

WEBVTT

NOTE duration:"00:43:40"

NOTE recognizability:0.827

NOTE language:en-us

NOTE Confidence: 0.89862874111111

00:00:00.000 --> 00:00:03.080 Get this recorded so good

NOTE Confidence: 0.89862874111111

00:00:03.080 --> 00:00:05.544 morning and happy Tuesday.

NOTE Confidence: 0.89862874111111

00:00:05.550 --> 00:00:07.426 For those who know me and for

NOTE Confidence: 0.89862874111111

00:00:07.426 --> 00:00:09.670 those who don't, I am Tony too.

NOTE Confidence: 0.89862874111111

00:00:09.670 --> 00:00:11.830 I am your training and education

NOTE Confidence: 0.89862874111111

00:00:11.906 --> 00:00:14.510 project manager in the Yale Cancer

NOTE Confidence: 0.89862874111111

00:00:14.510 --> 00:00:17.510 Center's trial Operation Department.

NOTE Confidence: 0.89862874111111

00:00:17.510 --> 00:00:20.270 Sarah Ramona has asked that I

NOTE Confidence: 0.89862874111111

00:00:20.270 --> 00:00:22.753 present today's training on good

NOTE Confidence: 0.89862874111111

00:00:22.753 --> 00:00:24.981 documentation practices and I'm

NOTE Confidence: 0.89862874111111

00:00:24.981 --> 00:00:27.766 really excited about this topic.

NOTE Confidence: 0.89862874111111

00:00:27.770 --> 00:00:31.150 In my prior clinical work,

NOTE Confidence: 0.89862874111111

00:00:31.150 --> 00:00:34.150 I was the one inspecting the trials in

NOTE Confidence: 0.89862874111111

00:00:34.150 --> 00:00:37.166 the site binders in preparation for
NOTE Confidence: 0.898628741111111

00:00:37.166 --> 00:00:41.000 the FDA to be coming in to our office.
NOTE Confidence: 0.898628741111111

00:00:41.000 --> 00:00:45.536 So I hope that you enjoy the session,
NOTE Confidence: 0.898628741111111

00:00:45.540 --> 00:00:49.270 and I think we're going to learn a lot today.
NOTE Confidence: 0.898628741111111

00:00:49.270 --> 00:00:52.258 So our goal is at the end of today's
NOTE Confidence: 0.898628741111111

00:00:52.258 --> 00:00:55.457 training is for you to understand what
NOTE Confidence: 0.898628741111111

00:00:55.457 --> 00:00:57.317 are good documentation practices,
NOTE Confidence: 0.898628741111111

00:00:57.320 --> 00:00:59.620 the importance of capturing
NOTE Confidence: 0.898628741111111

00:00:59.620 --> 00:01:01.920 documentation and clinical research,
NOTE Confidence: 0.898628741111111

00:01:01.920 --> 00:01:03.876 how long to keep these records,
NOTE Confidence: 0.898628741111111

00:01:03.880 --> 00:01:06.610 and what is required when corrections
NOTE Confidence: 0.898628741111111

00:01:06.610 --> 00:01:09.801 and changes need to be made using
NOTE Confidence: 0.898628741111111

00:01:09.801 --> 00:01:11.946 the principles of Alcoa plus.
NOTE Confidence: 0.898628741111111

00:01:11.950 --> 00:01:14.560 And provide you with some source
NOTE Confidence: 0.898628741111111

00:01:14.560 --> 00:01:17.115 document tation examples to kind of
NOTE Confidence: 0.898628741111111

00:01:17.115 --> 00:01:18.807 give some further clarification.

NOTE Confidence: 0.8434865666666667
00:01:21.970 --> 00:01:23.089 So what are?
NOTE Confidence: 0.8302338775
00:01:26.310 --> 00:01:27.270 Just trying to get my
NOTE Confidence: 0.8302338775
00:01:27.270 --> 00:01:28.551 slide to advance, sorry.
NOTE Confidence: 0.8302338775
00:01:28.551 --> 00:01:32.757 So what are good documentation practices?
NOTE Confidence: 0.8302338775
00:01:32.760 --> 00:01:33.930 Good documentation practices?
NOTE Confidence: 0.8302338775
00:01:33.930 --> 00:01:37.449 They offer us a record for our DART teams,
NOTE Confidence: 0.8302338775
00:01:37.450 --> 00:01:42.688 auditors, the FDA to review so we can assure
NOTE Confidence: 0.8302338775
00:01:42.688 --> 00:01:46.790 our trials are that we I am stuttering.
NOTE Confidence: 0.8302338775
00:01:46.790 --> 00:01:51.515 I apologize, this is very early apparently,
NOTE Confidence: 0.8302338775
00:01:51.520 --> 00:01:53.338 but it provides our auditors and
NOTE Confidence: 0.8302338775
00:01:53.338 --> 00:01:55.551 the FDA so they can review our
NOTE Confidence: 0.8302338775
00:01:55.551 --> 00:01:58.185 documents to make sure that we are in
NOTE Confidence: 0.8302338775
00:01:58.185 --> 00:02:00.185 compliance with all the applicable.
NOTE Confidence: 0.8302338775
00:02:00.190 --> 00:02:02.752 Regulations it provides a snapshot of
NOTE Confidence: 0.8302338775
00:02:02.752 --> 00:02:04.968 everything that has happened throughout
NOTE Confidence: 0.8302338775

00:02:04.968 --> 00:02:07.578 the lifecycle of the clinical trial,
NOTE Confidence: 0.8302338775

00:02:07.580 --> 00:02:10.032 from beginning to end.
NOTE Confidence: 0.8302338775

00:02:10.032 --> 00:02:13.097 Failure to maintain adequate records,
NOTE Confidence: 0.8302338775

00:02:13.100 --> 00:02:15.522 it's one of the most common violations
NOTE Confidence: 0.8302338775

00:02:15.522 --> 00:02:18.778 cited in an FDA warning letters every year.
NOTE Confidence: 0.8302338775

00:02:18.780 --> 00:02:21.215 So therefore our documentation must
NOTE Confidence: 0.8302338775

00:02:21.215 --> 00:02:23.962 be accurate, concise, legible,
NOTE Confidence: 0.8302338775

00:02:23.962 --> 00:02:26.620 traceable, contemporaneous available
NOTE Confidence: 0.8302338775

00:02:26.620 --> 00:02:31.050 and accessible and during complete.
NOTE Confidence: 0.8302338775

00:02:31.050 --> 00:02:31.602 Consistent,
NOTE Confidence: 0.8302338775

00:02:31.602 --> 00:02:34.362 credible and cooperate and we're
NOTE Confidence: 0.8302338775

00:02:34.362 --> 00:02:37.380 going to be going through.
NOTE Confidence: 0.8302338775

00:02:37.380 --> 00:02:38.994 These Alcoa definitions,
NOTE Confidence: 0.8302338775

00:02:38.994 --> 00:02:41.684 later on in our presentation.
NOTE Confidence: 0.8631058

00:02:46.720 --> 00:02:48.235 To understand the importance
NOTE Confidence: 0.8631058

00:02:48.235 --> 00:02:49.935 of good source documentation,

NOTE Confidence: 0.8631058

00:02:49.940 --> 00:02:52.334 we need to review the purpose of

NOTE Confidence: 0.8631058

00:02:52.334 --> 00:02:54.004 good documentation practices.

NOTE Confidence: 0.8631058

00:02:54.004 --> 00:02:59.118 There are a key principles in the ICHGCP.

NOTE Confidence: 0.8631058

00:02:59.118 --> 00:03:01.986 It's being able to reconstruct the

NOTE Confidence: 0.8631058

00:03:01.986 --> 00:03:04.459 clinical trial as it happened.

NOTE Confidence: 0.8631058

00:03:04.460 --> 00:03:06.830 The importance of being able to

NOTE Confidence: 0.8631058

00:03:06.830 --> 00:03:10.462 do that is to make sure that our

NOTE Confidence: 0.8631058

00:03:10.462 --> 00:03:12.917 clinical data and our subjects

NOTE Confidence: 0.8631058

00:03:12.917 --> 00:03:15.957 safety are maintained at all times.

NOTE Confidence: 0.8631058

00:03:15.960 --> 00:03:19.360 It's accountability of our investigational

NOTE Confidence: 0.8631058

00:03:19.360 --> 00:03:21.872 of our investigational product.

NOTE Confidence: 0.8631058

00:03:21.872 --> 00:03:24.384 Accountability of subject recruitment,

NOTE Confidence: 0.8631058

00:03:24.390 --> 00:03:26.568 enrollment and participation.

NOTE Confidence: 0.880253844666667

00:03:32.370 --> 00:03:34.466 In research, the only thing that we can

NOTE Confidence: 0.880253844666667

00:03:34.466 --> 00:03:36.889 test to our efforts is the documentation.

NOTE Confidence: 0.880253844666667

00:03:36.890 --> 00:03:38.648 The Golden rule is if it.
NOTE Confidence: 0.880253844666667

00:03:38.650 --> 00:03:42.045 If it's not documented, it never happened,
NOTE Confidence: 0.880253844666667

00:03:42.050 --> 00:03:44.310 and that's very important.
NOTE Confidence: 0.880253844666667

00:03:44.310 --> 00:03:47.990 One of an inspection that we had.
NOTE Confidence: 0.880253844666667

00:03:47.990 --> 00:03:49.680 The inspector says we know
NOTE Confidence: 0.880253844666667

00:03:49.680 --> 00:03:51.370 that you have two meetings,
NOTE Confidence: 0.880253844666667

00:03:51.370 --> 00:03:52.830 but you're not capturing it.
NOTE Confidence: 0.880253844666667

00:03:52.830 --> 00:03:55.130 Where are your meeting notes?
NOTE Confidence: 0.880253844666667

00:03:55.130 --> 00:03:57.482 That was a huge red flag that we
NOTE Confidence: 0.880253844666667

00:03:57.482 --> 00:04:00.029 had to get resolved immediately,
NOTE Confidence: 0.880253844666667

00:04:00.030 --> 00:04:02.730 so it's it's remembering to
NOTE Confidence: 0.880253844666667

00:04:02.730 --> 00:04:04.446 document pretty much everything,
NOTE Confidence: 0.880253844666667

00:04:04.446 --> 00:04:06.798 anything and everything that happens on
NOTE Confidence: 0.880253844666667

00:04:06.798 --> 00:04:09.374 a clinical trial that may be needed in
NOTE Confidence: 0.880253844666667

00:04:09.374 --> 00:04:11.815 the future to tell the complete story
NOTE Confidence: 0.880253844666667

00:04:11.815 --> 00:04:15.256 of that clinical trial from beginning to end.

NOTE Confidence: 0.880253844666667
00:04:15.256 --> 00:04:17.708 This includes saving essential
NOTE Confidence: 0.880253844666667
00:04:17.708 --> 00:04:18.934 email correspondences.
NOTE Confidence: 0.880253844666667
00:04:18.940 --> 00:04:20.395 Between the sponsor,
NOTE Confidence: 0.880253844666667
00:04:20.395 --> 00:04:21.850 the site staff,
NOTE Confidence: 0.880253844666667
00:04:21.850 --> 00:04:24.298 the clinical research associate
NOTE Confidence: 0.880253844666667
00:04:24.298 --> 00:04:26.134 monitors the PII.
NOTE Confidence: 0.880253844666667
00:04:26.140 --> 00:04:27.612 The list goes on.
NOTE Confidence: 0.880253844666667
00:04:27.612 --> 00:04:29.820 If we don't save these email
NOTE Confidence: 0.880253844666667
00:04:29.900 --> 00:04:32.622 correspondence and we have to go back
NOTE Confidence: 0.880253844666667
00:04:32.622 --> 00:04:34.878 and trying to figure out what happened,
NOTE Confidence: 0.880253844666667
00:04:34.880 --> 00:04:37.816 that's the missing piece of the puzzle that
NOTE Confidence: 0.880253844666667
00:04:37.816 --> 00:04:41.000 we need to kind of clarify what happened.
NOTE Confidence: 0.880253844666667
00:04:41.000 --> 00:04:43.072 So we have to be able to
NOTE Confidence: 0.880253844666667
00:04:43.072 --> 00:04:43.960 document and explain.
NOTE Confidence: 0.880253844666667
00:04:43.960 --> 00:04:46.960 So when someone reads what is happening now,
NOTE Confidence: 0.880253844666667

00:04:46.960 --> 00:04:49.516 510, fifteen, 20 years from now.

NOTE Confidence: 0.880253844666667

00:04:49.520 --> 00:04:51.536 They know what is happening today.

NOTE Confidence: 0.99638057

00:04:54.280 --> 00:04:56.790 I also want to remind that email

NOTE Confidence: 0.99638057

00:04:56.790 --> 00:04:58.940 correspondence they can be audited.

NOTE Confidence: 0.99638057

00:04:58.940 --> 00:05:01.415 They can be used in a court of law

NOTE Confidence: 0.99638057

00:05:01.415 --> 00:05:03.918 as well as requested by the IRB.

NOTE Confidence: 0.99638057

00:05:03.920 --> 00:05:07.135 I had a study that the we

NOTE Confidence: 0.99638057

00:05:07.135 --> 00:05:08.910 received an amendment about six

NOTE Confidence: 0.99638057

00:05:08.910 --> 00:05:10.920 months late from the sponsor.

NOTE Confidence: 0.99638057

00:05:10.920 --> 00:05:14.160 It involved risk changes that

NOTE Confidence: 0.99638057

00:05:14.160 --> 00:05:16.752 was impacting subject safety.

NOTE Confidence: 0.99638057

00:05:16.760 --> 00:05:20.015 The IRB requested to see the email

NOTE Confidence: 0.99638057

00:05:20.015 --> 00:05:23.290 correspondence to show when we received them.

NOTE Confidence: 0.99638057

00:05:23.290 --> 00:05:24.544 From the sponsor.

NOTE Confidence: 0.99638057

00:05:24.544 --> 00:05:26.216 The amendment was submitted

NOTE Confidence: 0.99638057

00:05:26.216 --> 00:05:28.419 within 30 days of receiving

NOTE Confidence: 0.99638057

00:05:28.419 --> 00:05:30.609 the amendment from the sponsor,

NOTE Confidence: 0.99638057

00:05:30.610 --> 00:05:34.095 but the sponsor was late by six months,

NOTE Confidence: 0.99638057

00:05:34.095 --> 00:05:35.435 getting it to us.

NOTE Confidence: 0.6346715

00:05:42.470 --> 00:05:44.590 Here are some examples of some email

NOTE Confidence: 0.6346715

00:05:44.590 --> 00:05:46.630 correspondence is what should we say?

NOTE Confidence: 0.6346715

00:05:46.630 --> 00:05:47.770 What should not be saved?

NOTE Confidence: 0.6346715

00:05:47.770 --> 00:05:50.260 That is a very frequent question

NOTE Confidence: 0.6346715

00:05:50.260 --> 00:05:53.170 that pops up the letter on the

NOTE Confidence: 0.6346715

00:05:53.170 --> 00:05:57.010 left is about an SAE for our site

NOTE Confidence: 0.6346715

00:05:57.010 --> 00:06:00.125 about hyperthyroidism Grade 3 and

NOTE Confidence: 0.6346715

00:06:00.125 --> 00:06:03.479 being related within an attachment.

NOTE Confidence: 0.6346715

00:06:03.480 --> 00:06:05.360 So that should be, say,

NOTE Confidence: 0.6346715

00:06:05.360 --> 00:06:08.380 email correspondence on the right.

NOTE Confidence: 0.6346715

00:06:08.380 --> 00:06:10.925 It's basically asking and informing

NOTE Confidence: 0.6346715

00:06:10.925 --> 00:06:14.324 the monitors here on site and if

NOTE Confidence: 0.6346715

00:06:14.324 --> 00:06:17.012 they can enter time in the database

NOTE Confidence: 0.6346715

00:06:17.012 --> 00:06:19.400 and pick up the time later.

NOTE Confidence: 0.6346715

00:06:19.400 --> 00:06:20.412 That's something that doesn't

NOTE Confidence: 0.6346715

00:06:20.412 --> 00:06:21.424 need to be saved.

NOTE Confidence: 0.6346715

00:06:21.430 --> 00:06:23.642 That says that doesn't

NOTE Confidence: 0.6346715

00:06:23.642 --> 00:06:25.650 pertain to the protocol.

NOTE Confidence: 0.6346715

00:06:25.650 --> 00:06:28.350 The other thing when we're looking

NOTE Confidence: 0.6346715

00:06:28.350 --> 00:06:31.262 at email correspondences is to be

NOTE Confidence: 0.6346715

00:06:31.262 --> 00:06:34.154 able to read the email communication

NOTE Confidence: 0.6346715

00:06:34.234 --> 00:06:37.000 thoroughly and make sure that it's.

NOTE Confidence: 0.6346715

00:06:37.000 --> 00:06:41.200 That nothing inappropriate is in the email.

NOTE Confidence: 0.6346715

00:06:41.200 --> 00:06:42.046 If need be,

NOTE Confidence: 0.6346715

00:06:42.046 --> 00:06:44.440 reach out to the person and let them

NOTE Confidence: 0.6346715

00:06:44.440 --> 00:06:46.918 know that you're going to be sending

NOTE Confidence: 0.6346715

00:06:46.918 --> 00:06:49.294 them another email that they need to

NOTE Confidence: 0.6346715

00:06:49.294 --> 00:06:51.722 reply to because the first response

NOTE Confidence: 0.6346715
00:06:51.722 --> 00:06:54.577 that they provided us contains
NOTE Confidence: 0.6346715
00:06:54.577 --> 00:06:57.349 something that shouldn't be in there.
NOTE Confidence: 0.6346715
00:06:57.350 --> 00:06:59.373 I was talking with Sarah about this
NOTE Confidence: 0.6346715
00:06:59.373 --> 00:07:01.440 last week on the sponsor side when
NOTE Confidence: 0.6346715
00:07:01.440 --> 00:07:03.749 I worked when I was doing an audit,
NOTE Confidence: 0.6346715
00:07:03.750 --> 00:07:06.032 I was looking at the site communications
NOTE Confidence: 0.6346715
00:07:06.032 --> 00:07:08.937 and I came across and reading the email.
NOTE Confidence: 0.6346715
00:07:08.940 --> 00:07:10.980 The email contained pertinent information
NOTE Confidence: 0.6346715
00:07:10.980 --> 00:07:13.390 about the protocol and the sign,
NOTE Confidence: 0.6346715
00:07:13.390 --> 00:07:16.870 but in there it captured language
NOTE Confidence: 0.6346715
00:07:16.870 --> 00:07:19.607 between the study coordinator and
NOTE Confidence: 0.6346715
00:07:19.607 --> 00:07:22.360 PII about going out to dinner and
NOTE Confidence: 0.6346715
00:07:22.360 --> 00:07:24.710 dating and that obviously should not
NOTE Confidence: 0.6346715
00:07:24.710 --> 00:07:27.629 have been piled in the site Binder.
NOTE Confidence: 0.6346715
00:07:27.630 --> 00:07:30.780 So you really need to be able to go
NOTE Confidence: 0.6346715

00:07:30.780 --> 00:07:33.319 through and read and make sure what
NOTE Confidence: 0.6346715

00:07:33.319 --> 00:07:36.438 we are going to file is appropriate.
NOTE Confidence: 0.8770915

00:07:42.040 --> 00:07:46.144 Types of the relevant regulatory email
NOTE Confidence: 0.8770915

00:07:46.144 --> 00:07:49.876 correspondences that we should be saving.
NOTE Confidence: 0.8770915

00:07:49.880 --> 00:07:52.118 Is when the trial status changes
NOTE Confidence: 0.8770915

00:07:52.118 --> 00:07:54.999 when we go to open to accrual,
NOTE Confidence: 0.8770915

00:07:55.000 --> 00:07:57.345 when we go from open to accrual,
NOTE Confidence: 0.8770915

00:07:57.350 --> 00:07:58.514 to close to accrual,
NOTE Confidence: 0.8770915

00:07:58.514 --> 00:08:01.120 or when the study is suspended or terminated,
NOTE Confidence: 0.8770915

00:08:01.120 --> 00:08:04.279 we need to be able to keep those records.
NOTE Confidence: 0.8770915

00:08:04.280 --> 00:08:08.100 The sponsor NPI communications agendas,
NOTE Confidence: 0.8770915

00:08:08.100 --> 00:08:10.900 meetings, telephone call reports,
NOTE Confidence: 0.8770915

00:08:10.900 --> 00:08:13.000 agreements between organizations,
NOTE Confidence: 0.8770915

00:08:13.000 --> 00:08:15.286 and people that impact the study.
NOTE Confidence: 0.87813668

00:08:17.440 --> 00:08:19.213 Protocol violations and
NOTE Confidence: 0.87813668

00:08:19.213 --> 00:08:20.986 adverse event reporting.

NOTE Confidence: 0.905241115
00:08:23.210 --> 00:08:26.142 Communications with our medical
NOTE Confidence: 0.905241115
00:08:26.142 --> 00:08:29.374 monitors about an example of a
NOTE Confidence: 0.905241115
00:08:29.374 --> 00:08:31.428 subject that's not that's ineligible,
NOTE Confidence: 0.905241115
00:08:31.428 --> 00:08:33.976 but we're going to allow to continue
NOTE Confidence: 0.905241115
00:08:33.976 --> 00:08:36.546 to participate on the clinical trial.
NOTE Confidence: 0.905241115
00:08:36.550 --> 00:08:38.881 Those are key factors that we need
NOTE Confidence: 0.905241115
00:08:38.881 --> 00:08:41.701 to be able to document and be able
NOTE Confidence: 0.905241115
00:08:41.701 --> 00:08:44.410 to explain and tell the whole story.
NOTE Confidence: 0.905241115
00:08:44.410 --> 00:08:45.950 All these different points.
NOTE Confidence: 0.885294706
00:08:52.090 --> 00:08:55.500 Source data and source documents.
NOTE Confidence: 0.885294706
00:08:55.500 --> 00:08:57.965 Source documents are or the
NOTE Confidence: 0.885294706
00:08:57.965 --> 00:09:01.110 original documents or the data and
NOTE Confidence: 0.885294706
00:09:01.110 --> 00:09:03.490 records in electronic database.
NOTE Confidence: 0.885294706
00:09:03.490 --> 00:09:06.268 All the information and the records.
NOTE Confidence: 0.885294706
00:09:06.270 --> 00:09:08.640 Are certified copies of the original
NOTE Confidence: 0.885294706

00:09:08.640 --> 00:09:10.784 records of clinical findings, observations,
NOTE Confidence: 0.885294706

00:09:10.784 --> 00:09:14.168 or other activities in a clinical
NOTE Confidence: 0.885294706

00:09:14.168 --> 00:09:17.129 trial necessary for the reconstruction
NOTE Confidence: 0.885294706

00:09:17.129 --> 00:09:20.074 and reevaluation of the trial?
NOTE Confidence: 0.885294706

00:09:20.080 --> 00:09:22.236 So when we talk about source documents,
NOTE Confidence: 0.885294706

00:09:22.240 --> 00:09:26.144 just keep in mind it's the original document.
NOTE Confidence: 0.868885505454546

00:09:29.360 --> 00:09:33.048 Here on the right are examples of source
NOTE Confidence: 0.868885505454546

00:09:33.048 --> 00:09:36.432 documents for the ICHGCPE 6 regulations,
NOTE Confidence: 0.868885505454546

00:09:36.432 --> 00:09:39.252 subject files, subject Diaries,
NOTE Confidence: 0.868885505454546

00:09:39.252 --> 00:09:42.076 lab Notes, hospital records,
NOTE Confidence: 0.868885505454546

00:09:42.080 --> 00:09:43.772 patient questionnaires,
NOTE Confidence: 0.868885505454546

00:09:43.772 --> 00:09:47.156 the pharmacy dispensing records,
NOTE Confidence: 0.868885505454546

00:09:47.160 --> 00:09:50.570 all of this we have to make sure that we
NOTE Confidence: 0.868885505454546

00:09:50.664 --> 00:09:53.994 are using good documentation practices
NOTE Confidence: 0.868885505454546

00:09:53.994 --> 00:09:57.324 and maintaining these source documents.
NOTE Confidence: 0.868885505454546

00:09:57.330 --> 00:10:01.474 Records and reports the PII needs to

NOTE Confidence: 0.868885505454546
00:10:01.474 --> 00:10:04.026 ensure the accuracy, the legibility,
NOTE Confidence: 0.868885505454546
00:10:04.026 --> 00:10:06.354 the completeness and timeliness of the
NOTE Confidence: 0.868885505454546
00:10:06.354 --> 00:10:08.725 data reported to the sponsor in the case.
NOTE Confidence: 0.868885505454546
00:10:08.730 --> 00:10:13.049 Report forms and all other required reports.
NOTE Confidence: 0.868885505454546
00:10:13.050 --> 00:10:15.710 Data reported on the CRF that are
NOTE Confidence: 0.868885505454546
00:10:15.710 --> 00:10:18.280 derived from source documents should be
NOTE Confidence: 0.868885505454546
00:10:18.280 --> 00:10:20.992 consistent with the source documents or
NOTE Confidence: 0.868885505454546
00:10:20.992 --> 00:10:24.190 the discrepancies we need to be able to
NOTE Confidence: 0.868885505454546
00:10:24.190 --> 00:10:27.504 explain that if there is a change to the CRF,
NOTE Confidence: 0.868885505454546
00:10:27.510 --> 00:10:30.821 we need to make sure that we're
NOTE Confidence: 0.868885505454546
00:10:30.821 --> 00:10:33.070 following good documentation practices
NOTE Confidence: 0.868885505454546
00:10:33.070 --> 00:10:36.610 and making sure that the corrections
NOTE Confidence: 0.868885505454546
00:10:36.610 --> 00:10:38.808 were being able to date.
NOTE Confidence: 0.868885505454546
00:10:38.808 --> 00:10:41.445 When the correction is made, initial,
NOTE Confidence: 0.868885505454546
00:10:41.445 --> 00:10:44.415 explain why a correction was made.
NOTE Confidence: 0.868885505454546

00:10:44.420 --> 00:10:47.010 Making sure that the original entry we
NOTE Confidence: 0.868885505454546

00:10:47.010 --> 00:10:49.371 can still read through the correction.
NOTE Confidence: 0.868885505454546

00:10:49.371 --> 00:10:52.990 And has to be able to be audited
NOTE Confidence: 0.868885505454546

00:10:52.990 --> 00:10:56.017 and to be able to to explain the
NOTE Confidence: 0.868885505454546

00:10:56.017 --> 00:10:57.525 difference between the original
NOTE Confidence: 0.868885505454546

00:10:57.525 --> 00:10:59.033 entry and the correction.
NOTE Confidence: 0.470940953333333

00:11:05.470 --> 00:11:09.238 Note to files. No to files are
NOTE Confidence: 0.470940953333333

00:11:09.238 --> 00:11:10.666 allowed in clinical research.
NOTE Confidence: 0.470940953333333

00:11:10.670 --> 00:11:13.374 We just need to be very careful and
NOTE Confidence: 0.470940953333333

00:11:13.374 --> 00:11:15.777 cautious that we don't use too many
NOTE Confidence: 0.470940953333333

00:11:15.777 --> 00:11:17.920 notice files on a clinical trial,
NOTE Confidence: 0.470940953333333

00:11:17.920 --> 00:11:20.769 because that can raise a red flag
NOTE Confidence: 0.470940953333333

00:11:20.770 --> 00:11:23.452 to an inspector when auditor that
NOTE Confidence: 0.470940953333333

00:11:23.452 --> 00:11:26.349 something here is just not right or
NOTE Confidence: 0.470940953333333

00:11:26.349 --> 00:11:29.720 going on and then they start to dig a
NOTE Confidence: 0.470940953333333

00:11:29.720 --> 00:11:32.600 little bit further to find out more.

NOTE Confidence: 0.47094095333333
00:11:32.600 --> 00:11:34.598 If there's something else that they
NOTE Confidence: 0.47094095333333
00:11:34.598 --> 00:11:36.980 need to be looking at for findings.
NOTE Confidence: 0.47094095333333
00:11:36.980 --> 00:11:39.948 It's also not a replacement or substitute
NOTE Confidence: 0.47094095333333
00:11:39.948 --> 00:11:42.719 for notifying the IRB or notify Isles.
NOTE Confidence: 0.47094095333333
00:11:42.719 --> 00:11:45.137 It should allow us to document
NOTE Confidence: 0.47094095333333
00:11:45.137 --> 00:11:47.679 and clarify an error omission.
NOTE Confidence: 0.47094095333333
00:11:47.680 --> 00:11:50.320 A discrepancy in the research to
NOTE Confidence: 0.47094095333333
00:11:50.320 --> 00:11:53.629 document a problem or corrective action.
NOTE Confidence: 0.923246057142857
00:11:56.160 --> 00:11:57.609 When we do the note to files,
NOTE Confidence: 0.923246057142857
00:11:57.610 --> 00:12:00.826 it should include the root cause.
NOTE Confidence: 0.923246057142857
00:12:00.830 --> 00:12:04.708 The Kappa plan is the Kappa plan.
NOTE Confidence: 0.923246057142857
00:12:04.710 --> 00:12:09.694 Did it resolve the discrepancy in the issue?
NOTE Confidence: 0.923246057142857
00:12:09.700 --> 00:12:11.814 And where should we be filing these
NOTE Confidence: 0.923246057142857
00:12:11.814 --> 00:12:14.198 note to files if it's steady related,
NOTE Confidence: 0.923246057142857
00:12:14.200 --> 00:12:16.076 it needs to go in the study
NOTE Confidence: 0.923246057142857

00:12:16.076 --> 00:12:17.660 Binder where it's relevant to.

NOTE Confidence: 0.923246057142857

00:12:17.660 --> 00:12:20.999 If it's related to a study participant,

NOTE Confidence: 0.923246057142857

00:12:21.000 --> 00:12:23.340 then it should go with the

NOTE Confidence: 0.923246057142857

00:12:23.340 --> 00:12:24.510 participant study records.

NOTE Confidence: 0.845209394

00:12:30.680 --> 00:12:32.810 Here again, it's covering when to

NOTE Confidence: 0.845209394

00:12:32.810 --> 00:12:35.717 use and not to use a note to file.

NOTE Confidence: 0.845209394

00:12:35.720 --> 00:12:39.760 We cannot emphasize this enough.

NOTE Confidence: 0.845209394

00:12:39.760 --> 00:12:42.714 So. To use a note to file,

NOTE Confidence: 0.845209394

00:12:42.720 --> 00:12:46.647 its to clarify or add additional information.

NOTE Confidence: 0.845209394

00:12:46.650 --> 00:12:49.245 It might be clarifying why

NOTE Confidence: 0.845209394

00:12:49.245 --> 00:12:52.730 a subject was out of window.

NOTE Confidence: 0.845209394

00:12:52.730 --> 00:12:54.575 Clarifying information related

NOTE Confidence: 0.845209394

00:12:54.575 --> 00:12:57.035 to the source documents.

NOTE Confidence: 0.845209394

00:12:57.040 --> 00:12:59.245 It's record any discrepancy that

NOTE Confidence: 0.845209394

00:12:59.245 --> 00:13:01.450 applies to a single participant

NOTE Confidence: 0.845209394

00:13:01.522 --> 00:13:03.862 or multiple participants that are

NOTE Confidence: 0.845209394

00:13:03.862 --> 00:13:06.202 participating in a clinical trial.

NOTE Confidence: 0.905215524444444

00:13:09.940 --> 00:13:12.802 Again, when not to use a note to file,

NOTE Confidence: 0.905215524444444

00:13:12.810 --> 00:13:15.995 we don't use it as a replacement

NOTE Confidence: 0.905215524444444

00:13:15.995 --> 00:13:17.820 for notifying the IRB.

NOTE Confidence: 0.905215524444444

00:13:17.820 --> 00:13:19.948 And we don't use it for adverse

NOTE Confidence: 0.905215524444444

00:13:19.948 --> 00:13:21.350 or serious adverse events.

NOTE Confidence: 0.850193527142857

00:13:24.400 --> 00:13:26.780 An example of a note to file.

NOTE Confidence: 0.850193527142857

00:13:26.780 --> 00:13:29.468 This one is talking about that there

NOTE Confidence: 0.850193527142857

00:13:29.468 --> 00:13:32.064 was a clinical research personnel

NOTE Confidence: 0.850193527142857

00:13:32.064 --> 00:13:35.712 that was participating on a study.

NOTE Confidence: 0.850193527142857

00:13:35.720 --> 00:13:37.976 And was added to this trial,

NOTE Confidence: 0.850193527142857

00:13:37.980 --> 00:13:40.800 but was added in error.

NOTE Confidence: 0.850193527142857

00:13:40.800 --> 00:13:42.880 And then they're going to

NOTE Confidence: 0.850193527142857

00:13:42.880 --> 00:13:45.410 be removed off of the DOA.

NOTE Confidence: 0.897163702222222

00:13:48.170 --> 00:13:50.599 So in this example, this is very

NOTE Confidence: 0.897163702222222

00:13:50.599 --> 00:13:52.783 appropriate to have a note to
NOTE Confidence: 0.897163702222222

00:13:52.783 --> 00:13:54.573 file to explain that discrepancy.
NOTE Confidence: 0.9072250228

00:13:57.970 --> 00:13:59.998 Clinical trial documents that we need
NOTE Confidence: 0.9072250228

00:13:59.998 --> 00:14:02.651 to be making sure that we're paying
NOTE Confidence: 0.9072250228

00:14:02.651 --> 00:14:05.123 attention to for our good documentation
NOTE Confidence: 0.9072250228

00:14:05.123 --> 00:14:07.318 practices is our pre study activities,
NOTE Confidence: 0.9072250228

00:14:07.320 --> 00:14:10.880 site selection communication feasibility.
NOTE Confidence: 0.9072250228

00:14:10.880 --> 00:14:17.102 Why a site may not or should be feasible
NOTE Confidence: 0.9072250228

00:14:17.102 --> 00:14:20.440 to participate meeting minutes?
NOTE Confidence: 0.9072250228

00:14:20.440 --> 00:14:24.740 Study initiation the DOA.
NOTE Confidence: 0.9072250228

00:14:24.740 --> 00:14:27.280 Review of the protocol.
NOTE Confidence: 0.9072250228

00:14:27.280 --> 00:14:29.560 Our training activities making
NOTE Confidence: 0.9072250228

00:14:29.560 --> 00:14:32.980 sure that we are capturing and
NOTE Confidence: 0.9072250228

00:14:33.081 --> 00:14:36.286 filing and documenting the city,
NOTE Confidence: 0.9072250228

00:14:36.286 --> 00:14:38.578 training the medical licenses,
NOTE Confidence: 0.9072250228

00:14:38.580 --> 00:14:40.532 the Protocol Pacific training.

NOTE Confidence: 0.9072250228

00:14:40.532 --> 00:14:43.460 I'm reading of the particular asopis.

NOTE Confidence: 0.9072250228

00:14:43.460 --> 00:14:45.446 All of that needs to be

NOTE Confidence: 0.9072250228

00:14:45.446 --> 00:14:46.439 maintained and documented.

NOTE Confidence: 0.9072250228

00:14:46.440 --> 00:14:48.644 Using good documentation practices.

NOTE Confidence: 0.9072250228

00:14:48.644 --> 00:14:50.848 Communication with the subject.

NOTE Confidence: 0.9072250228

00:14:50.850 --> 00:14:53.318 The sponsor, the IRB,

NOTE Confidence: 0.9072250228

00:14:53.318 --> 00:14:56.403 the FDA informed consent process.

NOTE Confidence: 0.9072250228

00:14:56.410 --> 00:14:58.874 Individual documentation for all

NOTE Confidence: 0.9072250228

00:14:58.874 --> 00:15:01.338 subjects and protocol activities.

NOTE Confidence: 0.73357262

00:15:04.340 --> 00:15:06.926 At first events serious adverse events,

NOTE Confidence: 0.73357262

00:15:06.930 --> 00:15:09.840 unanticipated problems, deviations.

NOTE Confidence: 0.73357262

00:15:09.840 --> 00:15:13.720 When deviations are happening,

NOTE Confidence: 0.73357262

00:15:13.720 --> 00:15:15.660 we should be asking ourselves

NOTE Confidence: 0.73357262

00:15:15.660 --> 00:15:17.600 should the protocol be amended.

NOTE Confidence: 0.73357262

00:15:17.600 --> 00:15:20.030 Should the aesopi be revised?

NOTE Confidence: 0.901510993125

00:15:23.210 --> 00:15:25.874 With deviations we need to make
NOTE Confidence: 0.901510993125

00:15:25.874 --> 00:15:28.265 sure that we're smoothing according
NOTE Confidence: 0.901510993125

00:15:28.265 --> 00:15:30.925 to the IRB reporting timelines.
NOTE Confidence: 0.901510993125

00:15:30.930 --> 00:15:33.560 The Protocol and regulatory deviations
NOTE Confidence: 0.901510993125

00:15:33.560 --> 00:15:37.857 we need to be making sure that we're
NOTE Confidence: 0.901510993125

00:15:37.857 --> 00:15:41.007 really looking at at that thoroughly.
NOTE Confidence: 0.901510993125

00:15:41.010 --> 00:15:43.738 The P needs to assess the reason for
NOTE Confidence: 0.901510993125

00:15:43.738 --> 00:15:46.502 the deviation in real time and assess
NOTE Confidence: 0.901510993125

00:15:46.502 --> 00:15:48.512 the potential risk to participants.
NOTE Confidence: 0.859003542

00:15:51.020 --> 00:15:53.460 Corrective and preventive action plans.
NOTE Confidence: 0.859003542

00:15:53.460 --> 00:15:55.970 Being able to capture the
NOTE Confidence: 0.859003542

00:15:55.970 --> 00:15:57.476 deviation from reoccurring.
NOTE Confidence: 0.859003542

00:15:57.480 --> 00:15:59.560 Documenting the implementation of the
NOTE Confidence: 0.859003542

00:15:59.560 --> 00:16:02.089 Kappa and remember to follow up on.
NOTE Confidence: 0.88985696

00:16:05.480 --> 00:16:07.820 One thing when we were looking
NOTE Confidence: 0.88985696

00:16:07.820 --> 00:16:09.830 at deviations is when something

NOTE Confidence: 0.88985696

00:16:09.830 --> 00:16:13.260 is reported is to kind of take a

NOTE Confidence: 0.88985696

00:16:13.260 --> 00:16:16.314 wider scope and determine was it

NOTE Confidence: 0.88985696

00:16:16.314 --> 00:16:18.396 only one patient that was impacted,

NOTE Confidence: 0.88985696

00:16:18.400 --> 00:16:20.668 or were there there other patients

NOTE Confidence: 0.88985696

00:16:20.668 --> 00:16:23.083 or subjects that were impacted on

NOTE Confidence: 0.88985696

00:16:23.083 --> 00:16:25.879 the clinical trial? As well as.

NOTE Confidence: 0.88985696

00:16:25.879 --> 00:16:27.418 Could this event?

NOTE Confidence: 0.88985696

00:16:27.420 --> 00:16:29.820 Is it also occurring on additional

NOTE Confidence: 0.88985696

00:16:29.820 --> 00:16:30.620 clinical trials?

NOTE Confidence: 0.88985696

00:16:30.620 --> 00:16:32.776 So those are questions that we need

NOTE Confidence: 0.88985696

00:16:32.776 --> 00:16:35.944 to be asking in regulatory when we are

NOTE Confidence: 0.88985696

00:16:35.944 --> 00:16:37.684 reviewing deviations and reporting.

NOTE Confidence: 0.9505497

00:16:43.390 --> 00:16:45.930 Documentation of PII oversight

NOTE Confidence: 0.9505497

00:16:45.930 --> 00:16:49.816 with the ES este ES and the

NOTE Confidence: 0.9505497

00:16:49.816 --> 00:16:52.188 anticipated problems is reviewing

NOTE Confidence: 0.9505497

00:16:52.188 --> 00:16:53.967 the eligibility criteria,
NOTE Confidence: 0.9505497

00:16:53.970 --> 00:16:56.665 review of lab and other protocol procedures.
NOTE Confidence: 0.9505497

00:16:56.670 --> 00:16:58.800 Results subject accountability,
NOTE Confidence: 0.9505497

00:16:58.800 --> 00:17:00.220 enrollment logs.
NOTE Confidence: 0.845038928888889

00:17:02.700 --> 00:17:05.280 Drug Accountability progress notes.
NOTE Confidence: 0.845038928888889

00:17:05.280 --> 00:17:08.505 Review of case report forms.
NOTE Confidence: 0.845038928888889

00:17:08.510 --> 00:17:10.508 Documentation of sponsor
NOTE Confidence: 0.845038928888889

00:17:10.508 --> 00:17:12.506 investigator over sign.
NOTE Confidence: 0.845038928888889

00:17:12.510 --> 00:17:14.229 Monitoring the responsibilities
NOTE Confidence: 0.845038928888889

00:17:14.229 --> 00:17:17.094 and communication with other sites.
NOTE Confidence: 0.756946441666667

00:17:21.280 --> 00:17:25.456 Our good documentation practices always use
NOTE Confidence: 0.756946441666667

00:17:25.460 --> 00:17:27.899 if it's in a paper form and we're using.
NOTE Confidence: 0.728488236

00:17:30.020 --> 00:17:32.640 Always use an ink pad.
NOTE Confidence: 0.728488236

00:17:32.640 --> 00:17:35.668 Black and Blues preferred.
NOTE Confidence: 0.728488236

00:17:35.670 --> 00:17:39.126 Try to always avoid or never use gel pens,
NOTE Confidence: 0.728488236

00:17:39.130 --> 00:17:41.086 or with erasable ink.

NOTE Confidence: 0.728488236
00:17:41.086 --> 00:17:43.531 Never used whiteout or corrective
NOTE Confidence: 0.728488236
00:17:43.531 --> 00:17:45.803 tape for corrections if you
NOTE Confidence: 0.728488236
00:17:45.803 --> 00:17:48.347 do need to make a correction,
NOTE Confidence: 0.728488236
00:17:48.350 --> 00:17:52.678 you need to make sure that we're following.
NOTE Confidence: 0.833417933636364
00:17:55.580 --> 00:17:57.518 Being able to.
NOTE Confidence: 0.833417933636364
00:17:57.518 --> 00:18:01.394 Do a strikethrough through the error
NOTE Confidence: 0.833417933636364
00:18:01.394 --> 00:18:05.420 in making a note and initialing
NOTE Confidence: 0.833417933636364
00:18:05.420 --> 00:18:10.108 and dating it for the correction.
NOTE Confidence: 0.833417933636364
00:18:10.110 --> 00:18:11.951 We need to make sure that we're
NOTE Confidence: 0.833417933636364
00:18:11.951 --> 00:18:13.036 signing initialing dating entries
NOTE Confidence: 0.833417933636364
00:18:13.036 --> 00:18:14.536 at the time that they're made.
NOTE Confidence: 0.814009154285714
00:18:17.190 --> 00:18:20.442 So that way those entries are
NOTE Confidence: 0.814009154285714
00:18:20.442 --> 00:18:21.726 contemporaneous date entries
NOTE Confidence: 0.814009154285714
00:18:21.726 --> 00:18:23.934 must be signed or initialed by
NOTE Confidence: 0.814009154285714
00:18:23.934 --> 00:18:25.969 the person entering the data.
NOTE Confidence: 0.814009154285714

00:18:25.970 --> 00:18:29.760 And interest must remain legible.

NOTE Confidence: 0.814009154285714

00:18:29.760 --> 00:18:32.301 Don't go back and post or pre

NOTE Confidence: 0.814009154285714

00:18:32.301 --> 00:18:34.848 date don't keep any blank spaces.

NOTE Confidence: 0.814009154285714

00:18:34.850 --> 00:18:36.887 If there's a space on the form

NOTE Confidence: 0.814009154285714

00:18:36.887 --> 00:18:38.689 that needs to be completed.

NOTE Confidence: 0.814009154285714

00:18:38.690 --> 00:18:40.916 It needs to go ahead and be

NOTE Confidence: 0.814009154285714

00:18:40.916 --> 00:18:42.370 completed in that field.

NOTE Confidence: 0.814009154285714

00:18:42.370 --> 00:18:44.138 Don't use Ditto symbols.

NOTE Confidence: 0.814009154285714

00:18:44.138 --> 00:18:45.464 Never use pencils.

NOTE Confidence: 0.919731417142857

00:18:48.140 --> 00:18:50.486 And most important, don't use sticky

NOTE Confidence: 0.919731417142857

00:18:50.486 --> 00:18:54.040 notes to record data or information.

NOTE Confidence: 0.919731417142857

00:18:54.040 --> 00:18:56.376 One of the sites that I was auditing

NOTE Confidence: 0.919731417142857

00:18:56.376 --> 00:18:59.024 on I came across multiple sticky

NOTE Confidence: 0.919731417142857

00:18:59.024 --> 00:19:01.016 notes throughout the clinical

NOTE Confidence: 0.919731417142857

00:19:01.016 --> 00:19:03.120 trial and you know, I was.

NOTE Confidence: 0.919731417142857

00:19:03.120 --> 00:19:04.000 I was pulling, you know,

NOTE Confidence: 0.919731417142857
00:19:04.000 --> 00:19:06.376 the sticky note off at the the documents.

NOTE Confidence: 0.919731417142857
00:19:06.380 --> 00:19:08.606 Like why does this in reference

NOTE Confidence: 0.919731417142857
00:19:08.606 --> 00:19:10.090 to who wrote it?

NOTE Confidence: 0.919731417142857
00:19:10.090 --> 00:19:13.666 No one could could answer or explain it.

NOTE Confidence: 0.919731417142857
00:19:13.670 --> 00:19:15.290 Those bring up red flags

NOTE Confidence: 0.919731417142857
00:19:15.290 --> 00:19:16.586 and an audit situation.

NOTE Confidence: 0.919731417142857
00:19:16.590 --> 00:19:18.065 Those are things that we

NOTE Confidence: 0.919731417142857
00:19:18.065 --> 00:19:19.540 don't want to be able.

NOTE Confidence: 0.91984238125
00:19:21.730 --> 00:19:23.834 To be in a pickle with the FDA.

NOTE Confidence: 0.732342062
00:19:28.020 --> 00:19:30.175 So for good documentation practices

NOTE Confidence: 0.732342062
00:19:30.175 --> 00:19:33.489 we use a term called ECHO Applause.

NOTE Confidence: 0.732342062
00:19:33.490 --> 00:19:36.948 So for Alcoa its meaning its attributable,

NOTE Confidence: 0.732342062
00:19:36.950 --> 00:19:39.062 legible, contemporaneous,

NOTE Confidence: 0.732342062
00:19:39.062 --> 00:19:42.230 original, accurate, complete,

NOTE Confidence: 0.732342062
00:19:42.230 --> 00:19:47.640 consistent, enduring in. Available.

NOTE Confidence: 0.732342062

00:19:47.640 --> 00:19:50.532 If we follow these sets of
NOTE Confidence: 0.732342062

00:19:50.532 --> 00:19:51.978 good documentation practices,
NOTE Confidence: 0.732342062

00:19:51.980 --> 00:19:54.290 that can make sure that.
NOTE Confidence: 0.732342062

00:19:54.290 --> 00:19:57.146 We aren't creating things and entering
NOTE Confidence: 0.732342062

00:19:57.146 --> 00:20:00.368 things on time when they should be.
NOTE Confidence: 0.732342062

00:20:00.370 --> 00:20:02.550 We're making sure that it's
NOTE Confidence: 0.732342062

00:20:02.550 --> 00:20:04.294 attributable and identifiable to
NOTE Confidence: 0.732342062

00:20:04.294 --> 00:20:06.374 the person that recorded the data.
NOTE Confidence: 0.732342062

00:20:06.374 --> 00:20:09.708 So when we look at a document or data entry,
NOTE Confidence: 0.732342062

00:20:09.710 --> 00:20:11.926 we should be able to tie it back
NOTE Confidence: 0.732342062

00:20:11.926 --> 00:20:14.276 to the person that created that
NOTE Confidence: 0.732342062

00:20:14.276 --> 00:20:16.436 document or created that entry.
NOTE Confidence: 0.92992327875

00:20:19.710 --> 00:20:22.594 So we need to make sure that
NOTE Confidence: 0.92992327875

00:20:22.594 --> 00:20:24.910 overall it's attributable
NOTE Confidence: 0.92992327875

00:20:24.910 --> 00:20:26.626 dates and document versions.
NOTE Confidence: 0.92992327875

00:20:26.626 --> 00:20:28.771 Make sure that for dates

NOTE Confidence: 0.92992327875
00:20:28.771 --> 00:20:30.970 we include the full year.
NOTE Confidence: 0.92992327875
00:20:30.970 --> 00:20:33.706 We don't want to use a partial year.
NOTE Confidence: 0.92992327875
00:20:33.710 --> 00:20:37.220 It was when we switched over to
NOTE Confidence: 0.878948424285714
00:20:39.430 --> 00:20:43.746 2021. I remember last year there was no.
NOTE Confidence: 0.878948424285714
00:20:43.746 --> 00:20:46.450 Don't just use like.
NOTE Confidence: 0.878948424285714
00:20:46.450 --> 00:20:49.096 Ten 12:20 if someone could go back
NOTE Confidence: 0.878948424285714
00:20:49.096 --> 00:20:51.797 and fill in the last two years
NOTE Confidence: 0.878948424285714
00:20:51.797 --> 00:20:54.722 of making it maybe 2019 or 2018,
NOTE Confidence: 0.878948424285714
00:20:54.722 --> 00:20:59.570 when actually it's 2021. So.
NOTE Confidence: 0.878948424285714
00:20:59.570 --> 00:21:02.153 We do have a set clear form
NOTE Confidence: 0.878948424285714
00:21:02.153 --> 00:21:04.610 and how dates are formatted,
NOTE Confidence: 0.878948424285714
00:21:04.610 --> 00:21:06.899 making sure that there are version dates
NOTE Confidence: 0.878948424285714
00:21:06.899 --> 00:21:09.189 and numbers in the document footers.
NOTE Confidence: 0.878948424285714
00:21:09.190 --> 00:21:10.000 That's important,
NOTE Confidence: 0.878948424285714
00:21:10.000 --> 00:21:12.025 so our clinical research team.
NOTE Confidence: 0.878948424285714

00:21:12.030 --> 00:21:13.870 We know which protocol version.

NOTE Confidence: 0.878948424285714

00:21:13.870 --> 00:21:15.130 Which consent version that

NOTE Confidence: 0.878948424285714

00:21:15.130 --> 00:21:16.705 we are working off that.

NOTE Confidence: 0.878948424285714

00:21:16.710 --> 00:21:18.440 So there is no confusion.

NOTE Confidence: 0.90510537

00:21:21.300 --> 00:21:24.560 Examples of incorrect written dates.

NOTE Confidence: 0.90510537

00:21:24.560 --> 00:21:27.120 The top example here is a mixture of

NOTE Confidence: 0.90510537

00:21:27.120 --> 00:21:30.006 written and typed dates and all the

NOTE Confidence: 0.90510537

00:21:30.006 --> 00:21:32.898 dates are have a sequential order.

NOTE Confidence: 0.90510537

00:21:32.900 --> 00:21:35.100 In the bottom example,

NOTE Confidence: 0.90510537

00:21:35.100 --> 00:21:38.400 the end date is not legible.

NOTE Confidence: 0.90510537

00:21:38.400 --> 00:21:41.790 Is that? 930 eighteen.

NOTE Confidence: 0.90510537

00:21:41.790 --> 00:21:45.566 Is that a seven? Is it a four?

NOTE Confidence: 0.90510537

00:21:45.566 --> 00:21:47.810 I can't make out the month.

NOTE Confidence: 0.90510537

00:21:47.810 --> 00:21:49.976 And then the bottom the PRI

NOTE Confidence: 0.90510537

00:21:49.976 --> 00:21:52.597 initialed for a no date on a DOA.

NOTE Confidence: 0.936830403

00:21:55.230 --> 00:21:57.946 So those were things that would have

NOTE Confidence: 0.936830403

00:21:57.946 --> 00:22:00.838 to be explained in an audit situation.

NOTE Confidence: 0.772189551666667

00:22:04.220 --> 00:22:06.620 Can you sign for the Pi?

NOTE Confidence: 0.772189551666667

00:22:06.620 --> 00:22:09.196 No, you can't sign for the Pi.

NOTE Confidence: 0.772189551666667

00:22:09.200 --> 00:22:13.112 No one can sign for the Pi if you if someone

NOTE Confidence: 0.772189551666667

00:22:13.112 --> 00:22:15.639 asks you that you need to tell them no.

NOTE Confidence: 0.772189551666667

00:22:15.640 --> 00:22:18.720 Only the Pi can sign for themselves.

NOTE Confidence: 0.772189551666667

00:22:18.720 --> 00:22:21.036 I actually had a study coordinator

NOTE Confidence: 0.772189551666667

00:22:21.036 --> 00:22:23.862 reached out to me wanting to complete

NOTE Confidence: 0.772189551666667

00:22:23.862 --> 00:22:26.669 the Pi city training on his behalf

NOTE Confidence: 0.772189551666667

00:22:26.746 --> 00:22:29.050 because the Pi was on vacation.

NOTE Confidence: 0.772189551666667

00:22:29.050 --> 00:22:30.730 And I was like, no,

NOTE Confidence: 0.772189551666667

00:22:30.730 --> 00:22:33.418 we cannot do that.

NOTE Confidence: 0.772189551666667

00:22:33.420 --> 00:22:35.592 They asked if they could change

NOTE Confidence: 0.772189551666667

00:22:35.592 --> 00:22:37.886 the training to the piece personal

NOTE Confidence: 0.772189551666667

00:22:37.886 --> 00:22:40.190 email address and we came back

NOTE Confidence: 0.772189551666667

00:22:40.190 --> 00:22:42.928 and said no because with his IWRS
NOTE Confidence: 0.772189551666667

00:22:42.928 --> 00:22:44.908 account and everything else that
NOTE Confidence: 0.772189551666667

00:22:44.908 --> 00:22:47.137 was setting up for the training,
NOTE Confidence: 0.772189551666667

00:22:47.140 --> 00:22:49.330 it had to be 1 consistent
NOTE Confidence: 0.772189551666667

00:22:49.330 --> 00:22:51.770 email which was his work email.
NOTE Confidence: 0.8431572

00:22:55.570 --> 00:22:58.845 The P though, can delegate appropriate
NOTE Confidence: 0.8431572

00:22:58.845 --> 00:23:01.960 task to study team members.
NOTE Confidence: 0.8431572

00:23:01.960 --> 00:23:03.840 In order to do that,
NOTE Confidence: 0.8431572

00:23:03.840 --> 00:23:06.792 the P is going to make sure that they
NOTE Confidence: 0.8431572

00:23:06.792 --> 00:23:09.288 are trained and they are appropriate
NOTE Confidence: 0.8431572

00:23:09.288 --> 00:23:12.500 for this task to be delegated to,
NOTE Confidence: 0.8431572

00:23:12.500 --> 00:23:15.428 though when that happens you must
NOTE Confidence: 0.8431572

00:23:15.428 --> 00:23:19.124 sign your own name, not the PI's name.
NOTE Confidence: 0.8431572

00:23:19.124 --> 00:23:22.990 And if you're not delegated to do something.
NOTE Confidence: 0.8431572

00:23:22.990 --> 00:23:24.436 You should not be doing it.
NOTE Confidence: 0.80862824

00:23:28.580 --> 00:23:30.765 When we're working with good

NOTE Confidence: 0.80862824
00:23:30.765 --> 00:23:31.639 documentation practices,
NOTE Confidence: 0.80862824
00:23:31.640 --> 00:23:34.360 we need to make sure things are legible.
NOTE Confidence: 0.80862824
00:23:34.360 --> 00:23:36.576 That means that we're able to read it.
NOTE Confidence: 0.80862824
00:23:36.580 --> 00:23:38.662 Clearly, it's preserved.
NOTE Confidence: 0.80862824
00:23:38.662 --> 00:23:42.826 It's recorded in a durable way.
NOTE Confidence: 0.80862824
00:23:42.830 --> 00:23:46.110 Entries should not be obscured.
NOTE Confidence: 0.80862824
00:23:46.110 --> 00:23:47.706 We're going to use a strikethrough
NOTE Confidence: 0.80862824
00:23:47.706 --> 00:23:50.114 with a single line, initial date,
NOTE Confidence: 0.80862824
00:23:50.114 --> 00:23:54.146 and add an explanation if needed.
NOTE Confidence: 0.80862824
00:23:54.150 --> 00:23:57.382 Here are examples of.
NOTE Confidence: 0.80862824
00:23:57.382 --> 00:23:58.190 Corrections.
NOTE Confidence: 0.80862824
00:23:58.190 --> 00:24:00.138 Got earned, not legible.
NOTE Confidence: 0.831954782857143
00:24:03.440 --> 00:24:07.164 If we're reading in the top example.
NOTE Confidence: 0.831954782857143
00:24:07.170 --> 00:24:10.145 There aren't reasons why there's
NOTE Confidence: 0.831954782857143
00:24:10.145 --> 00:24:13.086 a cross through. And I can not
NOTE Confidence: 0.831954782857143

00:24:13.086 --> 00:24:14.820 sure what the year dates are.

NOTE Confidence: 0.908388828888889

00:24:17.650 --> 00:24:19.774 And it looks like maybe there is a reason,

NOTE Confidence: 0.908388828888889

00:24:19.780 --> 00:24:22.132 but I'm really not quite sure what

NOTE Confidence: 0.908388828888889

00:24:22.132 --> 00:24:24.678 that entry is in this example here.

NOTE Confidence: 0.817792024

00:24:26.750 --> 00:24:29.550 In the bottom bottom example,

NOTE Confidence: 0.817792024

00:24:29.550 --> 00:24:31.850 the resident the regulatory designate

NOTE Confidence: 0.817792024

00:24:31.850 --> 00:24:35.269 typed in a date into the DOA page.

NOTE Confidence: 0.817792024

00:24:35.270 --> 00:24:37.280 There's not an initial update

NOTE Confidence: 0.817792024

00:24:37.280 --> 00:24:38.486 with correction change,

NOTE Confidence: 0.817792024

00:24:38.490 --> 00:24:40.426 it's a scan. Document,

NOTE Confidence: 0.817792024

00:24:40.426 --> 00:24:44.110 which also down here at the bottom.

NOTE Confidence: 0.817792024

00:24:44.110 --> 00:24:46.894 And cut off the PI's initials

NOTE Confidence: 0.817792024

00:24:46.894 --> 00:24:49.460 for the study in dates.

NOTE Confidence: 0.817792024

00:24:49.460 --> 00:24:51.357 So if you are scanning a document

NOTE Confidence: 0.817792024

00:24:51.357 --> 00:24:53.360 in to a permanent record,

NOTE Confidence: 0.817792024

00:24:53.360 --> 00:24:55.145 you need to double check that the

NOTE Confidence: 0.817792024

00:24:55.145 --> 00:24:57.109 scan does not cut off the document.

NOTE Confidence: 0.900416925555555

00:25:01.660 --> 00:25:06.124 In this example of how to make a correction?

NOTE Confidence: 0.900416925555555

00:25:06.130 --> 00:25:09.258 Up here in the green circle.

NOTE Confidence: 0.900416925555555

00:25:09.260 --> 00:25:11.800 The original entry they only

NOTE Confidence: 0.900416925555555

00:25:11.800 --> 00:25:15.059 put in a partial year of 21.

NOTE Confidence: 0.900416925555555

00:25:15.060 --> 00:25:17.232 So they corrected it.

NOTE Confidence: 0.900416925555555

00:25:17.232 --> 00:25:20.290 By adding 2021 and with the explanation

NOTE Confidence: 0.900416925555555

00:25:20.290 --> 00:25:22.700 that they added the full year,

NOTE Confidence: 0.900416925555555

00:25:22.700 --> 00:25:25.381 they initialed it and they dated the

NOTE Confidence: 0.900416925555555

00:25:25.381 --> 00:25:28.138 day that they made the correction.

NOTE Confidence: 0.900416925555555

00:25:28.140 --> 00:25:30.220 They made the correction on the same day.

NOTE Confidence: 0.9145786

00:25:36.610 --> 00:25:37.760 Contemporaneous

NOTE Confidence: 0.942069654444445

00:25:40.140 --> 00:25:42.300 it needs to be happening at the same time.

NOTE Confidence: 0.853208611666667

00:25:44.790 --> 00:25:47.886 Recorded like in the same day,

NOTE Confidence: 0.853208611666667

00:25:47.890 --> 00:25:49.030 within a few minutes.

NOTE Confidence: 0.853208611666667

00:25:49.030 --> 00:25:50.740 We're not going to be doing
NOTE Confidence: 0.853208611666667

00:25:50.800 --> 00:25:52.720 those entries like 2 weeks later.
NOTE Confidence: 0.850888127142857

00:25:55.940 --> 00:26:00.805 So for physicians cosigns on clinic notes,
NOTE Confidence: 0.850888127142857

00:26:00.810 --> 00:26:03.449 this should be happening within 24 hours.
NOTE Confidence: 0.35612032

00:26:10.230 --> 00:26:13.070 Here is an example of where
NOTE Confidence: 0.35612032

00:26:13.070 --> 00:26:15.650 contemporaneous was not being followed.
NOTE Confidence: 0.35612032

00:26:15.650 --> 00:26:17.912 We have the Pi where they
NOTE Confidence: 0.35612032

00:26:17.912 --> 00:26:20.350 drew a line through initially.
NOTE Confidence: 0.35612032

00:26:20.350 --> 00:26:22.625 What should have been happening
NOTE Confidence: 0.35612032

00:26:22.625 --> 00:26:27.429 is the Pi initially on the DOA.
NOTE Confidence: 0.35612032

00:26:27.430 --> 00:26:29.536 In a timely manner and initialing
NOTE Confidence: 0.35612032

00:26:29.536 --> 00:26:30.940 by each person's name.
NOTE Confidence: 0.35612032

00:26:30.940 --> 00:26:34.065 So if each of these persons was.
NOTE Confidence: 0.35612032

00:26:34.065 --> 00:26:36.468 Added. On these days,
NOTE Confidence: 0.35612032

00:26:36.468 --> 00:26:38.890 that's when the Pi should be initialing.
NOTE Confidence: 0.864448640454545

00:26:42.460 --> 00:26:44.492 And then we have at the bottom example

NOTE Confidence: 0.864448640454545
00:26:44.492 --> 00:26:46.394 the Pi went ahead and signed off
NOTE Confidence: 0.864448640454545
00:26:46.394 --> 00:26:48.459 on the DOA before the study ended.
NOTE Confidence: 0.8783733875
00:26:51.120 --> 00:26:54.500 That's a huge discrepancy.
NOTE Confidence: 0.8783733875
00:26:54.500 --> 00:26:57.250 How can you sign off?
NOTE Confidence: 0.8783733875
00:26:57.250 --> 00:27:00.208 If the study is still ongoing,
NOTE Confidence: 0.8783733875
00:27:00.210 --> 00:27:02.429 those are things that when we see,
NOTE Confidence: 0.8783733875
00:27:02.430 --> 00:27:04.020 you need to be asking yourself.
NOTE Confidence: 0.790649186666667
00:27:10.750 --> 00:27:12.640 So what does contemporaneous mean
NOTE Confidence: 0.790649186666667
00:27:12.640 --> 00:27:15.409 for us for our for our office?
NOTE Confidence: 0.790649186666667
00:27:15.410 --> 00:27:18.322 It needs timely entry at the CRC
NOTE Confidence: 0.790649186666667
00:27:18.322 --> 00:27:21.040 CRA in clinic notes, the Physician
NOTE Confidence: 0.790649186666667
00:27:21.040 --> 00:27:23.530 Coast signature on the clinic notes.
NOTE Confidence: 0.613407264
00:27:25.630 --> 00:27:28.390 He has signatures on labs.
NOTE Confidence: 0.613407264
00:27:28.390 --> 00:27:30.526 Adverse events tumor loss.
NOTE Confidence: 0.613407264
00:27:30.526 --> 00:27:32.593 Deal ways the 1572.
NOTE Confidence: 0.613407264

00:27:32.593 --> 00:27:34.445 Study team signatures on
NOTE Confidence: 0.613407264

00:27:34.445 --> 00:27:36.760 training us to CAITIANS and
NOTE Confidence: 0.613407264

00:27:36.843 --> 00:27:39.158 review the Ind safety report.
NOTE Confidence: 0.81490254

00:27:42.330 --> 00:27:44.296 At the bottom are items that our
NOTE Confidence: 0.81490254

00:27:44.296 --> 00:27:46.279 monitors have brought to our attention.
NOTE Confidence: 0.9361387

00:27:48.840 --> 00:27:50.958 So in the first example here,
NOTE Confidence: 0.9361387

00:27:50.960 --> 00:27:53.990 for staff qualifications and training,
NOTE Confidence: 0.9361387

00:27:53.990 --> 00:27:57.038 it was noted that the signatures
NOTE Confidence: 0.9361387

00:27:57.038 --> 00:27:59.070 acknowledging the updated protocol
NOTE Confidence: 0.9361387

00:27:59.147 --> 00:28:01.647 training was not contemporaneous.
NOTE Confidence: 0.9361387

00:28:01.650 --> 00:28:03.246 There were several investigators
NOTE Confidence: 0.9361387

00:28:03.246 --> 00:28:05.640 who signed more than one version
NOTE Confidence: 0.9361387

00:28:05.704 --> 00:28:07.664 of the Protocol on the same day,
NOTE Confidence: 0.9361387

00:28:07.670 --> 00:28:09.880 but the protocols were approved
NOTE Confidence: 0.9361387

00:28:09.880 --> 00:28:11.648 roughly 3 months apart.
NOTE Confidence: 0.843018626

00:28:15.280 --> 00:28:16.960 In the bottom example,

NOTE Confidence: 0.843018626
00:28:16.960 --> 00:28:19.480 it's noted that the research project,
NOTE Confidence: 0.843018626
00:28:19.480 --> 00:28:21.735 the Research Nurse Progress notes
NOTE Confidence: 0.843018626
00:28:21.735 --> 00:28:25.058 have not been cosigned by the treating
NOTE Confidence: 0.843018626
00:28:25.058 --> 00:28:27.518 investigator in a timely manner.
NOTE Confidence: 0.843018626
00:28:27.520 --> 00:28:30.190 As a result, cannot confirm
NOTE Confidence: 0.843018626
00:28:30.190 --> 00:28:31.258 contemporaneous review,
NOTE Confidence: 0.843018626
00:28:31.260 --> 00:28:33.668 CONMED and toxicity assessment
NOTE Confidence: 0.843018626
00:28:33.668 --> 00:28:36.076 recorded in these notes.
NOTE Confidence: 0.9355148
00:28:42.000 --> 00:28:44.485 Documentation and we need to make
NOTE Confidence: 0.9355148
00:28:44.485 --> 00:28:46.843 sure that it is original that this is
NOTE Confidence: 0.9355148
00:28:46.843 --> 00:28:48.799 the first time something is written.
NOTE Confidence: 0.9355148
00:28:48.800 --> 00:28:52.650 If we transfer nodes to another document.
NOTE Confidence: 0.9355148
00:28:52.650 --> 00:28:56.850 The new source is not the original.
NOTE Confidence: 0.9355148
00:28:56.850 --> 00:28:58.782 Taking notes in a clinic and
NOTE Confidence: 0.9355148
00:28:58.782 --> 00:29:00.380 transferring them to the CRC.
NOTE Confidence: 0.787712252727273

00:29:02.410 --> 00:29:04.785 CRC note and epic. Allowances
NOTE Confidence: 0.787712252727273

00:29:04.785 --> 00:29:07.860 can be made for certified copies.
NOTE Confidence: 0.7896986

00:29:13.020 --> 00:29:17.030 Accurate all records need to be accurate.
NOTE Confidence: 0.7896986

00:29:17.030 --> 00:29:20.330 We need to avoid documenting in
NOTE Confidence: 0.7896986

00:29:20.330 --> 00:29:24.030 multiple places if it's not necessary.
NOTE Confidence: 0.7896986

00:29:24.030 --> 00:29:26.635 A source documents not truly
NOTE Confidence: 0.7896986

00:29:26.635 --> 00:29:28.719 considered accurate unless it
NOTE Confidence: 0.7896986

00:29:28.719 --> 00:29:31.377 adheres to other Alcoa principles.
NOTE Confidence: 0.7896986

00:29:31.380 --> 00:29:33.788 We also need to make sure that
NOTE Confidence: 0.7896986

00:29:33.788 --> 00:29:35.775 we are consistent if multiple
NOTE Confidence: 0.7896986

00:29:35.775 --> 00:29:37.975 documents record the same data,
NOTE Confidence: 0.7896986

00:29:37.980 --> 00:29:41.120 they should all agree.
NOTE Confidence: 0.7896986

00:29:41.120 --> 00:29:42.840 And it should also reflect
NOTE Confidence: 0.7896986

00:29:42.840 --> 00:29:44.216 what has truly happened.
NOTE Confidence: 0.866848295454545

00:29:48.090 --> 00:29:51.390 So we have our KOA and then we have the plot.
NOTE Confidence: 0.866848295454545

00:29:51.390 --> 00:29:54.298 The plus means complete,

NOTE Confidence: 0.866848295454545
00:29:54.298 --> 00:29:57.933 consistent and during and available.
NOTE Confidence: 0.866848295454545
00:29:57.940 --> 00:30:01.096 That's the way that we stored
NOTE Confidence: 0.866848295454545
00:30:01.096 --> 00:30:04.130 the information recorded.
NOTE Confidence: 0.866848295454545
00:30:04.130 --> 00:30:07.434 It allows this information to be able
NOTE Confidence: 0.866848295454545
00:30:07.434 --> 00:30:10.692 to be accurate in its reporting and
NOTE Confidence: 0.866848295454545
00:30:10.692 --> 00:30:13.479 and interpretation and verification.
NOTE Confidence: 0.94787248
00:30:16.510 --> 00:30:18.330 Complete all records should have
NOTE Confidence: 0.94787248
00:30:18.330 --> 00:30:20.580 an audit trail to show that
NOTE Confidence: 0.94787248
00:30:20.580 --> 00:30:22.734 nothing has been deleted or lost.
NOTE Confidence: 0.94787248
00:30:22.740 --> 00:30:25.348 Again, ten 1520 years from now we should
NOTE Confidence: 0.94787248
00:30:25.348 --> 00:30:27.674 be able to piece together everything
NOTE Confidence: 0.94787248
00:30:27.674 --> 00:30:30.760 that has happened today and in the past.
NOTE Confidence: 0.94787248
00:30:30.760 --> 00:30:33.014 Telling a full story on the clinical
NOTE Confidence: 0.94787248
00:30:33.014 --> 00:30:35.305 trial as well as the subjects
NOTE Confidence: 0.94787248
00:30:35.305 --> 00:30:37.400 participation in the clinical trial.
NOTE Confidence: 0.94787248

00:30:37.400 --> 00:30:40.840 Consistent or are all elements
NOTE Confidence: 0.94787248

00:30:40.840 --> 00:30:42.904 in chronological order?
NOTE Confidence: 0.94787248

00:30:42.910 --> 00:30:45.532 In during making sure that the
NOTE Confidence: 0.94787248

00:30:45.532 --> 00:30:48.540 records exist for the entire period.
NOTE Confidence: 0.94787248

00:30:48.540 --> 00:30:49.632 And being available,
NOTE Confidence: 0.94787248

00:30:49.632 --> 00:30:52.180 can the data be accessed for review
NOTE Confidence: 0.94787248

00:30:52.248 --> 00:30:54.198 over the lifetime of a record?
NOTE Confidence: 0.878880598571429

00:30:59.360 --> 00:31:02.204 Examples of good documentation
NOTE Confidence: 0.878880598571429

00:31:02.204 --> 00:31:04.337 practices using Alcoa?
NOTE Confidence: 0.878880598571429

00:31:04.340 --> 00:31:05.996 We have a strikethrough,
NOTE Confidence: 0.878880598571429

00:31:05.996 --> 00:31:08.480 the note with it being completed.
NOTE Confidence: 0.878880598571429

00:31:08.480 --> 00:31:10.685 We have the initial JS with the
NOTE Confidence: 0.878880598571429

00:31:10.685 --> 00:31:13.108 date that the correction was made.
NOTE Confidence: 0.5729322

00:31:18.870 --> 00:31:21.690 For data transmission methods documentation.
NOTE Confidence: 0.5729322

00:31:21.690 --> 00:31:26.154 If you get information from a conversation
NOTE Confidence: 0.5729322

00:31:26.154 --> 00:31:29.850 or or mobile heartbeat need to

NOTE Confidence: 0.5729322

00:31:29.850 --> 00:31:32.779 document the conversation took place.

NOTE Confidence: 0.5729322

00:31:32.780 --> 00:31:35.264 We should only be using approved

NOTE Confidence: 0.5729322

00:31:35.264 --> 00:31:37.821 methods for personal health information

NOTE Confidence: 0.5729322

00:31:37.821 --> 00:31:41.680 transmission using your personal cell phone.

NOTE Confidence: 0.5729322

00:31:41.680 --> 00:31:45.180 To tax. Is not an approved method.

NOTE Confidence: 0.6000128

00:31:48.510 --> 00:31:51.418 Record storage maintenance and retention.

NOTE Confidence: 0.873287931428571

00:31:54.570 --> 00:31:57.378 For the FDA, we need to be able

NOTE Confidence: 0.873287931428571

00:31:57.378 --> 00:32:00.150 to keep records for two years.

NOTE Confidence: 0.873287931428571

00:32:00.150 --> 00:32:06.638 HIPAA, the six years HSS is 3 years I CHG CP.

NOTE Confidence: 0.873287931428571

00:32:06.640 --> 00:32:08.776 We need to be keeping records

NOTE Confidence: 0.873287931428571

00:32:08.776 --> 00:32:11.040 for two years and the sponsor

NOTE Confidence: 0.873287931428571

00:32:11.040 --> 00:32:13.898 has their requirements there.

NOTE Confidence: 0.873287931428571

00:32:13.900 --> 00:32:16.028 But we need to make sure that we

NOTE Confidence: 0.873287931428571

00:32:16.028 --> 00:32:17.112 implement administrative, physical,

NOTE Confidence: 0.873287931428571

00:32:17.112 --> 00:32:19.320 and technical safeguards that

NOTE Confidence: 0.873287931428571

00:32:19.320 --> 00:32:21.528 are reasonable and appropriately
NOTE Confidence: 0.873287931428571

00:32:21.528 --> 00:32:23.540 protect the confidentiality,
NOTE Confidence: 0.873287931428571

00:32:23.540 --> 00:32:25.968 integrity and availability of
NOTE Confidence: 0.873287931428571

00:32:25.968 --> 00:32:27.789 electronic protected health
NOTE Confidence: 0.873287931428571

00:32:27.789 --> 00:32:30.320 information that it creates.
NOTE Confidence: 0.873287931428571

00:32:30.320 --> 00:32:33.640 Receives, maintains or transmits.
NOTE Confidence: 0.873287931428571

00:32:33.640 --> 00:32:35.860 Keeping information making sure that
NOTE Confidence: 0.873287931428571

00:32:35.860 --> 00:32:38.563 the cabinets are kept law limiting
NOTE Confidence: 0.873287931428571

00:32:38.563 --> 00:32:41.461 access to those who truly need
NOTE Confidence: 0.873287931428571

00:32:41.461 --> 00:32:44.430 to have access and making sure.
NOTE Confidence: 0.873287931428571

00:32:44.430 --> 00:32:47.560 Password protection on electronic systems.
NOTE Confidence: 0.791219569166667

00:32:51.520 --> 00:32:54.652 For the electronic records and electronic
NOTE Confidence: 0.791219569166667

00:32:54.652 --> 00:32:57.919 signatures or eras regulation for compliance.
NOTE Confidence: 0.791219569166667

00:32:57.920 --> 00:33:02.840 In March 1997, the FDA issued final part
NOTE Confidence: 0.791219569166667

00:33:02.840 --> 00:33:05.660 11 regulations that provide criteria
NOTE Confidence: 0.791219569166667

00:33:05.660 --> 00:33:09.856 for acceptance by the FDA under certain

NOTE Confidence: 0.791219569166667
00:33:09.856 --> 00:33:12.248 circumstances of electronic records,
NOTE Confidence: 0.791219569166667
00:33:12.250 --> 00:33:15.268 electronic signatures and
NOTE Confidence: 0.791219569166667
00:33:15.268 --> 00:33:17.280 handwritten signatures.
NOTE Confidence: 0.791219569166667
00:33:17.280 --> 00:33:19.925 Two electronic records as equivalent
NOTE Confidence: 0.791219569166667
00:33:19.925 --> 00:33:22.570 to paper records and handwritten
NOTE Confidence: 0.791219569166667
00:33:22.647 --> 00:33:24.867 signatures executed on paper.
NOTE Confidence: 0.791219569166667
00:33:24.870 --> 00:33:25.714 These regulations,
NOTE Confidence: 0.791219569166667
00:33:25.714 --> 00:33:28.668 which apply to all FDA program areas,
NOTE Confidence: 0.791219569166667
00:33:28.670 --> 00:33:31.502 were intended to permit the widest
NOTE Confidence: 0.791219569166667
00:33:31.502 --> 00:33:34.048 possible use of electronic technology
NOTE Confidence: 0.791219569166667
00:33:34.048 --> 00:33:37.090 compatible with the FDA's responsibility
NOTE Confidence: 0.791219569166667
00:33:37.090 --> 00:33:40.340 to protect the public health.
NOTE Confidence: 0.791219569166667
00:33:40.340 --> 00:33:45.226 So what is 21 CRF part 11?
NOTE Confidence: 0.791219569166667
00:33:45.230 --> 00:33:47.930 It's the code for federal regulation.
NOTE Confidence: 0.791219569166667
00:33:47.930 --> 00:33:51.002 It details the criteria under which
NOTE Confidence: 0.791219569166667

00:33:51.002 --> 00:33:53.050 electronic records and signatures
NOTE Confidence: 0.791219569166667

00:33:53.131 --> 00:33:55.541 are considered to be trustworthy
NOTE Confidence: 0.791219569166667

00:33:55.541 --> 00:33:57.951 and equivalent to paper records.
NOTE Confidence: 0.791219569166667

00:33:57.960 --> 00:33:59.163 The electronic records,
NOTE Confidence: 0.791219569166667

00:33:59.163 --> 00:34:00.767 a combination of text,
NOTE Confidence: 0.791219569166667

00:34:00.770 --> 00:34:02.576 graphic data, pictorial,
NOTE Confidence: 0.791219569166667

00:34:02.576 --> 00:34:05.586 audio and other information represented
NOTE Confidence: 0.791219569166667

00:34:05.586 --> 00:34:08.558 in digital form that is created,
NOTE Confidence: 0.791219569166667

00:34:08.560 --> 00:34:09.924 modified, maintain,
NOTE Confidence: 0.791219569166667

00:34:09.924 --> 00:34:11.288 archive, retrieve,
NOTE Confidence: 0.791219569166667

00:34:11.288 --> 00:34:15.380 or distributed by a computer system.
NOTE Confidence: 0.791219569166667

00:34:15.380 --> 00:34:17.975 The electronic signature is a
NOTE Confidence: 0.791219569166667

00:34:17.975 --> 00:34:20.570 computer data compilation of any
NOTE Confidence: 0.791219569166667

00:34:20.658 --> 00:34:23.339 symbol or series of symbols executed,
NOTE Confidence: 0.791219569166667

00:34:23.339 --> 00:34:25.853 adopted or authorized by an individual
NOTE Confidence: 0.791219569166667

00:34:25.853 --> 00:34:28.951 to the legal binding equivalent of

NOTE Confidence: 0.791219569166667
00:34:28.951 --> 00:34:31.307 the individuals handwritten signature.

NOTE Confidence: 0.753707526666667
00:34:34.130 --> 00:34:35.639 For electronic records.

NOTE Confidence: 0.871015666666667
00:34:39.340 --> 00:34:41.680 At least as secure as paper,

NOTE Confidence: 0.871015666666667
00:34:41.680 --> 00:34:44.080 we need to maintain the

NOTE Confidence: 0.871015666666667
00:34:44.080 --> 00:34:46.000 data security and integrity.

NOTE Confidence: 0.871015666666667
00:34:46.000 --> 00:34:48.384 Making sure it's reliable,

NOTE Confidence: 0.871015666666667
00:34:48.384 --> 00:34:50.768 the software is validated.

NOTE Confidence: 0.871015666666667
00:34:50.770 --> 00:34:53.155 Being able to copy and

NOTE Confidence: 0.871015666666667
00:34:53.155 --> 00:34:55.063 retrieve and control access,

NOTE Confidence: 0.871015666666667
00:34:55.070 --> 00:34:58.184 making sure that timestamp and audit

NOTE Confidence: 0.871015666666667
00:34:58.184 --> 00:35:01.030 trails in the electronic records,

NOTE Confidence: 0.871015666666667
00:35:01.030 --> 00:35:03.490 training ESO peas,

NOTE Confidence: 0.871015666666667
00:35:03.490 --> 00:35:05.950 Epic erect training.

NOTE Confidence: 0.871015666666667
00:35:05.950 --> 00:35:07.486 We still need to make sure

NOTE Confidence: 0.871015666666667
00:35:07.486 --> 00:35:09.056 that we're following the good

NOTE Confidence: 0.871015666666667

00:35:09.056 --> 00:35:10.030 documentation practices.
NOTE Confidence: 0.871580197692308

00:35:12.750 --> 00:35:13.798 Translated documents,
NOTE Confidence: 0.871580197692308

00:35:13.798 --> 00:35:16.418 documents that are translated into
NOTE Confidence: 0.871580197692308

00:35:16.418 --> 00:35:19.150 other languages also follow the good.
NOTE Confidence: 0.871580197692308

00:35:19.150 --> 00:35:21.220 The same good documentation practices
NOTE Confidence: 0.871580197692308

00:35:21.220 --> 00:35:23.992 we need to make sure they're
NOTE Confidence: 0.871580197692308

00:35:23.992 --> 00:35:26.492 organized and identify attaining
NOTE Confidence: 0.871580197692308

00:35:26.492 --> 00:35:28.367 the translation certificates.
NOTE Confidence: 0.871580197692308

00:35:28.370 --> 00:35:30.310 Examples of these documents that
NOTE Confidence: 0.871580197692308

00:35:30.310 --> 00:35:33.150 would be need to be translated,
NOTE Confidence: 0.871580197692308

00:35:33.150 --> 00:35:34.590 informed consents.
NOTE Confidence: 0.871580197692308

00:35:34.590 --> 00:35:38.648 Hip US subject questionaries subject Diaries.
NOTE Confidence: 0.871580197692308

00:35:38.648 --> 00:35:41.593 All subject materials and marketing
NOTE Confidence: 0.871580197692308

00:35:41.593 --> 00:35:44.914 materials we need to make sure
NOTE Confidence: 0.871580197692308

00:35:44.914 --> 00:35:47.354 that we have the translation
NOTE Confidence: 0.871580197692308

00:35:47.354 --> 00:35:51.790 certificates for those documents.

NOTE Confidence: 0.871580197692308
00:35:51.790 --> 00:35:54.034 Making sure that these documents
NOTE Confidence: 0.871580197692308
00:35:54.034 --> 00:35:56.214 are organized and identified and
NOTE Confidence: 0.871580197692308
00:35:56.214 --> 00:35:58.696 detained so they correspond with
NOTE Confidence: 0.871580197692308
00:35:58.696 --> 00:36:00.175 the translation certificates.
NOTE Confidence: 0.829603048333333
00:36:04.570 --> 00:36:09.160 In summary, all study related documents.
NOTE Confidence: 0.829603048333333
00:36:09.160 --> 00:36:11.220 Documentation whether it be pepper,
NOTE Confidence: 0.829603048333333
00:36:11.220 --> 00:36:14.058 paper or electronic should be organized,
NOTE Confidence: 0.829603048333333
00:36:14.060 --> 00:36:16.515 identified and retained so it
NOTE Confidence: 0.829603048333333
00:36:16.515 --> 00:36:18.479 can be accurately understood
NOTE Confidence: 0.829603048333333
00:36:18.479 --> 00:36:20.988 by an independent reviewer.
NOTE Confidence: 0.829603048333333
00:36:20.990 --> 00:36:23.370 Can I reconstruct what happened?
NOTE Confidence: 0.829603048333333
00:36:23.370 --> 00:36:25.430 Can identify who did what,
NOTE Confidence: 0.829603048333333
00:36:25.430 --> 00:36:26.822 when and where?
NOTE Confidence: 0.829603048333333
00:36:26.822 --> 00:36:30.070 Am I confident in the accuracy and
NOTE Confidence: 0.829603048333333
00:36:30.170 --> 00:36:33.330 authenticity of the research data?
NOTE Confidence: 0.829603048333333

00:36:33.330 --> 00:36:35.130 Without the documentation,
NOTE Confidence: 0.829603048333333

00:36:35.130 --> 00:36:37.530 there is no research.
NOTE Confidence: 0.829603048333333

00:36:37.530 --> 00:36:40.650 Our records should be able to tell the
NOTE Confidence: 0.829603048333333

00:36:40.650 --> 00:36:43.268 complete story of the study on its own.
NOTE Confidence: 0.961716499

00:36:46.190 --> 00:36:49.067 We need to make sure that we
NOTE Confidence: 0.961716499

00:36:49.067 --> 00:36:50.300 maintain adequate records.
NOTE Confidence: 0.961716499

00:36:50.300 --> 00:36:52.685 The source documentation is where
NOTE Confidence: 0.961716499

00:36:52.685 --> 00:36:55.070 the information is first recorded.
NOTE Confidence: 0.961716499

00:36:55.070 --> 00:36:57.368 Making sure that the data is,
NOTE Confidence: 0.961716499

00:36:57.370 --> 00:37:00.002 we can verify it and we can
NOTE Confidence: 0.961716499

00:37:00.002 --> 00:37:02.331 follow an audit trail using
NOTE Confidence: 0.961716499

00:37:02.331 --> 00:37:04.547 the Alcoa plus principles.
NOTE Confidence: 0.961716499

00:37:04.550 --> 00:37:06.590 Corrections to source documents,
NOTE Confidence: 0.961716499

00:37:06.590 --> 00:37:10.256 making sure that we draw a line
NOTE Confidence: 0.961716499

00:37:10.256 --> 00:37:13.364 through those corrections we date it,
NOTE Confidence: 0.961716499

00:37:13.370 --> 00:37:15.185 initial it and provide the

NOTE Confidence: 0.961716499
00:37:15.185 --> 00:37:16.637 reason for the correction.
NOTE Confidence: 0.88875876
00:37:20.040 --> 00:37:24.260 So in review. Alcoa means
NOTE Confidence: 0.55481574
00:37:26.530 --> 00:37:31.376 AB or CA is accurate
NOTE Confidence: 0.55481574
00:37:31.376 --> 00:37:33.180 attributable contemporaneous.
NOTE Confidence: 0.55481574
00:37:33.180 --> 00:37:35.750 Legible original.
NOTE Confidence: 0.55481574
00:37:35.750 --> 00:37:37.754 Be attributable, legible,
NOTE Confidence: 0.55481574
00:37:37.754 --> 00:37:40.426 correct, original and accurate
NOTE Confidence: 0.55481574
00:37:40.430 --> 00:37:43.238 or C attributable legible,
NOTE Confidence: 0.55481574
00:37:43.238 --> 00:37:46.046 contemporaneous original and appropriate.
NOTE Confidence: 0.55481574
00:37:46.050 --> 00:37:52.250 If you can provide your answers in the chat.
NOTE Confidence: 0.55481574
00:37:52.250 --> 00:37:54.806 We'll see what our group majority
NOTE Confidence: 0.55481574
00:37:54.806 --> 00:37:57.580 thinks what is correct for number 1?
NOTE Confidence: 0.904082766
00:38:10.240 --> 00:38:11.695 We have some answers coming
NOTE Confidence: 0.904082766
00:38:11.695 --> 00:38:13.150 and see you are correct.
NOTE Confidence: 0.846676204166667
00:38:15.450 --> 00:38:18.984 Thank you Briana and Ashley and
NOTE Confidence: 0.846676204166667

00:38:18.984 --> 00:38:22.790 Stephanie for for sharing your answers.

NOTE Confidence: 0.846676204166667

00:38:22.790 --> 00:38:26.108 And two is good documentation practice.

NOTE Confidence: 0.846676204166667

00:38:26.110 --> 00:38:27.796 In good documentation,

NOTE Confidence: 0.846676204166667

00:38:27.796 --> 00:38:28.920 practice contemporary,

NOTE Confidence: 0.846676204166667

00:38:28.920 --> 00:38:30.708 contemporaneous means the data

NOTE Confidence: 0.846676204166667

00:38:30.708 --> 00:38:33.390 was recorded at the time the

NOTE Confidence: 0.846676204166667

00:38:33.466 --> 00:38:36.201 observation was made and the

NOTE Confidence: 0.846676204166667

00:38:36.201 --> 00:38:38.389 associated signature date confirmed.

NOTE Confidence: 0.846676204166667

00:38:38.390 --> 00:38:40.838 This is this true or false?

NOTE Confidence: 0.947712958571429

00:38:48.560 --> 00:38:50.604 You are correct, it would be true.

NOTE Confidence: 0.807239376666667

00:38:53.310 --> 00:38:56.376 Just gonna move that over there.

NOTE Confidence: 0.807239376666667

00:38:56.380 --> 00:38:59.105 #3I CHG CP defines source

NOTE Confidence: 0.807239376666667

00:38:59.105 --> 00:39:01.733 document as a hospital records.

NOTE Confidence: 0.807239376666667

00:39:01.733 --> 00:39:03.777 Clinical charts and webnotes

NOTE Confidence: 0.807239376666667

00:39:03.780 --> 00:39:05.932 subject Diaries and files.

NOTE Confidence: 0.807239376666667

00:39:05.932 --> 00:39:08.084 Pharmacy records and diagnosis.

NOTE Confidence: 0.807239376666667
00:39:08.090 --> 00:39:14.800 Test results or all of the above. Or EA&C.
NOTE Confidence: 0.807239376666667
00:39:14.800 --> 00:39:16.600 What do you guys think the answer is?
NOTE Confidence: 0.716495863333333
00:39:23.680 --> 00:39:27.670 Day that is correct all above.
NOTE Confidence: 0.716495863333333
00:39:27.670 --> 00:39:30.505 Electronic records must be a be a
NOTE Confidence: 0.716495863333333
00:39:30.505 --> 00:39:33.748 secured as paper records be use validate,
NOTE Confidence: 0.716495863333333
00:39:33.750 --> 00:39:35.830 assistance with audit trails.
NOTE Confidence: 0.716495863333333
00:39:35.830 --> 00:39:38.950 CB supportive with training and ESO
NOTE Confidence: 0.716495863333333
00:39:39.030 --> 00:39:43.040 peas D all of the above or E8 and B.
NOTE Confidence: 0.927697486
00:39:49.080 --> 00:39:50.670 So why do you guys think
NOTE Confidence: 0.927697486
00:39:50.670 --> 00:39:51.730 electronic records must be?
NOTE Confidence: 0.696217523333333
00:40:02.620 --> 00:40:03.808 Yes day again.
NOTE Confidence: 0.870813545625
00:40:06.060 --> 00:40:07.975 And our last question records
NOTE Confidence: 0.870813545625
00:40:07.975 --> 00:40:10.977 must be retained for two years if
NOTE Confidence: 0.870813545625
00:40:10.977 --> 00:40:13.009 HIPAA authorizations are obtained.
NOTE Confidence: 0.870813545625
00:40:13.010 --> 00:40:14.760 Is that true or false?
NOTE Confidence: 0.835401762857143

00:40:29.770 --> 00:40:32.437 The answer is actually false for that.
NOTE Confidence: 0.93486889

00:40:39.760 --> 00:40:42.231 Does anyone remember the how many years
NOTE Confidence: 0.93486889

00:40:42.231 --> 00:40:44.830 that you need to keep those records?
NOTE Confidence: 0.835792055

00:40:56.210 --> 00:40:58.534 I believe there that it was three
NOTE Confidence: 0.835792055

00:40:58.534 --> 00:41:00.585 years I'm trying to go back to
NOTE Confidence: 0.835792055

00:41:00.585 --> 00:41:02.660 that slide to a pull up for you.
NOTE Confidence: 0.64260103

00:41:23.020 --> 00:41:24.300 There it is. Slide 35.
NOTE Confidence: 0.8293731066666667

00:41:29.220 --> 00:41:31.146 Oh, I was wrong six years.
NOTE Confidence: 0.7682514

00:41:40.030 --> 00:41:40.530 OK.
NOTE Confidence: 0.930478223636364

00:41:46.960 --> 00:41:51.073 OK. Well, at this point I do want to
NOTE Confidence: 0.930478223636364

00:41:51.073 --> 00:41:54.570 open up for discussion or for questions.
NOTE Confidence: 0.947892212142857

00:42:29.440 --> 00:42:31.612 I'm not quite sure where this
NOTE Confidence: 0.947892212142857

00:42:31.612 --> 00:42:34.199 presentation is going to be saved at yet.
NOTE Confidence: 0.947892212142857

00:42:34.200 --> 00:42:36.636 I will follow up with Sarah
NOTE Confidence: 0.947892212142857

00:42:36.636 --> 00:42:38.610 where it's going to be.
NOTE Confidence: 0.947892212142857

00:42:38.610 --> 00:42:40.738 Doing this presentation with

NOTE Confidence: 0.947892212142857
00:42:40.738 --> 00:42:42.866 another group on Thursday,
NOTE Confidence: 0.947892212142857
00:42:42.870 --> 00:42:44.290 which will also be reported.
NOTE Confidence: 0.947892212142857
00:42:44.290 --> 00:42:48.530 So between the two recordings.
NOTE Confidence: 0.947892212142857
00:42:48.530 --> 00:42:50.574 We're gonna save the the better one,
NOTE Confidence: 0.947892212142857
00:42:50.580 --> 00:42:52.490 and I apologize for coughing.
NOTE Confidence: 0.947892212142857
00:42:52.490 --> 00:42:54.170 I have seemed to have caught
NOTE Confidence: 0.947892212142857
00:42:54.170 --> 00:42:56.298 my daughter's head cold.
NOTE Confidence: 0.896630926363636
00:43:04.840 --> 00:43:07.451 Well, if no one has any questions
NOTE Confidence: 0.896630926363636
00:43:07.451 --> 00:43:09.220 about good documentation practice,
NOTE Confidence: 0.896630926363636
00:43:09.220 --> 00:43:11.308 you can follow up with me,
NOTE Confidence: 0.896630926363636
00:43:11.310 --> 00:43:14.040 your regulatory manager.
NOTE Confidence: 0.896630926363636
00:43:14.040 --> 00:43:15.580 If you have further questions,
NOTE Confidence: 0.896630926363636
00:43:15.580 --> 00:43:18.520 I appreciate everyone's time in
NOTE Confidence: 0.896630926363636
00:43:18.520 --> 00:43:21.576 today's training and I look forward
NOTE Confidence: 0.896630926363636
00:43:21.576 --> 00:43:24.390 to talking to you guys later.
NOTE Confidence: 0.896630926363636

00:43:24.390 --> 00:43:27.430 Enjoy the rest of your morning. Bye.