

WEBVTT

NOTE duration:"00:26:35.010000" language:en-us

NOTE Confidence: 0.920485615730286

00:00:00.050 --> 00:00:20.050 Where can send a grand rounds and we're very fortunate today to have 2 are really very interesting areas that we're going to focus on both of which in some respects rely on the coordination between clinical care and research in terms of sample collections to advance.

NOTE Confidence: 0.892507553100586

00:00:20.850 --> 00:00:40.850 And our first talk is is emblematic of that important concept. I guess bill before I start. I should point out the slide that Doctor Lynch. My predecessor in my classmate in fellowship will be talking tomorrow, so tomorrow right if for those of you want to attend, but

NOTE Confidence: 0.872445225715637

00:00:41.650 --> 00:00:45.810 Let me let me open up with our first.

NOTE Confidence: 0.751619458198547

00:00:47.470 --> 00:00:48.110 Talk.

NOTE Confidence: 0.754689395427704

00:00:51.120 --> 00:00:53.320 Which is it is this you?

NOTE Confidence: 0.670869886875153

00:00:54.440 --> 00:00:59.470 OK thanks so we

NOTE Confidence: 0.93490469455719

00:01:01.220 --> 00:01:21.220 You know, I think one thing we really wanted to do in the past 2 years is to make sure that we enable great science through interactions between our growing clinical operational laboratories between our clinical trials, an individuals who are trying to understand sensitivity resistance and R.

NOTE Confidence: 0.902810096740723

00:01:22.020 --> 00:01:42.020 Present today are going to share the work, they're doing with our clinical research support laboratory so about roughly about a year ago. Doctor Stephanie Helene took over as the director of RCRSL and Stephanie's you know is an asos.

NOTE Confidence: 0.900787889957428

00:01:42.820 --> 00:02:02.820 This in her laboratory has done valuable science. Understanding the biology of leukemia, mild dysplasia and how to leverage that biology to define new therapeutic approaches and I'll let Stephanie Open and

then introduce colleagues? Who are advancing the mission of the CRS LTO expn.

NOTE Confidence: 0.623352646827698

00:02:03.620 --> 00:02:04.550 Live sites.

NOTE Confidence: 0.863373100757599

00:02:05.470 --> 00:02:06.960 Thank you.

NOTE Confidence: 0.863827407360077

00:02:08.270 --> 00:02:28.270 Thank you everyone for coming today, so this is a joint presentation between myself and Debbie and Talia has not been well so I'm presenting on her half but she gets all the credit and every mistake is all mine. So where are the clinical research report lab or CR and how do we make research happen well so you?

NOTE Confidence: 0.881594061851501

00:02:29.070 --> 00:02:49.070 What do we actually do all day I can tell you we're busy we're doing great work and we have a vision for the future. So Rocco kindly provided me. With this history, which is I think very helpful to understand where we are now and where the CR Sala and research, it yet is coming from so understandably, it all started.

NOTE Confidence: 0.881185352802277

00:02:50.030 --> 00:03:10.030 And then basic science labs for example, blood sample would just walk over itself to the basic science lab, and then processed and generate nice data at some point, though people realize that need to be people helping with that because it can just be a postdoc walking over all the time and so.

NOTE Confidence: 0.867829263210297

00:03:10.830 --> 00:03:30.830 Child's office stuff actually dealt with the patient consented to them about trials, etc. And then a clinical trials office stuff actually walked the sample 2 different basic science lab that yells and processes samples and in around 2006 Nancy Harris, then director of Wrestling Cology and Kevin.

NOTE Confidence: 0.874686658382416

00:03:31.630 --> 00:03:51.630 You oncologix had this idea that they really needed to be a central lab processing. These specimens because things were getting more complicated. And so they founded the self processing lab and hired Rocco Carbone Research Specialist and I was a jail for quite some time. Everybody knew rock whenever.

NOTE Confidence: 0.861180543899536

00:03:52.430 --> 00:04:12.430 Rocco because he is just a wonderful wonderful resource and so anyone. Bracho started processing clinical trial samples with

a desk and a bench and then how it works, who took over as CTO clinical trials office director and he found it the clinical research support lab and higher Lindback Wilder as AC.

NOTE Confidence: 0.905052959918976

00:04:13.230 --> 00:04:33.230 Who then Lynn and raffle 2 people started processing about 40 clinical trials and you can see in the picture around this time. Smilow happened and changed everything and so then over the years, the trials went from 40 to something around 400 staff grew from 22 over 28.

NOTE Confidence: 0.875149965286255

00:04:34.030 --> 00:04:54.030 Rocco stayed with a CR cell and just had a 35 years at Yale. So congratulations and it's the wonderful wonderful resource. Lynn actually moved over to the rapid Keizer term in group and is going to work closely collaborating with her there and then we were so fortunate to have Talia Mitchell join us as administrative director.

NOTE Confidence: 0.859422922134399

00:04:54.830 --> 00:05:01.690 And eh bronica share as the technical director of the CR cell and then now making things happen when my life is incredibly easy now.

NOTE Confidence: 0.905922949314117

00:05:02.700 --> 00:05:22.700 So this is our current structure, so again with the clinical research report lab and as you can see we're very centrally located between the clinical trials office and research happening and we kind of have a division. But this is a unity work as a very close team between kind of dry land team.

NOTE Confidence: 0.878646433353424

00:05:23.500 --> 00:05:43.500 Talia's behalf what that is about and then we have a wet lab team and Debbie will tell you about that. So when are physicians have smarter deers or medications that very, very interesting brain into the patients that comes with stacks and stacks of papers so clinical trial protocols and of course, also with laboratory.

NOTE Confidence: 0.900687515735626

00:05:44.300 --> 00:06:04.300 Many many pages and then cute diagrams that somehow have to be translated into the clinic and this is what our project managers do and currently Talia and Rocco are happy now because we are swamped. But we're doing, it and so our project managers take these laboratory manuals and translate them.

NOTE Confidence: 0.845660746097565

00:06:05.100 --> 00:06:25.100 Which electronic resource and what's to come beaker and Beacon? Etc and eventually out conditions are able to bring these

new medications to our patients, So what do our project project manager team do? They review the clinical trial protocol and the manual?

NOTE Confidence: 0.877990305423737

00:06:25.900 --> 00:06:45.900 Feasibility they build the epic beacon building the reviewer they construct templates. They provide workflow instructions for blood tissues and anything else involved with you know with samples with clinical trials and then I'll show you pictures of kids so every trial account with a lot of kids and a lot of tubes.

NOTE Confidence: 0.921421527862549

00:06:46.700 --> 00:07:06.700 They transfer files so that we can communicate electronically. They're parted kickoff meetings that very, very closely integrated with disease teams and the clinical trials office in many meetings that very critical to all communication between physicians patients clinical trials office sponsors Central Laboratories.

NOTE Confidence: 0.891743123531342

00:07:07.500 --> 00:07:27.500 Course they're always questions and they answer the mall. So this has all gone again from 40. Studies 280 open studies that are enrolling patients every week. Every day and then we have about 400 active studies, meaning studies that are either pending so being processed right now that nobody knows anything about or studies that still have patients that are maybe.

NOTE Confidence: 0.900370895862579

00:07:28.300 --> 00:07:48.300 And so I told you about kids so when people think inventory. They think about this. Yeah, boxes stored somewhere. Nobody asked to look at but that is not true our inventories life inventory. So we have all these boxes that are full of tubes and paperwork that have to every day go to the clinic and prob.

NOTE Confidence: 0.898331344127655

00:07:49.100 --> 00:08:09.100 120 of these kids go to the clinic everyday then get set up on racks and Debbie will tell you all about that deploy for patients and then the samples get shipped back so just recently removed from this kind of dead storage where people select? Why is my study not accruing to live inventory? We just moved temporarily.

NOTE Confidence: 0.883489727973938

00:08:09.900 --> 00:08:29.900 2 thousand square foot location and 100 short St South, which is a bit far away. But we have careers and delivery assistance and that is actually thanks to prove McCann, who's really helped us out. So So what happened to these things to kids and all that, well as you can tell everything has been growing and smile oh.

NOTE Confidence: 0.91168600320816

00:08:30.700 --> 00:08:50.700 A few kids a few studies to something like 16,000 kids that we now have about 2000 kids. Go in-n-out every month. And I'm again. About 100 or more kids. Go to the clinic every day. And this is pretty much a straight line up so as people open more clinical trials is definitely grow.

NOTE Confidence: 0.897727787494659

00:08:51.500 --> 00:08:59.060 We're trying to keep up. We're trying to get ahead and we're trying to make it happen. So let me hand over 2.

NOTE Confidence: 0.71064567565918

00:09:09.880 --> 00:09:18.610 OK can everybody hear me.

NOTE Confidence: 0.822393834590912

00:09:19.700 --> 00:09:27.780 OK, so like Doctor Helene said I am the technical director of piano.

NOTE Confidence: 0.869815528392792

00:09:30.890 --> 00:09:50.890 Set better thank you and the technical director of the CRS cell and what we're really doing is working as a team with the whole clinical trials organization as stepping mentioned you were putting together all these study protocols and member, she was talking about.

NOTE Confidence: 0.906606435775757

00:09:51.000 --> 00:10:08.850 Over 289 active open studies right now that we have to work with everybody from the principle investigators to the dark teams in our project. Managers put all that together in a lab manual and they're forming the templates that we use in the lab to collect the samples.

NOTE Confidence: 0.890461981296539

00:10:10.750 --> 00:10:27.990 So once the dark teams have the studies open. They actually schedule placed patients that are eligible for the studies to come in and they send us treatment schedule slips that went too far they send us treatment schedules so that we know the patients are scheduled for certain days.

NOTE Confidence: 0.873058438301086

00:10:29.860 --> 00:10:49.860 This is where the CR self comes in incorporating and coordinate all the visits for examples that are coming in each day we planted a week at a time as much as we can, but there's always updates and changes that we have to keep track of and we're basically is on the protocol and lab manuals for each individual study we?

NOTE Confidence: 0.903499782085419

00:10:50.660 --> 00:11:10.660 Scheduling team that has just been formed, Marissa and Sarah and they are ordering study specific kits, according to the lab schedule that we form, they prepare the visit templates for each individual patient and they prepare the sample collection racks for each individual visit that is required for each day and.

NOTE Confidence: 0.909886062145233

00:11:11.460 --> 00:11:18.210 Orders that deliver all these racks to the individual clinics and 4 locations, so that when the patients come in. It's ready for love.

NOTE Confidence: 0.870715737342834

00:11:19.140 --> 00:11:34.920 And again we are collecting blood bone marrow tumor biopsies. Beelze stool, urine anything. That's required for certain trial. We will be collecting those OK, So what do we actually doing this wet lab?

NOTE Confidence: 0.903635561466217

00:11:36.080 --> 00:11:56.080 First thing to do is transport the tubes to the lab from every area of the hospital to lab where we were going to go ahead and centrifuge aliquot blood making sure that we follow the study. Specific lab manuals and again remember, we're looking at over 289 lab manuals that.

NOTE Confidence: 0.906076729297638

00:11:56.880 --> 00:12:02.970 We need to have study specific kits and documentation shipping instructions for each study.

NOTE Confidence: 0.920605838298798

00:12:05.010 --> 00:12:16.550 We also support collecting biopsies and processing those and shipping them out appropriately so that means that we are going into the or's working with the surgeons to make sure that we are collecting the biopsy appropriately.

NOTE Confidence: 0.91789174079895

00:12:18.740 --> 00:12:38.740 Our number one priority is the patient and their samples. We want to make sure that you were taking care of their precious samples not only for their health. But for the future of the research of cancer research at the same time, we're making sure that the patient is safe that we are working appropriately and safely with those biological samples.

NOTE Confidence: 0.895477473735809

00:12:39.540 --> 00:12:59.540 Filling out the appropriate documentation or following HIPAA rules and good clinical practices and that all of our staff are certified per shipping. These samples out anywhere in the country or the world. This chart here is just an example of last 2 months that we've been processing Sam.

NOTE Confidence: 0.90210348367691

00:13:00.340 --> 00:13:20.340 Or sell it is organized by date and processing time so a lot of the dots are interlinked here. But you can see the bigger the line is the more patients. There are the axes are the median number of samples that we have and then it's spread out by the time it takes to process each sample.

NOTE Confidence: 0.916216373443604

00:13:21.140 --> 00:13:35.210 And see that there's a couple samples in here that are taking hours to process based on what the protocol requires and there's something that you know just have an ambient sample that needs to be shipped so it's very specific per protocol what we're doing.

NOTE Confidence: 0.902736663818359

00:13:38.260 --> 00:13:58.260 I'd like to give you some idea of how we're advancing our lab, so recent advance that we did. We've actually changed all of the lab manuals to a digital form. So, if you can picture 2893 ring binders. All lined up in the laboratory now that we've gotten digital all the lab notebooks are gone from the laboratory and we

NOTE Confidence: 0.821128606796265

00:13:59.060 --> 00:14:06.040 Surface pros at each workstation and the lab techs can go into each.

NOTE Confidence: 0.902353167533875

00:14:07.160 --> 00:14:16.110 Surface pro and go into our shared drives open up the protocols and follow the lab manual step by step as their processing the samples.

NOTE Confidence: 0.900420546531677

00:14:18.860 --> 00:14:35.420 What we would like to do in the future and we are looking into it this year is kind of going into 21st century provide some LIS laboratory information software that can track our workflow increase our efficiencies and eliminate paper.

NOTE Confidence: 0.876214444637299

00:14:36.550 --> 00:14:56.550 This is a group picture of our staff in the wet lab in CR cell here in New Haven. So we are growing growing. I'm happy to announce that we have a lab manager that just accepted position social reporting to me and managing the day-to-day activity.

NOTE Confidence: 0.884111225605011

00:15:00.230 --> 00:15:20.230 So where are we and this is really fun so follow along with me here OK so our main wet lab isn't smilow North Pavilion on the eighth floor and we also have another wet lab on Cedar Street. So we're actually taking specimens in on the eighth floor smile.

NOTE Confidence: 0.903523325920105

00:15:21.030 --> 00:15:41.030 Bring them to the wet lab on Cedar Street in order to process them. We have to split stuff on both sides. But in order to get the bulk of the work done. We have to move to Cedar Street, there. Just isn't enough space for us all to do it in one space. We also have a space on the 11th floor right above us in the North from billions that is.

NOTE Confidence: 0.864384770393372

00:15:41.830 --> 00:15:50.470 Used for storage, but we're converting that to a scheduling and tube setup area so that we can have more room in the NP 8 lab.

NOTE Confidence: 0.895333230495453

00:15:51.830 --> 00:16:11.830 Is that we have some other storage facilities that in the past? We've use all way in York Street? We don't use those anymore. And we also have a storage space on Lci, which we are using for shipper storage. If you can imagine all these big boxes in each study in each sponsor wants us to use certain boxes to ship them out. So we need lots of space.

NOTE Confidence: 0.881663739681244

00:16:12.630 --> 00:16:32.630 And then as a doctor clean mentioned 100 church, St Self. We have the individual kits that need to be delivered to lab so that we can make the collection racks and send them out to the floors, so In addition to everything that we do here on campus. We also have care centers so you'll smile.

NOTE Confidence: 0.879661440849304

00:16:33.430 --> 00:16:35.760 Is all over the state?

NOTE Confidence: 0.922540366649628

00:16:37.310 --> 00:16:57.310 Well before you can go there. Let's talk about those challenges. So our challenges are the distance between the supplies in the lab, but I've already mentioned were going between those areas and then the distance between the lab spaces and people so there's lots of challenges and timing if you can think about that how it's going to go from the patient to the lab and that.

NOTE Confidence: 0.879105925559998

00:16:58.110 --> 00:17:02.090 We can make sure these these samples are being processed appropriately.

NOTE Confidence: 0.882453858852386

00:17:03.320 --> 00:17:20.960 So here's our care centers. Smilow has care centers all across the state. You can see that we are looking at. You know anywhere from Torrington to Trumbull Derby, Orange Guilford Water Ferd and Hartford.

NOTE Confidence: 0.928942680358887

00:17:22.140 --> 00:17:30.550 So what we found was and it's pretty obvious as the distance from New Haven increases the time for us to process these samples decreases.

NOTE Confidence: 0.887316644191742

00:17:32.930 --> 00:17:47.470 So what we did for 2 locations, Trumbull in Saint Francis. We opened satellite CRSL labs, so they are staffed with a lab manager Anna lab technician in each lab each location.

NOTE Confidence: 0.902508497238159

00:17:49.710 --> 00:18:09.710 Now we couldn't do any of the coordination here up until now without Joes Hell. He is our person that is coordinating all the care center schedules couriers and you can imagine? How many careers. We have to go to all these locations. Some of them are doing it like in Trumbull and Saint Francis on their own but we still have.

NOTE Confidence: 0.888251483440399

00:18:10.510 --> 00:18:17.520 And then the other locations are actually still sending us. The samples there's a lot of coordination going on.

NOTE Confidence: 0.856695115566254

00:18:18.850 --> 00:18:28.630 These are our to Trumbull in Saint Francis lab staffed by John and Marias lab manager and Peter Gaijin Joelle's lab technicians.

NOTE Confidence: 0.914024531841278

00:18:29.900 --> 00:18:49.900 And just to give you an idea of our hours and are limiting factors so our New Haven site is open from 7 AM to 8 AM to 7 PM Monday through Friday. We are available for later hours for later. PK's and we are open weekends and holidays as the schedule requires.

NOTE Confidence: 0.897843241691589

00:18:50.700 --> 00:19:10.700 We have the capability of processing samples within 15 minutes of draw and of course, with late PK. Zora PK throughout the day. You know, we can do 12 hours post treatment were even talking about 13 and a half hours at this point, So what you need is will figure out how-to-do-it samples are also.

NOTE Confidence: 0.925688862800598

00:19:11.500 --> 00:19:22.760 But you know during surgery for biopsies. Interventional radiology and things like that, and we have the ability to add stabilizing reagents to the samples before they go out to where they need to go.

NOTE Confidence: 0.869901657104492

00:19:23.920 --> 00:19:43.920 We also are supporting other labs within yell so if you're on doctor Phil and we'll talk about that as well. But we will take

the samples in an process? What we need to, but then we will send them to the appropriate labs like Doctor Helene and shopper include her in school or so those are options for other labs if you.

NOTE Confidence: 0.490397155284882

00:19:43.960 --> 00:19:44.410 Need them.

NOTE Confidence: 0.885366797447205

00:19:45.460 --> 00:20:05.460 Our trouble in Saint Francis Hospital's you know, there's the challenge here, so this studies that are done at these care centers are chosen so that the timing can be done right, they can process within 15 minutes of collection. But the CTO itself isn't open that long so they can really only do 6 hours of PK's during the day.

NOTE Confidence: 0.893147826194763

00:20:08.080 --> 00:20:28.080 There is some biopsy type issues that you have to be specific per site. And there is some limitations like if you hoods and number of collections per day that type of thing that you have to consider when we're doing. These care centers. The other care centers. Fairfield North Haven. You just look here at the distance. It takes to get the samples.

NOTE Confidence: 0.910270035266876

00:20:28.880 --> 00:20:48.280 Processing and then of course, we've been alerted to the addition of Greenwich that should be coming this year. So we'll have to decide we're looking at 45 minutes away. So we're going to have to decide if we're going to open up. Another lab there or how the processing will be done depending on what type of trials will be done there.

NOTE Confidence: 0.81187891960144

00:20:50.980 --> 00:20:58.430 Really excited about that.

NOTE Confidence: 0.831898391246796

00:20:59.890 --> 00:21:18.750 OK, so I think what you can tell is that we're truly clinical research support lab and you know, we're supporting smilow care centers sponsors farmer gives us a drugs or even investigating shit trials. We ship things we connect to laboratories and.

NOTE Confidence: 0.887979209423065

00:21:19.760 --> 00:21:39.760 So the question is in oh can, we can. We do more and our vision for the future would be could we potentially be a central central research report lab so can, we maybe make additional research possible where we can now maybe provide pilot studies for people for you know how people was investigated initiated trials or whichever way.

NOTE Confidence: 0.892182648181915

00:21:40.560 --> 00:21:55.690 So we hope that as possible, and we are open for questions or suggestions and you know what we're doing now how we can improve things and maybe vision for the future and that be intaglio goes here, so if we have a little time to free to ask questions.

NOTE Confidence: 0.135693624615669

00:21:56.950 --> 00:22:05.870 OK.

NOTE Confidence: 0.804995536804199

00:22:06.890 --> 00:22:26.890 Let me start I can open the questions namely as we expand our network and realize that there's a growing population of of patience? How do you envision week sue to cover the ground you talked about other 2 CR cells now?

NOTE Confidence: 0.80753755569458

00:22:27.690 --> 00:22:37.580 Cells or figure out a fishing Courier services or some combination thereof other creative solutions.

NOTE Confidence: 0.906396567821503

00:22:38.600 --> 00:22:58.600 I think it'll depend mostly on what we're envisioning each location to achieve as far as patient work load. That's going to be off of these clinical studies, so for instance, in Greenwich and it and I think the distance is a major factor of it as well. We're just in the beginning stages of.

NOTE Confidence: 0.901376664638519

00:22:59.400 --> 00:23:19.400 No how big the facility is going to be as far as how many patients can be seen every day and what kind of cruel will be for different studies. I think it's going to be a case by case basis and for example, Waterbury is really too far away to transfer those samples so if there's going to be more.

NOTE Confidence: 0.888087391853333

00:23:20.200 --> 00:23:40.200 We're looking at different alternatives like the clinical lab processing the samples in the CTO shipping them out. If opening a lab is not feasible there and I think again. It's workload so if there's too much going on that. I think the clinical labs going to want to do it. So then if finances are available, then we would.

NOTE Confidence: 0.755505919456482

00:23:41.000 --> 00:23:43.970 I think it goes in steps.

NOTE Confidence: 0.705499649047852

00:23:45.060 --> 00:24:02.140 How are you handling I know you say as needed?

NOTE Confidence: 0.907935917377472

00:24:03.860 --> 00:24:23.860 Probably not as good as we'd like I think the huge indicator is communication specially when they're delayed. We had a tech have to stay right around Christmas time to almost 10 o'clock because of the delay. If we knew about that sooner. There could have been more organization to say she could've gone home for dinner or something like that.

NOTE Confidence: 0.798184514045715

00:24:24.660 --> 00:24:34.860 Anything that needs to be done is for the benefit of the patients will always work it out.

NOTE Confidence: 0.765622317790985

00:24:37.330 --> 00:24:56.660 You talked about like CTS or a longs. It depends on the actual study protocol. The lab manual as to whether we go or somebody else goes.

NOTE Confidence: 0.871324956417084

00:24:58.150 --> 00:25:18.150 Yeah, I think you know for example, some of some of that is happening in hematology already be cause for the hematology trialed. We actually don't have space to do the processing in the lab. We have right now, so in my lab actually started pressing so we have a technician in my lab location processing bone marrow biopsies that need to be filed called and just need longer processing so.

NOTE Confidence: 0.894401550292969

00:25:18.950 --> 00:25:38.950 Yeah, I think now that we're going to have Debbie Talia and lab manager. I think that we just need to be sure that we organize it better that we make sure we have monitoring we have ESO. Peas that we really formalize. This process and I think that's also something we're trying to do now, and so then yes.

NOTE Confidence: 0.90441906452179

00:25:39.750 --> 00:25:44.160 Was other research labs to may be maximized? What we can do together?

NOTE Confidence: 0.755349636077881

00:25:46.420 --> 00:25:52.080 Yeah, just to clarify are you available for Group Studies.

NOTE Confidence: 0.794608592987061

00:25:54.550 --> 00:26:14.550 Good question I think we have to pass that on to the true time. We were talking about it this morning. How do we build off of the great work that was doing to further enabled translation with service obviously there's?

NOTE Confidence: 0.900421738624573

00:26:15.350 --> 00:26:30.350 Joanne has been championing to build out our translational research infrastructure and as we continue to advance this. Maybe we leverage. The lab to help us enable that I think there's an opportunity. We should look closely at.