR. There will then be a report back to the SMRB in February about those issues.

But what we can now say already that has been proposed and passed by the SMRB is the creation of a center that has several components. One is the molecular library's program or at least major parts of it; a effort which has been supported through the common fund which provides support for assay development and high throughput screening.

Another is the Therapeutics are Rare and Neglected Diseases program, TRND, which has been in place now for about year and a half and which is devoted as the name suggests to both supplying resources to move promising compounds through the preclinical phase to an IND and onto clinical trial.

A third is a program called RAID, Rapid Access to Interventional Development, which supplies additional resources like GMP synthesis and animal toxicology for projects that are having promise of going towards human trials.

A fourth while still hypothetical is about to come into reality we believe, it's the Cure's Acceleration Network which was authorized in the Healthcare Reform Bill as a new and rather flexible means of promoting advances in therapeutics in creative partnerships with the private sector and which we understand is likely to find an appropriation in this current fiscal year although it will be modest for starters.

And additional component may well be the connections that we have developed with the FDA and particularly our regulatory science agenda which we are doing jointly with the FDA and which obviously fits as an important component of any effort to speed up translation to the point of human applications.

But perhaps the most significant in terms of existing budget and complexity component that is proposed to go into the new center and this was endorsed by the SMRB for the CTSAs themselves. The argument here was that this is a remarkably powerful network of clinical centers that have capacity to do many interesting protocols not limited of course to what one might traditionally call T1 research but obviously with that capacity is part of their capabilities.

The SMRB felt very strongly this was a very good fit and this would be both an opportunity for the new center to have the kind of clinical trial capabilities that any such translational medicine effort would need in a network fashion but might also provide a new environment for the CTSAs in terms of an exciting bunch of adjacencies to these other kinds of components.

I should stop here and say that none of this is intended to supplant or absorb the existing translational efforts in the larger ICs like NCI and NIAID and the

neuroscience institutes who all have efforts in this regard. But many of the smaller institutes have not really had the capabilities to provide this sort of pipeline for translational development. And this is an attempt to provide a hub of such activities at NIH.

Some have compared this - maybe I have - to the way in which the Genome Institute has provided a hub for genomics at NIH even though all of the institutes are invested in genomic research of various types. This is supposed to provide a similar hub for translation and particularly for technologies that may otherwise be difficult to assemble on a project by project basis.

It also is intended to provide an opportunity to look at the pipeline itself as a scientific problem instead of having each project considered in a one-off fashion. And that's critical as we consider the fact that the development of therapeutics has unfortunately been a very inefficient and high failure process.

Some of that is unavoidable. We happen to think that this could in fact be susceptible to a rigorous scientific analysis to try to put into place something along the lines of proposals that Steve Paul and others have recently put forward which means really identifying early on when a project is going to succeed or fail and not invest inappropriate resources if something is not going to be successful.

So, all of those things could become possible in this new center. By the way I've primarily focused on small molecules in the comments I've just made but this center could also be a very important home for the development of biologics especially monoclonal antibody therapies and also diagnostics although those plans are perhaps a little less clear than the small molecule efforts because that ladder already involves a number of major facilities that are in place that could be moved into this enterprise.

Now let me say something about CTSAs because I'm sure this will come up. I recognize having reviewed the overall portfolio and having had the privilege of actually visiting seven of the CTSAs over the last year that there's a lot of heterogeneity and diversity in what the areas of strength are of each one.

And we see that as a good thing. And certainly the kinds of research that are going on in the CTSAs while in some centers it does involve Phase 1 and Phase 2 trials first in human new therapeutics there's lots of other things going on there as well including comparative effectiveness research or other kinds of T2, T3 and T4 applications.

And we see that as an opportunity as well, offer NIH to make really major contributions to the benefit of human health. And the notion of moving the CTSAs into this new center is not intended to imply that those other activities are less critical.

It will obviously, over the course of time, be just as it has been in the past, an opportunity for us to assess what is making the best contribution to moving the ball forward in human health and that will happen in the new environment as it would have in the old environment.

But I want to reassure everybody that there's no intention here to force CTSAs into territories that they might not currently have planned to undertake unless of course it becomes scientifically appealing to the CTSAs to do so.

Similarly I know the CTSAs have a lot of investment in training and we see that as a really good thing. This may be an opportunity to include additional training efforts that relate specifically to the development of therapeutics although some of the CTSAs already have that.

We also see the community outreach part of the CTSAs as an important part of what they are and will want to consider carefully how that might also fit in a somewhat re-scoped kind of new plan for where these centers are going to be moved.

So that's the overall idea. And I hope you will see this as I do as an exciting opportunity. I should say before I can formally act on the recommendation from yesterday from the SMRB I need to consult with Secretary Sebelius who's already heard much about this and has generally been quite enthusiastic.

And also notify the Congress of these plans because that's required. And until that sort of series of steps has been conducted I'm not in a position to formally accept the recommendation. But as you can tell I'm quite excited and quite compelled by the arguments they have put forward.

And in order not to lose time I figured it would be appropriate to begin this conversation with all of you because this new plan will have significant implications for the CTSAs.

So let me just describe what the steps are that NIH will undertake provided the Secretary and others concur. One thing we need to do is to do a thorough review of scientific programs within NCRR and other parts of NIH to see if there are other programs that would appropriately move into this new center.

That of course is a critical question. So for instance comparative medicine program at NCRR is an effort to look at ways in which animal models can be utilized. And this is certainly one of the considerations should that potentially come along with the CTSAs to this new environment.

I've asked Larry Tabak who is the Principal Deputy Director at NIH and very experienced in these kinds of complex questions about structures and Alan Guttmacher who is the Director of the National Institute of Child Health and Human Development to co-lead this taskforce effort along with a number of other distinguished leaders here in order to do a careful analysis of the portfolios of the NCRR and a few other places to see what would make the most sense.

This is not an attempt to actually dismantle any programs; it is an idea of trying to figure out where they would best be assigned in order to support the research.

Maybe I'll stop for a minute and ask Larry to say a word about how this taskforce is going to be informed. And I should have said at the beginning in the room with me are Larry Tabak and Alan Guttmacher, also Kathy Hudson, the Deputy Director for Science Outreach and Policy, also Amy Patterson, the Director of the Office of Science Policy, also Pat White who oversees our legislative office and John Burklow whose voice you heard a minute ago who is the head of our communication shop.

Larry.

Larry Tabak: Thanks Dr. Collins. So as you've heard a taskforce has been formed. It consists of NIH deputy directors, NIH institute and center directors and several senior program officials from across the NIH.

And they are charged with doing an initial analysis of the various programs as outlined by Dr. Collins. Very importantly these efforts will be informed by folks from the NCRR that the NCRR has put forward has been appropriate to dialogue with.

And then once we have put in place a framework we will then engage stakeholders both across the NIH as well as in the extramural community. It's very important for us to receive feedback from the various stakeholders including of course the CTSA program directors and then informed by this information then we allow the science to drive whatever administrative organizational structural changes are needed at a very granular level.

So that's in general the approach that Dr. Guttmacher and I intend to follow.

Dr. Francis Collins: Great, thanks Larry. And again questions in just a moment can be directed at myself or at Larry about that part of the process.

So again as far as the timing if all goes smoothly this new center which we tentatively are going to give the name the National Center for Advancing Translational Sciences, which is NCATS if you want to say it out loud, will be included in the FY '12 budget and therefore if all goes well will be formally established next October 1, October 1, 2011.

I hope that we can now have a conversation about what some of the concerns and questions you might have. I will tell you that we'll be launching tomorrow an interactive Web site which is called NIH Feedback and the URL is feedback.nih.gov which will provide additional opportunities for us to post information about the process and to receive comments and questions and also to try to deal with the inevitable rumors that will be flying around. So watch for that starting tomorrow.

And of course we will welcome other opportunities to hear from all of you. The CTSAs are a critically important part of this plan. We want to do everything we can to build upon the considerable strengths of this network

and make sure that we take full advantage of the scientific opportunities now in front of us in this new set of adjacencies of other platform skills to be able to advance the therapeutic agenda.

So I'm going to stop now and turn it back to John and we'll get into the Q&A which will follow a process so that we don't have everybody stumbling over everybody.

John Burklow: Thanks very much Dr. Collins. And, (Laurie), our operator, will help us through the process and, (Laurie), if you want to bring up the first call. And please just a reminder to identify yourselves before you ask the question.

Coordinator: Thank you sir. We're now ready to begin the question and answer session. Please press star 1 on your touchtone phone. You will be prompted to record your name. Press star 1 and record your name please to ask a question. One moment, sir, for the first question.

Our first question comes from (Anasha Shakar), your line is open.

John Burklow: Okay, go ahead.

(Anasha Shakar): Dr. Collins, I'm calling from India. And there has been an issue of the National Center for - the Research Center at NIH, is that going to be part of this equation or how will we relate to them?

Dr. Francis Collins: I'm sorry, which center are you speaking of?

(Anasha Shakar): Oh the clinical center, sorry.

Dr. Francis Collins: Oh, oh, okay, yes, oh good point, yes. I meant to mention that and I jumped over it. So the Clinical Center has also been a topic of much discussion by the SMRB for more than a year. And they also debated this yesterday.

Their sense was two-fold, first of all that the Clinical Center is a remarkable national resource and ought to make itself available to extramural as well as intramural investigators. And that in fact will be happening by the Clinical Center moving its location in the scheme of things from a purely intramural budget line to one that also will allow an easier accommodation of extramural projects.

They also thought about whether the Clinical Center might then just moved into this National Center for Advancing Translational Sciences and felt that that was going to provide too many other complexities to make it currently feasible.

And so they decided against that formal structural connection but advocated strongly - and John Gallin embraced this in some comments the made yesterday about a very strong dotted line between the National Center for Advancing Translational Sciences and the NIH Clinical Center because of the potential to also carry out some exciting science there particularly Phase 1 and 2 trials and the Clinical Center also has a GNP facility that could turn out to be pretty useful.

(Anasha Shakar): Thank you.

John Burklow: Thank you. (Laurie), next question.

Coordinator: Our next question comes from Dr. Kronstein, your line is open.

Philip Kronstein: Hi Doctor. I'm calling from NYU. There seems to be a tremendous emphasis on essentially drug development in the proposal at least as you described it and the slides that we saw.

And I guess my question is how - is there going to be a similar emphasis on further development after first in human trials because just reading in the paper today for example the Healthcare Act supported a tax deduction for biotech companies because they've been unable to raise any money over the past couple of years.

And it seems that bringing things up to a certain stage and not being able to get them any further might be a problem and might make this seen as I guess over-promising and under-producing. So I was wondering if you could comment on that.

Dr. Francis Collins: Well there are a couple aspects to your question and I do appreciate it, it's an important point. So first of all as I tried to say I do think that CTSAs have clinical research capabilities that extend well beyond the sort of first in human testing for new small molecular therapeutics although it may appear from the slides you saw, if you saw the presentation from the working group, that there was a good deal of emphasis on that.

I think many of us do see that as one of several unique opportunities. And maybe one that particularly is in need of some structural rearrangement of the way in which we've been supporting that science at NIH to bring programs together in a more integrated way.

But understanding that the CTSAs have many other strengths that go beyond that initial phase of clinical testing we would certainly want to encourage and nurture those as well.

One of my other jobs is serving on the Board of PCORI, for instance, the Patient Centered Outcomes Research Institute, which is certainly focused on comparative effectiveness research. And we have certainly considered that the CTSAs ought to be a powerful engine for conducting some of those studies as well.

So please do not take this recommendation as in any way diminishing the importance of other aspects of clinical research, only an effort to particularly try to strengthen an area that we saw as having not quite fallen together as efficiently as it might.

Philip Kronstein: Thank you very much.

John Burklow: (Laurie), next call please.

Coordinator: Our next question comes from Julian Solway.

Julian Solway: Hi Dr. Collins and colleagues. I'm calling from the University of Chicago. And wonder about the RFA. Twelve of our institutions are going to be submitting renewal applications due June 11; response to the current RFA. Should we be responding to the RFA as written or do you anticipate that there will be changes in it?

Larry Tabak: So this is Larry Tabak. Please proceed responding to the RFA as written. Please don't try and anticipate any changes because that would be almost

impossible to do since this is obviously, you know, a work in progress. So respond to the RFA as written.

John Burklow: Thank you very much. Next question please.

Coordinator: Our next question comes from Dr. Harry Selker.

Dr. Francis Collins: Okay.

Harry Selker: Hello. This is Harry Selker from Tufts CTSI and also for Society for Clinical and Translational Science. First of all it's really delightful to hear that you heard us about, you know, the full spectrum of translational research, CER and community engagement.

In fact community engagement was a novel method for many of us and yet now we see it that, one, it works and, two, it's important for engaging the public so we're really glad to see that.

And we're also - I think many of us feel strongly that it's great to get the basic and T1 stuff better aligned with us. So I think there's a lot wonderful about this. I guess one of the things that I haven't heard you, Dr. Collins, elaborate on and I think it's so interesting that you have a theme that is supporting healthcare reform.

And I see some of these pieces as being that. I wonder if you could elaborate on that and as it relates to the CTSI's role? Does that make sense?

Dr. Francis Collins: Oh I think it does, yes, and I appreciate you referring to the theme number three there. Of course what we've been talking about in terms of the T1 part is very much theme number two in my little list of five that got published about

a year ago which is the taking the - building that bridge between basic discovery and therapeutic clinical trials that hopefully will be successful.

But I certainly see the need to provide scientific evidence to inform healthcare reform as a major responsibility and opportunity for NIH right now. I already mentioned comparative effectiveness research in that regard.

But one can also add some other areas that I know CTSAs are involved in pursuing; the whole personalized medicine questions, the pharmaco-genomic opportunities, the behavioral research that is going to be critical for particularly prevention strategies to understand how information does or does not motivate people in the real world.

As well as a host of other potential clinical applications that may shed light on health disparities which is a critical issue for NIH right now. Again without trying to be overly broad I think the CTSAs have potential all of those areas that I'm looking forward to seeing tapped.

And I think there's an enormous amount of energy and creativity and vision that I have seen when I visited the CTSAs. And I'm sorry I haven't been to all of them yet because there's a lot. It would be hard to do much else.

But it does seem to me that in a certain way could stand to be even more unleashed in this new environment of a very forward-looking, very ambitious new component of NIH.

Harry Selker: Thank you.

Coordinator: Thank you. Our next question comes from James Heubi.

James Heubi: Thank you. Dr. Collins I think that's a wonderful initiative. I'm coming from - I'm calling from Cincinnati and I'm the PI for the CTSA for the Children's Hospital and the University of Cincinnati.

I'm also a council member for NCRR and as a consequence I feel a little bit unfortunate that I haven't been able to be part of any of the other previous discussions. But as a council member I'm actually welcoming the opportunity for the CTSA to be aligned with these other elements.

But I'm worried a bit about - and maybe Dr. Tabak can comment on this - about some of the aspects of NCRR logically would fit under this new center including the Primary Center on Comparative Medicine. However projects like or programs like (COBRAY) and the shared instrument program and the construction grant program are going to have to find new homes.

And how will that be done to actually make sure that we still have those programs intact and effective for the future?

Larry Tabak: So you have articulated the issues very, very well. And of course we are very aware that a subset of the remaining - the NCRR programs would fit very well into the new center.

Others would find better adjacencies scientifically and other institutes and centers across the NIH. The key is that we are committed to keeping the programs intact.

And so whilst we're not yet quite prepared to identify which specific programs might wind up in a different center or institute we are prepared to say that we want to keep those programs intact recognizing their value and in many instances moving the individuals who have been so important in running those

programs at the NCRR together with the program to the new institute or center.

So thank you, you are exactly where we are in thinking. And we look forward to continued discussions with you and your colleagues to get, you know, additional input on these issues.

John Burklow: Thank you very much. Next question please.

Coordinator: Our next question comes from Curtis Lowery.

Curtis Lowery: Hi, thank you Dr. Collins. We've had discussions about the FDA and how the FDA is going to be aligned with the CTSAs in helping with drug development and instrumentation development. Can you comment on that?

Dr. Francis Collins: So, yes, that's a very appropriate question and very much part of our overall effort here to try to strengthen translational success. So Peggy Hamburg and I have started this conversation even before I was - formally finished the appointment process.

We have, as you may know, formed a leadership council between FDA and NIH which Peggy and I co-chair and which has identified a number of significant opportunities for collaboration to try to speed the process of getting approval for compounds that are safe and effective and also to look more creatively act clinical trial designs in unusual situations which are becoming, you know, less and less unusual, things like combination therapies and things like for instance the ability to look at very rare diseases where you can't find thousands of patients for a Phase 3 trial.

And I think that's going very well; it's very encouraging to see the openness on both sides. We are also, as you know, funding a joint effort in regulatory science that has issued its first RFA and funded its first set of grants with the expectation that there will be more to come in that regard.

So I do see this as a part of the package here if we're trying to accelerate this kind of research. If we didn't have the FDA connection we might stub our toe in all sorts of preventable ways.

And this is an effort both to inform NIH grantees who may be in larger numbers getting into the process of trying to develop an IND for instance but also to inform the FDA about the way in which science is providing new opportunities for creative clinical trial design that they hopefully will smile upon.

So, yes, it's going to be a very interesting and important part of the process.

John Burklow: Great, thank you very much. Next question please.

Coordinator: Our next question comes from Eric Orwall.

Eric Orwall: Dr. Collins, I'm calling from Oregon. I have an organizational question or two. You've referred to the new translational structure specifically as a center rather than institute and I wonder if you could differentiate how that would function as opposed to an institute?

And I wonder if you could comment yet on leadership and internal organization of the center?

Dr. Francis Collins: Both great questions. So in reality and NIH scheme of things institutes and centers have exactly the same authorities. There is no difference whatsoever in their ability to issue grants and contracts that have intramural components and so on.

That was not always true but it is true now based upon the way NIH was reauthorized most recently. So it's purely a matter of semantics. It is however more traditional for something new to start as a center and then if it seems to be going well to give it a promotion and change the name to an institute.

That's certainly what happened to my former part of NIH, the genome effort which was a center and became an institute. I think to have this named as an institute from the get-go might be seen as out of step with that usual tradition.

And it gets - it really creates no problems at all for the functioning to be called a center at the present time. So that was the general direction the conversation has gone.

As far as leadership clearly this new entity at NIH is going to need a leader of really substantial vision and breadth and energy and ability to bring together all these various scientific components.

This is not wired; we do not have a candidate in mind who has already thought of as the ideal person to lead this enterprise. This will be a broad, vigorous, national search involving candidates from academia but I suspect also candidates from the private sector who may bring a wealth of experience to this new set of opportunities.

So we will, before too much longer, be putting together a position description and sending out an opportunity for people to apply. We'll have a search

committee. We'll do what we do. And again the expectation is if all goes well we want to have that director in place in October when the center stand up in order to read it from the very beginning.

John Burklow: Thank you very much. Next question please.

Coordinator: Our next question comes from Robert Callis.

Robert Callis: Hello Dr. Collins. This is I think a really exciting day obviously causing a lot of anxiety but I think all the CTSA PIs and calls that we've had I think have looked forward to more concentration of translation in general.

So I think you've done a good job of answering the sort of process questions. I'm going to ask you sort of a philosophical question as we prepare our institutions for what's coming over the next several years.

You've made it clear it's a bit unpredictable but on the other hand, you know, we're all looking at a Congress and the budget which is less in increasing may be stable. Andy you are proposing some pretty big changes. So could you say a few words about your personal view of efficiency versus free-form research and how you hope to see things go as we talked it up among all of our anxious administrators and investigators at home?

Dr. Francis Collins: Well, Rob, that's a great question. And believe me I wish that we could imagine that this new enterprise could be salted with all kinds of dollar bills falling down upon it from a Congress that is ready to do so. But we all know that's not the case in the current climate.

As you said I think we will be fortunate if NIH over the next couple of years keeps up with inflation and we may very well find ourselves slipping back a little bit.

As a consequence some might say well why are you trying to do something bold and new right now? Two which I would say there could hardly be a better time. If you really have the scientific motivation to do something like this to miss that opportunity seems to me would put us in a position of not really being able to advocate that we should ever be in better times.

I do think, by the way, while it's not the reason to do this that the focus here on clinical translation and therapeutics it resonates very, very effectively with people in the administration and the Congress. And this could, as a new development, help our case a bit in terms of trying to advocate for the fact that NIH is not just a bunch of people playing in the lab but we actually are serious about human clinical benefits.

In terms of how we are going to handle the budget situation we're going to need to live with the pieces that we're talking about here are for the most part programs that already have funds but they are in different places and we're going to try to move them together then and try to take advantage of the efficiencies that are generated by that kind of integration without the expectation that there will be lots more new dollars to put into this at least not right away.

And that is going to vex people who will expect that somehow when there's something new there ought to be new money. And again as I wish there were that it is unlikely that there will be much in that regard for at least a little while. We will need to then look very hard at question about efficiency. And I think that's that your question is focused on, Rob.

Robert Callis: Yes.

Dr. Francis Collins: And that's going to be true across all of NIH not just in this new center. We are going to have the hard questions about things that are productive and things that are less productive. And in order to do new things we may have to figure out we can do less of some other things that are perhaps not quite as compelling.

NIH has been engaged in that process now for about a year in terms of anticipating what could even be cut in the budget. So it ain't going to be fun but this is actually I think a challenge to all of us. And I think frankly none of us could say that absolutely 100% of everything that we're doing in various parts of NIH is absolutely just the absolutely most top notch couldn't possibly cut it back kind of enterprise.

There will have to be some priorities and some decisions about that made but they are going to be made objectively based upon science and not politics.

John Burklow: Okay thanks very much. (Laurie), are there any other questions in the queue?

Coordinator: Sir, at this time I'm showing no further questions.

John Burklow: Okay. I'll turn it back over to Dr. Collins for closing comments.

Dr. Francis Collins: Well I really appreciate the chance to have this phone call with all of you. Obviously many questions you posed that we're giving fairly general answers to because this is all quite fresh, it's only been 27 hours I guess since the SMRB voted to recommend the creation of this new center.

And as I said even now this is a not entirely implemented effort because we have to go through the process of informing the Congress. But I do think the potential of a new and exciting way to conduct clinical research is coming into view.

We'll need to have many opportunities to interact with you all collectively and separately and I look forward to that. Again, the Web site that you might want to start to look at tomorrow -- feedback.nih.gov -- it'll be on the NIH home page in case you forget that URL, if you just go to nih.gov there will be a pointer to it.

It'll probably be a little chaotic at first until we begin to sort out exactly how to capture inputs and outputs but it should be a useful clearinghouse for information.

So I finally just want to close by thanking all of you for your leadership of the CTSAs, a very exciting, very important program that we have. And we hope very much to see this as a positive, as a new adventure for all of you as leaders to find your CTSAs able to conduct even more exciting research then you previously were able to do. And we'll be talking with you much about all of that. So I think what that we should probably sign off. Okay.

John Burklow: Thank you very much everyone.

Coordinator: Thank you that does conclude today's conference call. Thank you all for joining. You may disconnect at this time.

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