CHEMICAL HERITAGE FOUNDATION

DENNIS GILLINGS

Life Sciences Foundation

Transcript of a Research Interview
Conducted by

Brian Dick

San Diego, California

on

20 February 2014

(With Subsequent Corrections and Additions)

CHEMICAL HERITAGE FOUNDATION
Center for Oral History
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INTERVIEWEE

Dennis Gillings was born in London, England near the end of World War II. His father was a wholesale fish merchant who fought in the D-Day invasion, while his mother was a homemaker and milliner. During his adolescence, Gillings attended the Coopers' Company School. He received his bachelor's degree in mathematics from the University of Exeter and then received his diploma in mathematical statistics from Cambridge University. Gillings returned to the University of Exeter for his PhD, where his thesis was on mathematical models in health services. In 1971, Gillings was hired by the University of North Carolina at Chapel Hill to be an assistant professor in biostatistics. After a road trip across the African continent, Gillings left England for the United States. At Chapel Hill, Gillings became the associate director of the campus's health services research center. He was approached by the pharmaceutical company Hoechst-Roussel to help them introduce their anti-sulfonylurea to the United States. This inspired Gillings to create a program at Chapel Hill in which graduate students would be paid to assist him in his consulting work.

Gillings continued his consulting work alongside his professorship until 1988, when he left Chapel Hill to form his own clinical research company, Quintiles. The company's focus was primarily on analysis and data management, eventually expanding across the United States and then to Europe in 1993. Gillings took Quintiles public in 1994, after which Pamela Kirby replaced Gillings as the CEO. After economic issues, though, Gillings returned as CEO and privatized the company again. Quintiles continued to grow, seeing their revenue grow three times and their profits five times when the company went public again in February of 2013. Gillings's work and service to the pharmaceutical industry was honored in 2004 when he was appointed Commander of the Order of the British Empire.

INTERVIEWER

Brian Dick received his PhD in sociology from the University of California, Davis. Before coming to the Institute he was a research associate at the Life Sciences Foundation. His research interests include the history of agricultural biotechnology, the emergence of the biotech industry, and the Human Genome Project.

ABOUT THIS TRANSCRIPT

Staff of the Life Sciences Foundation conducted this interview, which became a part of our collections upon the merger of the Chemical Heritage Foundation and the Life Sciences Foundation into the Science History Institute in 2018. The Center for Oral History at the Science History Institute edited and formatted this transcript to match our style guide, but, as noted, Science History Institute staff members did not conduct the interview. The Center for Oral History, Science History Institute, is committed both to preserving the recording of each oral history interview in our collection and to enhancing research use of the interviews by

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INTERVIEWEE: **Dennis Gillings**

INTERVIEWER: **Brian Dick**

LOCATION: **San Diego, California**

DATE: **20 February 2014**

DICK: Okay. Today is February 20, 2014. We're here at the HUYA offices in San Diego with Dr. Dennis Gillings. This is Brian Dick conducting the interview. Now just to get started here, I was wondering if you could give some of your personal or family background growing up in England. For example, you know, what did your father do? What did your mother do?

GILLINGS: Okay. Well, I was born in London at the very end of the Second World War, so about the—two months before my father went over for the D-Day invasion, actually. So—of Normandy. So I was born in the London area in the UK, but evacuated because of the bombing and so forth. When my father came out of the Army, he took up his profession earlier, which was he's a wholesale fish merchant. So he used to buy fish from the ports and sell them to restaurants and fishmongers and other people that dealt in fish. And so we always had good fish growing up.

My mother was a homemaker, so prior to marriage, she was a milliner, made hats, and during the Second World War, she was a quality assurance person on bombs and their production. And so that's sort of a little bit of family background. I have one brother who's seven years younger than me. I was educated in London at a grammar school, Coopers' Company School, and then went to the University of Exeter to do a bachelor's degree in mathematics. I went to Cambridge to do a diploma in mathematical statistics.

DICK: Just to interrupt—I apologize for interrupting—

GILLINGS: It's all right.

DICK: —but you're going into college into mathematical statistics. How did—you know, for example, in high school, in grade school, were you particularly interested in mathematics? What led you to make that decision to study?

GILLINGS: Yeah, well, I was always good at it. I mean, I was way ahead, best in the class, so I guess you tend to follow your nose on certain things. So it was really that simple. I was always rather good at it, and so kept on studying it, and then did it at university.

DICK: Did your parents encourage you to go on to higher education?

GILLINGS: Oh, yes. They were very encouraging, although I didn't come from a family where anyone had ever been to university, so that wasn't the norm. But nevertheless, they were very encouraging. Yes.

DICK: Great. And go ahead and—I'll let you—you continued to 1967. You get your diploma in mathematical statistics.

GILLINGS: Then I was offered a—I guess a fellowship at the University—back at the University of Exeter to be a lecturer and do my PhD at the same time. So that gave me a paid salary while I was doing my PhD, which is what I did. So then I did that until 1970.

DICK: What was your PhD thesis on?

GILLINGS: Mathematics. It was on mathematical models in health services delivery.

DICK: [. . .] Why was the focus on health services at this point?

GILLINGS: Well, it was more because of the professor of statistics I had at the University of Exeter originally. He had worked for the National Coal Board, and had studied pneumoconiosis, the miners' lung disease. And so that carried through in all the early lectures on statistics I ever had, and oriented me towards the health side. So that—you know, that was like a role model back then.

DICK: I see. And who was the professor?

GILLINGS: John Ashford.

DICK: John Ashford.

GILLINGS: Yes. So then what happened then, I was offered a position at the University of North Carolina in Chapel Hill as a professor—well, it was starting as an assistant professor of biostatistics, as a result of my background, which included obviously mathematics and statistics, but then also included this understanding of health services and modeling. And they were looking for someone that would run the health services track of biostatistics.

So I'd never been to the United States. It came out of the blue. You know, wasn't part of my plan, like, oh, I'm going to the United States to work.

DICK: How did you find out about the position?

GILLINGS: Well, my thesis advisor, John Ashford, had made a tour of the United States, and he came back and **<T: 05 min>** told me biostatistics is a big thing, and there's a lack of them. There's a very good job opportunity for you in North Carolina. Would you like to follow it up? So he recommended me very highly.

So I met the chairman of the department, whose name was Bernard Greenberg, actually at the International Biometric meetings—oh, they were somewhere in Germany. I'm forgetting the exact location. So I flew over there, met with him, and he offered me a job on the spot.

DICK: Wow.

GILLINGS: So what—

DICK: Probably not typical of today's—

GILLINGS: That's right. So I was a little—you know, because that's a fairly big decision, moving countries and so forth. And in fact, I had plans to take a period of time to do an overland trip across Africa. So I entered into a negotiation, I said, "Well, if I'm going to do this and move, then my career will be really settled. I'll be working for the rest of my life. I'd like to continue with my planned Africa adventure." I said, "Can you delay it a year?" And we negotiated six months. [Laughter]

Typical business negotiation. So that's what I did. I went on my trip, which was driving all the way across the Sahara, across Central Africa, and all the way down to South Africa, then flew back and went to North Carolina. So—

DICK: What did you—you know, did you get what you were looking for in your trip to Africa? I mean, that's like the—

GILLINGS: Oh, yes, it was a sense of adventure, you know. Maybe back then it wasn't quite so common, doing some of these trips. But nevertheless, crossing the Sahara Desert is a reasonable undertaking. I don't know today whether it has any paved roads, but back then, there were paths, which had nothing, and so as you crossed from Algeria to Niger, you had about 700 miles of sand to negotiate.

DICK: Wow.

GILLINGS: So—

DICK: And was this all on your own, or—

GILLINGS: Well, there was four of us.

DICK: Okay.

GILLINGS: Friends of mine. And so we went—we did the trip. It was very exciting, actually, out in Morocco, Algeria, Niger, Nigeria, Central Africa Republic, Cameroon, the Congo, Uganda, Kenya, Tanzania, and then the Rhodesias, as they were called then, that now became Zimbabwe and Zambia, and then South Africa. So it was quite a—

DICK: That's quite a continental—

GILLINGS: Yes. So all the game reserves and, you know, lots and lots of things, quite—quite an extraordinary experience. So I thought that was actually quite character-forming. I'm glad I did it. I wouldn't change anything on that. And it complemented very well, I think being in a more rigorous academic program, to have that freedom. And then I arrived in North Carolina to take up my appointment.

DICK: What was your impression? Was this the first time that you had arrived in the States, coming, you know, landing for this job, basically?

GILLINGS: Yes. Well, it was a bit of a shock. I suppose it shows how naïve I was, to some extent, but you tend to think of America as America, the way it's portrayed on the movies, and you see, New York—you tend to see New York, LA, and maybe a few other places, Chicago, New Orleans. But you don't realize the more rural parts of the United States, they're not—back then, they were nowhere near as sophisticated as Europe. So it was quite a culture shock, to my surprise, because I was thinking, because of the material wealth, it would be more sophisticated. But it was far less sophisticated. A lot of things I was used to, unobtainable. I mean, there was—in North Carolina at the time, there was liquor by the—there was no liquor that you could buy when you weren't in a bar. So there were very extreme liquor laws.

DICK: I see.

GILLINGS: That were a hangover from the Depression, I suppose. And so wine was almost unheard of, and a lot of the gourmet foods you couldn't find. So very different world to what you are used to now in California. That's what—and particularly San Francisco.

DICK: Yes. Yes.

GILLINGS: I'm not saying that applied to New York. Of course it didn't. I mean, New York was very sophisticated. But I would say North Carolina was relatively unsophisticated at that time. Since then, it's changed dramatically.

DICK: Mm-hmm.

GILLINGS: But that was a little bit of a culture shock. But, you know, I suppose the academic side was very high. **<T: 10 min>** You know, the University of North Carolina at Chapel Hill, it was one of the top, if not the top, departments in my field of biostatistics. So it was an excellent place to be.

DICK: Mm-hmm. Yeah. So you start up in 1971.

GILLINGS: Nineteen seventy-one. May of '71. Yes.

DICK: And what are you working on? How many students are you teaching? What type of classes are you teaching?

GILLINGS: Yeah, over the course—I used to teach a different course every couple of years, but I taught the beginning course on linear models and regression. I taught the survey—sample survey methodology course. I used to teach mathematics for statisticians, which would involve matrices in calculus. I also taught a methodology course on health evaluation, health services evaluation, so bringing in a lot of issues of studies with control groups and how one identified bias in those studies, so with a lot of epidemiological designs. They were the main courses I taught.

DICK: I see. Now I have here this trailer 39, and I have here, it's 1974, Gary Koch relocating. Were you—were you starting off? Were you already in trailer 39?

GILLINGS: Yes.

DICK: Or are you in—

GILLINGS: I started off in trailer 39. I mean, as with all things, the school of public health was outgrowing itself, and I think Chapel Hill has been a particular case where the university has expanded rather dramatically. And so they had two trailers, one was 32 and one was 39, basically in the woods that were just adjacent—it was only like 20 yards away from the school. You walked across a parking area, and there were two trailers in the woods. So I was assigned to one of the trailers, which when I first got there, I thought, hmm, I had a better office—

[Laughter]

GILLINGS: —as a fellow in the University of Exeter. But it turned out to be rather good, because it was my own little empire, you know. And then Gary Koch, who is an outstanding statistician, decided to relocate there, and so we had, you know, our own little empire with our own students. And we had, I think, a good professional and social time there. Yes.

DICK: But how many people—you know, up until '74, about how many people were you working with in the trailer? Were these research assistants, grad students?

GILLINGS: Yep. They were all of the above. In addition, I was associate director later—well, I was a research associate, and then became associate director of the health services research center on the Chapel Hill campus, which is a freestanding institute. And that was the linkage between the health services research part and the biostatistics part. So I also ran the consulting for statistics across the whole of the health sciences campus, which included the school of medicine, the school of pharmacy, the school of nursing, the school of dentistry.

DICK: What did this involve? Consulting, is this making sort of outreach to industry or other people that would require services?

GILLINGS: Well, it really related to all the projects that professors of medicine were undertaking that they needed help on the design of them, and then the analysis of the data they would collect. So what I did, I got the students to be research assistants on a paid basis, and they would work then for me to manage the programs that were the consulting programs across the health sciences campus.

DICK: Okay. So they'd be able to help pay for their studies?

GILLINGS: That's right. And most of them needed some—I mean, the graduate students usually needed some work in order to supplement their income. The change I made was it started out, it was done free, and I didn't like that, so I changed it. I made the medical school pay an hourly rate. I think it was—back then, it was twenty-five [dollars] an hour. I can't remember—I'm pretty sure it was twenty-five [dollars] an hour. So that was a huge—had a huge impact, because we used to get a large number of what I would call rubbish questions. You know, the guy clearly hadn't thought through what he wanted, and was sort of like dumping.

So as soon as they had to pay twenty-five [dollars] an hour, their ability to describe and think through what they wanted was **<T: 15 min>** enormously improved. And so the service became quite a good service, and well-received in the medical school. And the medical school gave a grant to the professors to enable them to pay. And then in turn, that money got used either to support the department of biostatistics or the research assistants, giving them an hourly fee that was part of their research assistantship.

DICK: Do you recall around what year that that change, where you're able to start paying?

GILLINGS: Spanning the seventies, so let me think. I suppose that change took place more like the mid-seventies.

DICK: Okay.

GILLINGS: Yeah.

DICK: Great. So we have Gary Koch and his students relocate into trailer 39, and it's around this time that you begin to get into consulting with private industry.

GILLINGS: That's right.

DICK: Did this emerge from conversations among you and Gary Koch, or how did that—

GILLINGS: Well, it was—excuse me. Gary Koch had done some of his statistics training with a statistician called Ken Falter, and Ken became the head of statistics. He became the head of statistics at Hoescht-Roussel [Pharmaceuticals] in the United States, and Hoescht-Roussel was a subsidiary between Hoescht, the German company, and Roussel, the French company, and they had done a joint venture to have Hoescht Roussel in the United States. That company was trying to capitalize much, much more on the US market, because most of the revenues of these companies came actually from the European and other global markets, rather than the United States.

And they had an interesting issue. They wanted to introduce a drug into the United States that was associated with deaths in the then West Germany, fifty-six deaths, to be precise.

DICK: Wow.

GILLINGS: And it was an anti-sulfonylurea, which was quite a potent drug, and it reduced blood sugar. And they felt it was a very good drug. The fact that these deaths were associated with it merely meant these patients had died and were taking the drug. It meant no more than that. But of course, that raises a red flag.

So Ken wanted someone to really assess this whole program. He had spoken to Gary, I believe, and Gary and had said, "Well, Dennis is—would be great to do it." So out of the blue, Ken Falter called me up and asked me if I'd take on this consulting exercise. And that must have been at the very end of 1974, I believe. So I said, "Sure, I'd be happy to take it on." I didn't quite realize what I would receive, because a very short time later, I received fifty-six case reports from German hospitals, all in German. [Laughter] Because they were the fifty-six deaths.

DICK: I'm assuming you weren't fluent in German at the time.

GILLINGS: Not at all. So I was able to get the department of German involved. I asked for a budget, and they said yes. I didn't ask how much. I just said, "I've got a budget." And so then I got the department of medicine, the chairman of the department of medicine, David Ontjes was his name, who was a consultant. And I then went ahead and did the project.

It turned out very interesting, because as I went through all the charts as they were translated, I started building a big spreadsheet of all the information, of the sixty—fifty-six patients. I built it on a huge sheet of paper, right, because in those days [. . .] the data in each chart was different, so I had to work through and try to figure out, well, what are the common data elements? I'm trying to remember. I must have identified fifty data elements that then I abstracted from each chart, validated the fact that I abstracted them right, and then entered the database into a computer, and then started analyzing that. And I—what I found was quickly I realized, wow, these patients aren't excreting the drug. It hit me between the eyes, because they had liver compromise metabolism, or they had some kidney compromise. A few had a little bit of adrenal compromise.

<T: 20 min> So as I started looking at it, I said, "Well, this drug is being given to patients who have the ability to excrete the drug compromised, and these patients are old anyway, and so probably in this case, this patient pool is not the right pool, and the labeling should prevent these patients getting it, because the patients died of hypoglycemia, which is low blood sugar. And—

DICK: And this drug was to treat diabetes?

GILLINGS: Diabetes, when they had hyperglycemia, but they died of hypoglycemia. So that sort of proves it wasn't being excreted. So I wrote this report, which was very, very well-received, and ultimately led to the product then getting on the market.

DICK: Great. And—

GILLINGS: Glyburide was the product that it became.

DICK: Wait, I'm sorry. One more time.

GILLINGS: Glyburide.

DICK: Glyburide.

GILLINGS: Yeah. So it was the first product to be approved I think by—in metabolism for quite a time, because there was the UGDP stuff, which was the University Group Diabetes Project, where the cardiovascular effects of sulfonylureas and other diabetics, were under question. And that probably to some extent continues today.

And so there were two issues really going on. One was the UGDP stuff, and whether the drug would have cardiovascular effects, and the other was the association with these deaths in the first place. I basically solved that second question.

DICK: I see.

GILLINGS: The first question was more a matter of scientists that have already been set up getting comfortable that glyburide did not have a problem of cardiovascular side effects, and ultimately, they did get comfortable with that, and the product was approved in the early eighties. It became a major, major product in diabetes. So that was how I first got into the area.

DICK: Great. And so, you know, you get a call from Ken, but you can continue on with this consulting, right?

GILLINGS: Well, I suppose what happened, I mean, to be honest, the company was delighted. I mean, it solved a huge problem for them. And I solved it in a month, you know.

DICK: Wow.

GILLINGS: So they started asking me—doing other things, and then that snowballed, and other companies asked me to do things, which caused, you know, consulting undertaking. And it worked very well with my professorship at the time, because I would feed a lot of the things into projects for students. Papers would get published. And so it was a very, very good system. But it carried on that way. I also obviously made consulting income. All my students made consulting income, because they were able to help me with programs. So I suppose from ‘75 until ‘81, that six year period, we had quite a consulting endeavor going, both in industry and across the health sciences campus. And I managed all of that as part of my job at the University of North Carolina.

DICK: Was Koch also involved in this work?

GILLINGS: Yes, he was. Yeah.

DICK: Okay. What were some of—if you don't mind telling— some of the other companies that you were doing consulting work—was it all pharmaceutical, or—

GILLINGS: Gradually—yes. I mean, one was Ives Laboratories. I'm not sure what they've become now. Another one—well, Bristol Myers, they're still big, I mean, so—those were two that come to mind. One—oh, Boehringer Mannheim. Yes. So they were some that immediately come to mind.

DICK: And I have here, or I found a mention of Biometric Consulting Laboratory, formed in 1980.

GILLINGS: Yeah. Well, that was what I said about the health sciences campus. I might be collapsing or expanding time here a little bit. The biometrics consulting lab grew out of all the consulting activities across the health sciences campus, all the activities of the students, and we formalized it into a lab where students got credits and could also get paid as part of what they did. So it became a formal entity capturing a lot of things I'd mentioned.

DICK: I see. **<T: 25 min>** Great. And so it's 1982, that's when you decide to make the jump here. What led you to decide to form an actual company to carry out kind of the activities you'd already been conducting?

GILLINGS: Well, I was observing what was going on, because of the amount of consulting I was doing, and of course, Gary Koch was my friend and colleague, and he did a lot of consulting in the industry. And I felt that there wasn't really a huge efficiency in what was done. Now let me backtrack a little bit. During the seventies, and in fact the early eighties, there was a responsiveness to the 1962 Kefauver-Harris Amendments to the Food, Drug, and Cosmetic—Food, Drug, and Safety Act of 1938, where—in '38, it was safety. In '62, it became efficacy that had to be demonstrated by a new drug before it got approved.

Now as that legislation came out of the Kefauver-Harris Amendment, it's easy to write this in the law. You have to prove efficacy. But you then had to translate it into what exactly that meant.

DICK: Yeah.

GILLINGS: Now that was at least statistical as much as anything. Now at the same time, statistics was dramatically expanding because of the ability to computerize. A few breakthroughs in the theory were also discovered, but the biggest issue was the ability to computerize, which basically meant calculations that you'd done on a machine became rather standard, and you could write programs, obviously.

DICK: Mm-hmm.

GILLINGS: So that was the era where this transition was taking place. So what that meant, a lot of the analyses that really were rather tedious gradually could be formalized and done, you know, to a high degree of computerization.

Now the fact that we were in that era, there was—probably the other part of it, it wasn't totally rigorous, the standards for the analysis of a clinical trial, from the perspective you do a clinical trial, and then you—there's some data missing. You lose patients to follow up. What is it you actually do—how many patients have got to be included? How do you do it really rigorously so that you have high standards, both for the patients that drop out and for the data that's missing?

Now I think during this era, Gary and I began to be very rigorous about these things, and use common repeatable standards across the board. Now by the time you get to the late eighties, all that did become standard, but during that period, I suppose, early seventies, late seventies, early eighties, you had this computerization sweep through, the ability to do all these things that were harder historically—certainly when the Kefauver-Harris Amendments were passed—and then this pragmatic standardization of exactly how you did it, not only the math—applying the mathematical theory, but to exactly what data, exactly what patients you would include, and so forth.

So I think what we did, we helped that whole process, and were in the middle of using state of the art techniques.

DICK: Yeah. I was kind of curious, you mentioned in—you know, and this is the mid-seventies, that you were using computers. What type of system were you working with?

GILLINGS: Well, it was all mainframes then, because there were no PCs. So it was all mainframes. So you would have punch cards. You'd submit it, take it over at night, and get them back in the morning with a printout. I mean, it's quite a tedious effort, but nevertheless—

so that was how all these consulting programs would go. You'd compile a big series of inputs. They would all be put on punch cards that really revolved around big matrices, and you'd put all the numbers in according to the theory, and then you'd put them all on punch cards, and then they'd be submitted and run on mainframe.

DICK: These are the IBM machines that—

GILLINGS: That's right. That's right. So very different environment. **<T: 30 min>** Once the PC started coming in, obviously, you know, you can do it by menus.

DICK: Yeah.

GILLINGS: That was more the late eighties, before that, you know, was really feasible, and it was probably into the nineties before it was super easy and common.

DICK: Mm-hmm. Now you're mentioned this kind of lack of sort of a shared set of standards. The 1968 amendment had just come out. I know that during much of this period, many of the people would be involved in clinical trials were prisoners, but this was no longer possible after I think around 1979, 1980. And I'm wondering how—you know, then the need to search for clinical trial patients, if that had any change in terms of the need to standardize, and so on.

GILLINGS: I think when you're referring to prisoners, I would imagine you might be referring more to phase one. I'm not sure. I've never done a clinical trial on prisoners, but I'm aware this has been done, but I wouldn't—I mean, that's just a tiny, tiny, tiny part, and probably more related to phase one than anything else.

DICK: Okay.

GILLINGS: There may have been trials done on prisoners in later phases, but certainly I was never a part of that.

DICK: And in here, you're talking about these broader changes resulting here. I guess if you could speak to the pharmaceutical industry around this time, changes taking place as they begin to, for example, outsource various components of clinical trials, even research and development. Do you want to comment in terms of why this was occurring, and then how the rise of CROs such as Quintiles began to meet these needs?

GILLINGS: Well, let me start with the statistical side, because being professors at probably the best department in the country, I mean, you have an expertise that's at a very high level. I think it might be fair to say, you know, we could bring to bear an expertise that was certainly greater than the average expertise in the industry at that time. That is not the case now. I mean, the industry has recruited a huge amount of expertise, a lot of from the department of biostatistics in the University of North Carolina, people we trained, Gary and I.

So going back to them, you've got the computerization, the ability to do things, the standards of when you get a database, how exactly you do that, as well as apply the mathematical methods. Going on all that time, what it meant was as very high-powered experts started to do this, you know, it led to a very quick transformation, because the FDA were exposed to very state of the art stuff that would be done, perhaps on a more frequent basis. The industry talks very quickly. And so as state of the art things get used, other people, other companies, will use them, too.

And so I would say during the eighties, you got a fairly dramatic uplifting of the skillset within the whole biopharmaceutical industry in applied biostatistics. Now—let me try to—as you get into the nineties—let me jump a little bit—you had a huge surge in the number of new drug approvals. I think by 1996, there were 56. A lot of these were what I would call "me too products", products approved where there were similar approvals, but some were breakthrough products. So it was a very healthy era for the industry. And since programs get started in the eighties, they get approved in the nineties, you've got this sort of whole wave and trend going on.

So now think about it. You've got standards and the industry changing, much more rigor, also more data being collected. So the internal department's expanding, but there was almost no limit to how much was being required. And so outsourcing began to take **<T: 35 min>** place at the same time.

Now fortunately, being a high expert, I suppose, I was on the outsourcing end of not the routine work. It was the complex work where maybe, oh, how do we exactly analyze this? This is a funny situation. Or we can't quite be sure of the result here. How would you judge this?

So that gave us a nice edge, if you like, but it's in the background of all these things going on simultaneously. Maybe that's the best way. If we take it back to Quintiles, what I did was start out with the analysis, add data management, become then very competent at the whole front to back end of data management through analysis, through medical report writing, and then by about the late eighties, I had really built that very successfully, and built it internationally, across the United States and in Europe, because in '87, '88, I took it back to the United Kingdom, where I was born, and then expanded in Europe, in anticipation of the European Union on January the 1st, 1993, because I realized we had to gather a lot of things in place. Under the European Union structure, I figured there would be a broader regulatory regime.

DICK: Sort of necessary to prepare in advance—

GILLINGS: That's right. I figured, well, by '93, I've got to be here. So I began to build all this and put it in place. That's basically what I did. And then as the data and the statistical side became very strong, what I did, I then expanded into the clinical monitoring side, and gradually expanded that into doing the whole of clinical drug development.

DICK: And when would be the clinical monitoring—let's see, probably around the late eighties?

GILLINGS: Very late eighties, about '88, '89, edged into it. And then as we began—and in those days—I mean, it was interesting. You didn't necessarily need such a big track record to get into it. Life is much more competitive now. But we were pioneering—there weren't—whatever companies existed really didn't know each other very much. And so it was much more contracting, but because one had done a good job in the past, because one was reliable, then one could expand and do more. Very different to today, where a huge amount of due diligence and—I mean, that all started to—as outsourcing became a big deal by the middle nineties, you know, the standards for even getting a contract started to change, because the purchasing departments of big pharma companies in the early to mid-nineties started entering the picture and setting rigorous standards for how this was done.

But, I was on the front wave, obviously, and was able, you know, always to get through those things.

DICK: I see. And backing up a little bit here, forming Quintiles, I know that a lot of the scientists, molecular biologists, and others who were beginning to get involved in the industry in the late seventies and early eighties faced—I guess you might—were I guess in some ways looked down upon by their colleagues, seen as selling out, things like that. What was your experience in terms of—you know, because it sounds like the department was already involved in a lot of consulting. What was the reaction from the university from your colleagues?

GILLINGS: Well that was very interesting, because—this is a story that is fairly famous at the University of North Carolina in Chapel Hill. What I tried to do originally, before founding Quintiles, was set up a not-for-profit institute within the university where I wanted to head it, and I could swing in professors as needed who had the time. They would get paid consulting fees, and then the profits would go back to the university. And we had a number of discussions about that, and the university turned me down. They said that we can't do that.

DICK: Do you know why?

GILLINGS: I **<T: 40 min>** think it was just too forward-thinking. Yeah. The whole notion of bringing in financing from industry, and the competitive forces that get unleashed, and you don't get there unless you have a lot of financing, wasn't so well-entrenched. I mean, mainly, then the funding came I would say from grants from the government, state grants, and so forth, and tuition fees. And certainly as you move into the eighties, you see dramatic changes, where big trust funds are set up, and universities bring in much more money, and do more private ventures to do that. But back then, I would say late seventies, early eighties, it was much more unknown. And the private universities tended to be on the cutting edge, like Harvard, Stanford. The public universities, they were more followers of this trend.

DICK: Mm-hmm.

GILLINGS: So when I was turned down, I then said, "Well, you know, can I consult? Because is there a limitation to my consulting?" Well I'm trying to remember what the limitation was. I think a day a week, I think. But I cleared it with the university. Well, what do you mean by a day a week? They said, "Well, I mean, some people work two hours a day. Some people might work 24. And then you've got your weekends." So they were very flexible on that point. So I decided, as long as I didn't—as long as I did my duties, and even during the week, it could be as many as twenty-four hours, as long as that was above my forty, and on weekends there was no restriction. That's how I interpreted that, there was no real restriction on my consulting activities.

So once they had turned me down, but they gave me a green light for the consulting—

DICK: Did they have a formal policy at this point in terms of professors consulting or working for companies?

GILLINGS: Yes. But it really was as I said, a day a week. And as I just said, I went to the vice chancellor's office and asked what it meant, and that was the answer I got. So—and, you know, and that raised a lot of money in the university. They were trying to be helpful to me. So they clearly weren't stopping me doing what I wanted to do. And a lot of PhD dissertations came down to the students. It was very synergistic with the whole university program. So there was no question about that. But they had the policy of a day a week, and it was a matter of clarifying the freedom I had to go within that policy.

DICK: I see.

GILLINGS: Now since then I couldn't set up the institute, I then asked—there was no restriction on setting up your own company, and since the number of requests I was getting was large, I thought it made sense to formulate a company, push all those activities through that company.

DICK: I see. Who—so you're working with Gary Koch. Were there anybody else who was involved early on in—other than I guess you're bringing in grad students and others to do—

GILLINGS: The grad students, and staff, programming staff in the department of biostatistics. I mean, the department of biostatistics tend to have a lot of programming staff, because huge amounts of it is programming. You've got to work out the theory, but you've also then got the challenge of programming all this theory.

DICK: Yeah.

GILLINGS: So probably more programming than there is actual mathematics. So there were staff people there, and staff people, you know, I began to use and pay their salary through programs within the university structure. So I got them also to work on the side for me in the corporate structure.

Now as that then expanded, some people left, and entirely worked for me. Students used to carry on working on a part-time basis, because they would normally do part-time work anyway as part of their graduate training. So it was perfect, because this was real practical statistics. I mean, there was nothing else that was done.

DICK: Yeah. They're not kind of, you know, flipping burgers or something to make ends meet.

GILLINGS: That's right.

DICK: They're doing exactly—

GILLINGS: It was much, much—I mean, everyone recognized, **<T: 45 min>** this was much better to do than something else, which had nothing to do with their skill.

DICK: And this was still being worked out of the trailer 39?

GILLINGS: Yes, it was. When I say yes it was, within the university structure, but what happened at the end of 1981, I purchased a small commercial property, only just over 1,000 square feet—it was tiny—where then as the company was incorporated in February of 1982, I made that the home of the company.

DICK: I see. So not too much room, but enough for a—

GILLINGS: Four, five, six people. Yeah.

DICK: Yeah, yeah.

GILLINGS: Yeah. Yeah.

DICK: [Laughs] So let's see. Picking up—I guess if you could speak here, you know, in the early 1980s, were you aware of other CROs being founded. I know that Parexel was founded in 1982. PPD comes around 1985. What was your awareness or thoughts about these other CROs emerging?

GILLINGS: Yeah, I was aware of Parexel. I've known Joe von Rickenbach, the founder there. When I would have become aware of Parexel? Probably the middle eighties, I would say. PPD more '87, '88. You know, a couple of years after they were founded. Fred Eshelman, you know, I knew. But I didn't know him earlier, but he had worked for Glaxo. So, I mean, I was aware of what he'd done within Glaxo. So the answer is yes. Our paths didn't cross all that much. There wasn't the rigorous RFPs and the bidding quite like there is now. But as you hit the late eighties and the early nineties, you get this gradual evolution where you compete a little more. It was an evolution over that— let's say early eighties to early nineties— that ten year period.

DICK: I see. And you were mentioning in the mid to late 1980s the expansion to—throughout the United States and Europe, and I think—I'm trying to look at the list here, but in Germany, in the UK.

GILLINGS: Ireland, France, and then California, too.

DICK: Oh, okay.

GILLINGS: Because of the biotech industry.

DICK: Where in California?

GILLINGS: Started in San Francisco.

DICK: In San Francisco.

GILLINGS: And then here in San Diego, because in 1992, I bought a small company, International Clinical Research, that did CNS research, clinical research.

DICK: Okay. So very much expanding. Now 1986, you take a leave of absence from the university, and then this is after becoming a full professor in 1981.

GILLINGS: That's correct.

DICK: I mean, a tenured position. You know, many, many academics would love to have that. What led you to decide that you're going to—

GILLINGS: Well, I think it probably was—what was I—I think I was appointed when I was 36 as a tenured professor. So full professor. It was like you'd got close to the top. And I thought, wow, if I just stay here for the rest of my life. There's too much more of the same, is the thinking going through my mind. The other thought was, well, suppose I went on the administrative direction in the university. That didn't attract me too much, you know, either being a dean or managing a department or whatever, managing maybe the whole university. It doesn't really matter. I suppose it didn't attract me too much, because I thought, well, that you really get paid for administration, then. If I was going to do that, I'd sooner go into business, where you stand a chance of really being successful financially as well.

So my thinking was business **<T: 50 min>** seems to be the best avenue. If I could form a business that did much the same as what I was doing, and my consulting seemed to say, yes, there was a business doing what I was doing as a professor, than that might be the best of both worlds. I carried on in my professorial sort of knowledge, and also could build a business at the same time. So that was my thinking then, and that's why I did it. It was just before I started in

the UK. So in 1986—I'm trying to remember the revenues that we had. I think we got two hundred and eight-six thousand dollars of revenues in '82. What it would have been? I think it moved up to six hundred thousand [dollars] odd in '83. Then in '84 it went to nine hundred thousand [dollars] odd. In '85, it went to one point two million [dollars]. And in '86, it went to one point eight million [dollars]. Okay? So we were starting to get quite a trajectory.

DICK: Yeah.

GILLINGS: And the one point million [dollars], that was the '86, and I had a sense, you know, of how we'd do that year. I thought, well, if we carry on, we can expand to Europe. And in fact, in '87, if I recall, we did something like three point eight million [dollars]. I'm not sure I've got the numbers exactly right. You may have—

DICK: I have for '88, four million [dollars] in revenue.

GILLINGS: Eighty-eight, four million [dollars]. Okay. Fine. Well, I'm roughly in line. I'm trying to remember those numbers. So the point in '86, I thought, well, this could go, so I might as well give it my whole for two years. I was allowed a two-year leave of absence. I can expand to Europe. And if it works, that's what I'll do, and if doesn't work, I'll stay a professor.

DICK: So you've got—you have the fallback plan.

GILLINGS: That's right. So that's what I did. Well, it worked like a charm.

[Laughter]

GILLINGS: I mean, so I probably could have resigned my professorship after one year, '87, but the rules allow you two years, and so I didn't see any reason to give my notice in a year ahead of what I had to. So I took my two-year leave of absence, and then gave in my resignation.

DICK: Great. So you really—building—now Koch decided to stay in academia.

GILLINGS: Oh, yes. No, I mean, I think we're somewhat different temperaments, and he was a true academic through and through. And I'm not saying I was—I'm not a bit academic, but I

think I had the—my career horizons had a little more breadth. And so this combination of science and business or medicine and business did strike me as extremely attractive. So he wanted to be the professor. So it worked out very well, because he would then support me on much of the statistics, where I had done a good deal of it, sometimes all of it. He became the more technical supporter to enable me the time to build the business more.

DICK: I see.

GILLINGS: And bring in the business, and so forth. Because you can't—as you're building a company, it's hard to do everything yourself.

DICK: Yeah. Yeah.

[Laughter]

DICK: So you're continuously growing through the eighties. And I have here that you—in the 1988 to 1990, that you began expanding into things such as trial design, management, and so on. I mean you could see a big straightforward path, but what led you at that point that you were going to expand into those areas?

GILLINGS: Well, it's funny. When I started, I thought, well, if I can build a biostatistical, maybe some data management, consulting company that brings in about five million [dollars] in revenues ultimately, and, you know, is about five hundred thousand [dollars] of profits, I'll be doing really well, I felt, you know. I thought, well, that's probably possible. So this in 1982 was probably my thinking around that timeframe.

But as the company started growing quicker than you might think, and so it was at least 30, 40, 50 percent growth each year, **<T: 55 min>** and I thought, wow, this could go much, much bigger than I ever thought. So then I thought, well, and it's going well. I seem to be handling the management quite well. And seemed to be able to recruit people quite well. And so I said, "Well, we might expand our horizons, because it might be possible to grow a really big company."

DICK: Mm-hmm.

GILLINGS: So it's a funny story. I was talking to some venture capitalists, and this will be another story, because we began to grow faster than we could generate cash, so I had to bring in some equity investment. And that was a decision I had to make.

But nevertheless, on talking to some of these people, I said, "Oh, we're now about ten million [dollars] in revenues." I think that's what we were in 1990. I said, "We'll be one billion [dollars] by the end of the nineties. I really feel we can grow that much." And of course, they all started laughing at me." And we actually hit one billion [dollars] in '98, by the way.

DICK: Wow.

GILLINGS: But I only use that as an illustration because my mind started to go, wow, this—I can really snowball this. And so that's what I decided to do. And in order to grow quick enough—it's hard to do the organic growth in this business quite to multiply by 100 in eight years. So we needed a few acquisitions as well. So I combined a little bit of inorganic growth with organic growth. And by then, I had a good sense of the market landscape. And I said, "Well, we've got to be clearly bigger than anyone else by the end of the nineties. And if you do this, establish market share, then you'll be king of the industry niche."

So by about 1990, I overtly set out to do that. I cannot claim I overtly set out to do that in '82. But you can see over that period of time I—you know, my thoughts—and I understood the business, the possibilities, the global growth sorts of factors as well.

DICK: With—who were—if you don't mind mentioning some of the venture capitalists that you were talking to, and they invested, correct?

GILLINGS: Yes. Well, there were two in particular. One was Thompson Clive, which was out of London, in the UK, and the other was North Carolina National Bank, which is now really Bank America. I mean, there's been a lot of bank acquisitions. But then, it was NCNB, based in North Carolina. They were the two partners that came in. And I'm blocking on how much capital they provided. Probably it was the order of ten million [dollars] or something like that. They gave us our ability to grow more quickly, because we had to open our offices and recruit people ahead of the curve. To grow at the rate that I wanted to grow, we had to grow in Europe. And then by '93, I was starting to grow in Asia. So the part that probably I did different than anyone else, I had this global vision, because a drug, once it gets approved, it tends to get approved everywhere.

DICK: Yeah.

GILLINGS: The data are roughly similar that you'd need in any regulatory zone. And so I figured, if you can build up this global empire and connect it with harmonious sort of overarching IT, you will really have a powerful business. But it's actually quite hard and expensive to do traveling all over the world, trying to find the people, and then—

DICK: Yeah.

GILLINGS: —you know, you have to use a local system, and then you got to connect it to a global system, and then people argue over is it the UK bit or the American bit or the French bit? But over the years, I pushed all these things, and kept battling away, and made the investments. I would say in the nineties, over-invested in this, even when we were public. We could have made a lot more profit if we'd invested for the present solely. But I was trying to build a company long term for the future.

DICK: Mm-hmm.

GILLINGS: So, we put the investments for long term growth and built then **<T: 60 min>** a presence across Asia, you know, and now we have an extremely large presence all the way across Asia, for example.

DICK: Yeah. Later on, I'll definitely want to—

GILLINGS: But the roots of all that were sown in the early nineties.

DICK: Yeah, so it sounds like the—you know, really this late eighties, 1988, 1990 period, you're really consciously, seeing, this is how we're going to build the company. You're taking a look at the broader market here. Could you expand your thoughts? What was it about the market? How did you view, say, competitors, potential clients, and so on?

GILLINGS: I thought we were better than everyone else, so—

[Laughter]

GILLINGS: I mean, you have to have that degree of arrogance to go for it. I feel I was more aggressive than our competitors, so that enabled us to get quite a bit lead by the end of the nineties. And so I was just lucky, I suppose.

[Laughter]

DICK: Was there serious competition at this point? Were you ever worried about say losing a client or something like that to another CRO? Or was—you know, Quintile was pretty—

GILLINGS: [. . .] I wouldn't call it as serious as it is today, where there are other publicly traded well-organized companies. Then I would say through our aggression we certainly had a bit of an edge. And if you take the outcome, we grew faster than other people, then you'd say that was proven, you know. I think our competition might dispute that, but that's my belief, what I've just said. And I really could see drug development, and then subsequently, a lot of market access and commercialization, really being outsourced in a real partnering sense, for the simple reason that—I began to realize, if you could grow scale and critical mass, you could invest in the IT, you could minimize the human labor, and then be more efficient, which I think if you look at our results now, you'll see our business is actually doing. But it's taken a long while to get there, because the business, you don't have that much of the same thing. In other words, it's not—you manufacture a car, well, you know, you build this big manufacturing line, and then people all come in and do their bit, whereas drug development, I mean, you don't develop all drugs in the same way. And so there's a lot of variability about what and how you do it. And so until you really get a lot of it and are able to then to say, ah, all these things are the same, all these things are somewhat similar, and then take the common elements and build software systems, and then the overarching control software systems, until you get to that stage where you've got the scale to be able to do it in the first place, it's hard to make progress.

DICK: Mm-hmm.

GILLINGS: As we grew over one billion [dollars], I could see that we would get to the scale, but I also realized, we have to get to multiple billions before we really get to the scale that will enable that ability to grow the business without every time you added a piece of work, you had to add a person.

DICK: Mm-hmm.

GILLINGS: So it was a long process. And of course, the fact it's a regulated business, the fact that you can't just change computer systems in the middle of a study, so bringing in a new

computer system, you've then got to have that as an extra system, because the FDA have this Part 11 validation, which basically means you can't put in a new system until it's totally validated, which pretty much means once you start a project on a system, you've got to keep it on that system.

DICK: I see. Now were you working with the FDA at all as you were beginning to develop this type of software and so on, to make sure that it would meet their standards?

GILLINGS: **<T: 65 min>** Yes. Obviously, a lot of frequent contact, and customers. But I think it was the customers that were more of the barrier, because the FDA moved quickly to wanting more standardized electronic submissions, and it tended to be the pharma companies that wanted to individualize more. And so a bigger problem was overcoming the fact that each of your contracts had to be customized to a particular pharmaceutical company.

DICK: I see.

GILLINGS: With particular reporting requirements, particularly fitting into a system that wasn't really an efficient system. I'm not trying to be critical of the pharma industry, but they're not the paradigm of IT effectiveness. You know, they're not like a Google. And then for us, you know, remember, a lot of this, as you get to the late nineties, you've got the internet era. So hard to recruit the best IT people as well. So during a lot of this time, I could see where we needed to get to, but it wasn't easy to employ all the state of the art people and get our customers to accept what we were doing, because they would say, "Oh, the [inaudible] you've got to report it like this." So you had a number of hands tied.

So I think we could have done everything ten years quicker in a less regulated and less individualistic customer system type of environment.

DICK: Now has that changed over time, where the—

GILLINGS: It's shifting now.

DICK: Okay.

GILLINGS: Yeah, the reason it's shifting is, you know, the demands of the stock market, and profitability, and growth, and it becomes reasonably obvious as you look at numbers of people and expenditures that the per FTE allocated costs in our industry is about half of that in big

pharma. I've done those calculations a lot. And we've also taken over big pharma entities, small entities, and so been able to compute the costs under the structure we took over to produce something that we were producing. And certainly historically the CRO industry has been about half the cost.

Now I believe a lot of pharma could dispute this, but the dispute centers around whether you're fully loading the costs all the way up the system, or whether you're just selecting out the marginal costs. Of course, on marginal costs, we're the same. We pay the same salaries. I mean, how can the marginal costs be any different? But on the fully loaded costs, where you've got efficient IT systems, and a much smaller bureaucracy in this costing structure, it becomes evident that it's much smaller.

DICK: Mm-hmm.

GILLINGS: Now I think that underpins the success of our industry, to be honest, as well as the fact, in the end, we've delivered patients more quickly and delivered final reports more quickly.

DICK: Than what the pharma can do internally? That's—

GILLINGS: That's right. And that's partly because if all our customers were totally captive, so there would be less competition, then that would be less the case. But in an environment that truly is a market, if you can't deliver, you won't carry on. Whereas an internal group of a very, very large company, you know, that spends maybe multiple billions a year, and with huge internal budgets, there isn't the competition. It's all a matter of management reporting up. And so—

DICK: Inefficiencies—

GILLINGS: —I think it's—that's right.

DICK: —things like that can—

GILLINGS: But you can get around it. I mean, if you're bidding on a contract, and someone else bids one million [dollars] less, that's reality. So what do you do? You say, well, they won't deliver. Well, if they decide to go with them, you have to wait until that plays out. If they don't deliver, you were right. But if they do deliver, you've got to change your price.

DICK: Mm-hmm.

GILLINGS: So that inherent competitive framework brings a huge **<T: 70 min>** advantage to an industry like ours, once you put scale into it. And I think it took a long while for the pharma industry to accept what I'm saying, basically. Because I was always told we were too expensive. And I always challenged that. I said, we're obviously—because I remember someone called me up, and this is a funny story. How much would this cost? Let's say two hundred thousand [dollars]. And they said, "Well, I could hire two monitors and a secretary for one hundred and twenty thousand [dollars]." And I said, "Well, that's not the cost of doing the project. Of course you can. And if that's what you want to do, do it. I mean, that's not what we're competing against. We have a fully loaded system, total. If you come back three years later and want your data, we've got it, all archived. Everything is according to FDA standards. And you just hiring two people and a secretary, you've got an IT system, you've got a whole infrastructure, you've got offices, that you're not accounting for."

So, I mean, I think that epitomizes this whole notion of marginal costs versus fully loaded costs. Now to change fully loaded costs, you have to get into the whole guts of the whole organization, which is probably why our industry has grown strongly, but hasn't grown as quickly as it might have grown if that wasn't the case.

DICK: Mm-hmm.

GILLINGS: And being as it's in a regulated industry as well, it's always, oh, you know, if I change the infrastructure, will I fall afoul of the regulators? So there's a number of constraints on how it's gone. And now the business realities, as drug development, you know, more than one billion [dollars]—let me just leave it—you read that all over the place. It costs more than one billion [dollars] to develop a drug. Well, if that's correct, and obviously, there's calculations that make it correct—you can make the calculation bigger—that's a huge investment. And if someone says, "Well, you can do it for half this cost," then you do have to pay attention when the numbers get that big.

DICK: Yeah.

GILLINGS: So I think that's now what's happening. The quality of our industry, you know, an industry that grows up—with a sophisticated area, like drug development, you know, everything might not be in all the companies that are doing the business at the highest level of quality, because the industry is maturing. But you see, now the industry is quite mature, and I think it would be totally unreasonable to say there's less quality in a big pharma company than—or more quality in a big pharma company than in a CRO. That I think would be utter nonsense. But

I wouldn't claim that in the eighties the whole of the CRO industry was in that happy circumstance.

DICK: I see. So it's really the level of quality—it has increased as the industry's emerged. And here, I'm jumping a little bit ahead. I want to come back to the early 1990s. But were there the development of any type of industry trade associations?

GILLINGS: Yes.

DICK: And—

GILLINGS: ACRO. The Association of Clinical Research Organizations, or Contract Research Organizations. Yeah. And I was actually the founding chairman of ACRO in the United States. So yes.

DICK: What year was that? I should have it here.

GILLINGS: I want to say around 2000.

DICK: Let me—and I'll come back to that. We'll just back up a little bit to the early 1990s. You're expanding to France, Australia, Asia, Belgium, Italy, Tokyo, I have here. So really expanding globally. And then in '94, you have your IPO. Do I have the date right?

GILLINGS: Yes. April 21st, I think, 1994. Yeah.

DICK: And what led you to decide to bring the company public?

GILLINGS: Well, you know, again, I think it's the ability **<T: 75 min>** to bring more capital to bear on growth. First of all, you raise capital, so all this investment in our IT systems, our infrastructure, growth of offices around the world, is easier. During the nineties, I would say about half our growth was organic and half inorganic, so acquisition. You know, you've got a lot more capital, either through stock and through cash, for doing acquisitions.

So I think I played that pretty well. I mean, doing acquisitions, using stock, to do many acquisitions, and then growing the business to a much, much larger size. So—

DICK: Did you go out on a roadshow—

GILLINGS: Oh, yes.

DICK: —for that?

GILLINGS: Yes.

DICK: Do you have any stories or particular people that you were presenting to?

GILLINGS: Well, I found roadshows grueling. Wow.

DICK: [Laughs]

GILLINGS: I mean, you do ten one-on-ones in a day, and then you do it seven to ten days in a row, plus lunches with fifty people, and dinners, and breakfasts. I found that pretty grueling.

DICK: Mm-hmm.

GILLINGS: I think New York is tough, because you get the traffic. You've got seven or eight one-on-ones organized, and you're allowed like ten or fifteen minutes to get from one to the other, but if you're mixed in traffic, you know, the schedule goes haywire. So the haywire schedule is certainly one that you—because it's a bit nerve-wracking. And the first time I did an IPO, you are a bit nervous. It's a new thing for you. I've never sat on the other side of all these high-powered investment people. So you're a little bit nervous, and then you're a bit late for the appointment, and then they're a bit gruff with you. So that environment, it takes some getting used to.

But you've got to stand your ground, basically. The lesson I learned there is, you know, you've got to be confident, stand your ground, have a short, succinct story. Make it compelling, and make it have a return on investment.

DICK: What would be a real short, compelling story that you would tell them about Quintiles, that they should invest in it?

GILLINGS: Well, then or now?

DICK: Then. Then.

GILLINGS: Well, there, we were in an industry which had a lot of products to get to market, and they didn't have the internal resources to do that. So there was a huge opportunity to contract these resources to help them get these products on the market, because this was a once in a lifetime growth spurt for the pharma industry. That story went over pretty well.

DICK: I see.

GILLINGS: Because the number of NDAs or approvals, what, went to fifty-six, as I think I said earlier, in 1996, I believe.

DICK: Yeah. I think that was the peak there.

GILLINGS: That was then the peak. But that—I mean, that's a huge number.

DICK: Mm-hmm.

GILLINGS: And certainly it created a huge amount of effort and work going on. Yeah. And the profits of the industry I think peaked at the end of the nineties. That's when some of those products were really beginning to sell.

DICK: Yeah, you—I think—

GILLINGS: And the stock market prices of big pharma started peaking, I think, about '99, 2000, something like that. So, you know, you can see that wave moving through, and then we were part of that wave, enabling a lot of this stuff to be done that couldn't be done under internal structures.

DICK: Was it any different—well, I guess first off is did you have any formal business training? It seems like you're naturally sort of doing quite well. Did you have to seek out advice, things like that? Or [. . .] did it come relatively naturally to you?

GILLINGS: I have no formal business training. No. There's no question about that. Did it come natural to me? Well, I must admit, I didn't find it all that difficult. I mean, it seemed—a lot of statistical problems I'd formulated—I was quite good at taking a difficult problem and transforming it into something that was manageable.

I always remember once being given data on rats, **<T: 80 min>** and so some of the rats, they had more rats that died than they wanted. So that's a problem coming to me, and I said, "Well, how many cages?" I had no data on cages. I said, "How many cages are there?" So I think they said six. So I said, "Well, can you give me the rats by cage?" Well, all the deaths were in one cage. So I said, "Well, something's going on in that cage." Oh, and they were infected in that cage. Well, it's just a simple story. I solved this problem in about five minutes. Now you can argue, oh, that's easy, or you can argue it's difficult. It depends which, but these guys had spent weeks on this, and well, we've got too many rats dying.

[Laughter]

GILLINGS: I don't know. Do you have the insight to formulate things in a way that enables you? You go back and you say, "Well, how were these studies done? What could have gone wrong?" And then that sort of approach. I think I'm good at that. Sometimes other people are not so good, maybe.

DICK: I see. And did things change for you, running the business now as a public company as opposed to a private company?

GILLINGS: Well, yes. The whole issue of disclosure, you know, because if one person knows it, everyone has to know it. I think accounting being such a difficult matter to get a very definitive conclusion. And it may sound strange. I get frustrated with accounting, because particularly if you do an acquisition, it's very hard to get a real definitive answer on all the details you need. [. . .] You'd think of accounting as being a very precise exercise. Well, it is, once you've decided what rules you're going to use in that particular situation. But as you look at all the possible—you could account it under capital, or income, or under real estate. I mean, you've got a lot of overarching rules, and so choosing where you're going is a matter much more of opinion. And so I've found the—you know, getting definitive statements on the bottom line numbers, and dealing with all the disclosure rules, they're much more time consuming than they need be, in my opinion.

DICK: I see. Now I have here—let's see, IPO, 1995 is you're beginning to make acquisitions. I have here you acquired Syntex.

GILLINGS: Well, yeah, that was a subsidiary. It was the Scottish drug development entity that Syntex had invested in in Edinburgh.

DICK: I see.

GILLINGS: And then Roche acquired Syntex. When did they do that?

DICK: Ninety-four, I believe.

GILLINGS: Ninety-four. Yeah. That's right. So then when Roche had acquired Syntex, they decided they didn't really need this Edinburgh facility, so then I bought it off of Roche, and then we had quite a nice facility in the UK, with a lot of drug development expertise.

DICK: I see. Yeah. I was just kind of curious—you know, I read that, and I thought, Roche purchased that, and—

GILLINGS: So—yeah. So it was just something that Syntex had invested in, Roche owned, and then Roche didn't need it, so I bought it off them. Yeah.

DICK: Let's see. So again, continuing to grow, here between 1992 and 1997, that the average net revenue growth exceeded 50 percent.

GILLINGS: It probably did. I mean, we went from ten million [dollars] to one billion [dollars] in about eight or nine years, so it was—it wasn't dead smooth, but it was fairly smooth, you know. Yeah. So I would say there weren't that many years where there wasn't more than 50 percent growth, and some years, more than that.

DICK: And by 1999, your—Quintiles is listed on the S&P 500 index.

GILLINGS: Yes.

DICK: And how—I guess, what was your, you know, if you wouldn't mind giving—

GILLINGS: Oh, we were delighted. I mean, that was great. The one **<T: 85 min>** issue about privatizing, I thought, wow, you get to the S&P 500, and then we give it up. I must admit, I thought—I was very proud of being in the S&P 500. But we were there, and it was nice to be there. So that time when we got there was difficult, though, because, you know, we started to have a lot of volatility in the stock market as the internet boom, and then the prices went sky high, didn't they?

DICK: Yeah.

GILLINGS: And then they crashed. So I think that was an awkward time. A lot of internet companies were valued at a hundred or more times their revenues. I mean, it was like—with investment bankers trying to convince you this was a pretty reasonable value.

DICK: [Laughs]

GILLINGS: So that was a funny period.

DICK: Now I know in 2001, Pamela Kirby was brought in as CEO. Could you describe Pamela and why the change in CEO?

GILLINGS: Well we were public. I thought we were in a good place. And I guess I felt I wanted to make a CEO transition before I was, let's say, too old or something, couldn't function right. And then I thought, well, if it doesn't work out, I'll be able to come back in and run the company. I've still got plenty of time. So that was my thinking. And I suppose I thought, yeah, I've pretty much done what I wanted to do, built a nice company. It's growing well. And so this would be the time to bring in a CEO.

A few things, though, went wrong with that theory. The stock market started going all over the place. But the other thing, I like the idea that we would use our knowledge base to—as evidence for how you should design drug development, because we have so many programs in Quintiles. And then take a little risk with our customers on the programs they invest in. So rather than be a non-risk, purely a service entity, I was thinking we'd take a little more risk. So

those were the two things. The market didn't like the risk bit, and then the market also went all over the place with the internet bit.

DICK: Yeah.

GILLINGS: And so at this same time, you know, we started to get the stock price, ooh, going down, down, down, down, down. So I didn't like that, so then I decided to privatize it, because there was a lot of value there, but I realized I had to restructure somewhat. The market didn't like these risk things. And the price was cheap, and I wrote that in a letter to the board. I said, "The company is undervalued," so it struck me as a golden opportunity to buy the company back. So then once I did that, I ran it, and Pam exited.

DICK: I see. So the board, they understood that it was undervalued? It made sense for—

GILLINGS: Yes.

DICK: —to go through this? Now by 2000, or maybe you can give me a better date, I have here that you were pretty much a full service global CRO.

GILLINGS: Yes.

DICK: Was this even earlier, or was this basically by the 2000—

GILLINGS: Well, it was probably more by 1996. We did the acquisition of Innovex in 1996, and we'd also previously acquired Toxicol and this Edinburgh facility, where we did pre-clinical work. So we had all the pre-clinical work, all the clinical work, and then we had the **<T: 90 min>** commercialization through Innovex. So we were very, very full service. So yes, but clearly, by then, the year 2000, we were clearly full service, because—

DICK: Clearly—yeah.

GILLINGS: —we were there at about '96, '97.

DICK: Yeah. I have here it's around '96 that you pretty much had three operating divisions, the contract research, the Innovex, which could do the marketing and sales, and then Lewin-Benefit for—

GILLINGS: Yes.

DICK: —health economics and health policy.

GILLINGS: That's right.

DICK: And how did the Lewin-Benefit come about?

GILLINGS: Well, Benefit was a French company that I bought a little earlier, and Lewin was a US company. And I guess I was a bit before my time, which I've done quite a lot, you know, got into things where I knew it was going to happen, and then was a little too early, and it therefore didn't work out as well from the point of view of synergy. But the benefit-cost stuff being an enormous part of drug development, I thought was going to take place in the nineties, and it really didn't. It's more now it's taking place.

DICK: Yeah.

GILLINGS: Particularly with the outcome studies and the cost effectiveness studies. So I was probably fifteen years before its time with Benefit. And then with Lewin, I could see, you know, the pharma industry being much more involved in the management of treatments as a whole, so the pill was part of a whole therapy. And so there would have to be a greater interaction with the care of the patient, and therefore, health care information in general, and evaluation of health care, would be a bigger part of the pharma sector. Well, I think that's beginning to happen now, but that was again too early back then. So I would say it's a case of having the right idea in the wrong time.

So what happened, I mean, Benefit stayed in the organization, and ultimately, we sold off Lewin.

DICK: Okay.

GILLINGS: And so, you know, it was a nice company. We bought it for X and sold it for like 2X or something. I mean, it was quite a reasonable transaction. But I think Lewin then found a home probably in a better place.

DICK: I see. And coming back up to 2000 here, you know, full service, global CRO, certainly, and this is the time when ACRO is founded. Give me some background. What were your thoughts in terms of forming this industry? How did you go about reaching out to other CROs and so on?

GILLINGS: Well there was a fairly close-knit group of us, because there was only four or five companies, and all the CEOs knew each other, so I forget who it was that started having the conversations. I wasn't really the first to have the conversation, but I know I was brought into the conversations very quickly. And I was most supportive of a trade association, because it seemed our industry had got to the right size. And I think since we knew each other, we pretty much agreed, let's form it, and all the CEOs would sit on it. And then when it came to be the chairman, they thought I—I don't know quite whether I put myself—everyone thought I should be the first chairman. I had the biggest company. So it was like fairly easy. And then I was chairman for a year, and then I think Covance had the chairmanship, then PPD, and so forth. So the chairmanship went round.

DICK: I see. And what were sort of the goals or concerns that the association put together?

GILLINGS: Well, I mean, I think two things. One wanted to have standards for the industry, so that we were a little concerned that the smaller companies coming into the picture that might not have the same standards could affect the industry, and cause there to be adverse publicity and things like this. So standards in the industry was one thing.

There was some attempts to sort of have **<T: 95 min>** a better marketing, business development understanding through ACRO of our industry, but I didn't particularly subscribe so much to that myself, because we invested in our own marketing, and I thought differentiating Quintiles was better. But moving the industry to standards, where, you know, if you were part of ACRO, that you'd achieved a certain standard, probably was one of the more important things that we did. And that was certainly what I emphasized.

DICK: So basically allowing organizations membership into ARCO would—or ACRO would indicate, yes, these are the companies that are abiding by the standards that our industry wants to set?

GILLINGS: Exactly. Mm-hmm.

DICK: I know you were the first chairman. Have you been involved with it much since then? Or—

GILLINGS: Well, I was involved for the subsequent how many years? Probably four years. And then I thought, well, you can't just sit there forever, because the time would come for me to be chairman again. So then our chief governance officer Derek Winstanly became the ACRO representative, and in turn, he became chairman of ACRO for a one year term.

So I think it went, as probably is right, the CEO led it, and got it off the ground, got ACRO, you know, financially in good shape, with an agenda. And then a senior executive took over that from then on. And I think each of the other companies followed that suit after a while. I think I was the first one to move off and a senior executive come in, and then I believe now, except for the smaller companies, all of the bigger companies are represented by a senior executive.

DICK: I see. And 2004, you're awarded the CBE. Would you want to just mention that experience? So what—

GILLINGS: Well, I mean, you go to Buckingham Palace, and you get awarded it. It is quite an experience. But it grew out of—I became—I won the British North American Businessman of the Year, really, I think it was more between North Carolina and the UK. And that was awarded to me in Charlotte, North Carolina. And then people must have said, well, you know, you've helped shape the whole pharmaceutical services sector, and then since I was a Brit having maybe shaped a whole sub-industry, that became known, and then I was put up for the CBE, unbeknownst to me. I had no idea all that was going on. And I wasn't even aware in Britain they knew what I had done. So then that led to being nominated. And then I got a call, I remember, out of the blue—I think I was actually in Scotland at the time on business—the call had come to my office, and my office had tracked me down. And I got on the line, and there was someone from the UK embassy telling me I'd got the award. And they say things like, "We want to make sure you'll accept it before we give any publicity," because they don't want someone accepting it and then bad mouthing it. And of course, I was delighted. I mean, it's quite an honor, so I said, "Wonderful."

And then you go to the palace, and you get it, and it's rather a grand affair.

DICK: Great. I guess, you know, kind of bringing this up to 2010, how were things changing at Quintiles in terms of expansion, acquisitions? Had that growth begun to level off at that point? Or . . .

GILLINGS: Well, it wasn't 50 percent.

DICK: Yeah. [Laughs]

GILLINGS: But we've grown. The privatization occurred in 2003, and over the period **<T: 100 min>** 2003 to the present, our revenues would have multiplied by about three, and our profits by about five or so. So, you know, that's pretty good growth.

DICK: Yeah.

GILLINGS: And it's been pretty consistent. I mean, some years, sharper growth. Other years, a bit flatter. But a nice, steady trend on a moving average basis.

So yes, that has taken place but let me now back to the privatization to set the ground. Given our stock price was low, we had a fair amount of cash, it seemed to me a no brainer to buy the company back. It became clear to me, if we had a number of years where we really could invest, we could build some of the IT structure while we were private that we needed without the tough time that you tend to get in the public markets. If you're investing a lot of money and they say, "Well, when are you going to get a—when are you going to get a return?" And you say, "Well, next year," or, "Two years," whenever you say, and then you don't make it, you know, you get zinged. Well, it's not all that easy to predict some of these things.

DICK: Mm-hmm.

GILLINGS: And you can't really say, "Well, seven years," because they might say, "We're not interested. We shouldn't be investing." So I felt that we really need to upgrade our infrastructure to move to the web-based age. Now what we had to do, as I had said earlier, it is hard to recruit the high talent, but about 2004, we did get in a highly talented IT head, Bill Dean, who assembled a good team around him, who then was able to deliver some of the things that I wanted. And so we really transformed our IT space. And we continued to invest rather heavily. And I think now we have an IT infrastructure that enables us to build a platform which is not just people based. It's based on processes and systems that one can leverage, to a greater extent. Now that also causes job descriptions to change, training programs, the sort of things people do.

DICK: Mm-hmm.

GILLINGS: And so there's a lot of other changes going on. But I do believe that investment has set the stage for our future growth, which probably can accelerate over even our last ten years, because we really now have a broad-based platform for our IT and the movement of the data, the validation of processes, the validation of data, that we haven't really had in one big system before.

DICK: And that's really just coming to be at this point?

GILLINGS: Yes. So now I wouldn't say it's complete.

DICK: Yeah.

GILLINGS: But it's largely in place. And I think way ahead of the competition, in my opinion, from what I've seen.

DICK: Mm-hmm.

GILLINGS: And so as we begin to secure that—you know, it enables our profit margins to increase a bit, and things like that. So the period '05 to '11, we were more and more putting that in place, and that was a period where we were often running multiple systems. It's much harder to manage, but as you migrate to a more standardized system, you begin to get the whole structure in place. And I think I referred earlier to in a regulated industry, you know, you can't just switch a program on another system. I mean all the IT companies, I wish I could have that freedom. They send you an update, and that's it.

DICK: Yeah. [Laughs]

GILLINGS: And it's not really allowed in these big, regulated structures for drug development programs.

DICK: Right. So it sounds like this IT infrastructure is I guess in certain ways standardizing and making more efficient ultimately the entire process, and is this—and again, it's a regulated industry. So have you been working with clients and say the FDA to ensure that—

GILLINGS: Yes. Very **<T: 105 min>** heavily. And I mean, building a platform so that in a menu-driven sense you can pick out any administrative data, scientific data, link it together, so that you're not committing statistical errors of this data really isn't associated with that, so that you've got your units of analysis really honed in, linking it to country, to investigator, to drug. So the amount of data linkage that's gone on has been quite substantial. So, you know, I think we've got a very good system now. Yeah.

DICK: Great. And did you take the company public? Again, I have here that—

GILLINGS: Yes.

DICK: —in February—

GILLINGS: May of this year.

DICK: Of this year. Yeah.

GILLINGS: Or 2013.

DICK: Last year—last year—yes.

GILLINGS: Yes. We went public again in 2013. I mean, that was nine and a half years or nine years, eight months, after we'd gone private. And that was, again, nine years after we'd originally gone public. So I call them two ten-year periods. We had ten years of private, ten years of public, ten years of private, and now we're in our third—fourth decade of being public.

DICK: Of being public.

GILLINGS: Yeah. Yeah. I don't know whether I answered your question now.

DICK: Well, I guess considering you have had these waves, what were the differences between this IPO and the earlier one? You know, I guess probably same grueling roadshows, but did it become easier to sell to potential investors?

GILLINGS: Well I think we now have a level of professional management that's much, much greater. I mean, as you go back to when we first went public, I was an entrepreneur with a few other entrepreneurial types, and some managers. Now I'm chairman. Running the company is a whole professional management team, seasoned professional managers. So, I mean, that's, what, a passage of 19 years. A lot of that has gone on, and more in the last 12 years. So I think that's the natural evolution of a lot of companies. So we have seasoned professional managers running the whole company now. That's probably the biggest change. Now, you know, most of those people are more familiar with the publicly traded environment. Also, we're a much bigger company.

DICK: Mm-hmm.

GILLINGS: And we're regarded as a growth company. And so for a certain sort of investor, it's almost a must have stock.

DICK: Yeah.

GILLINGS: And that is to our advantage. We like that a lot.

DICK: Now let's see, where are we at? About a minute—or an hour and fifty minutes, so I don't want to take up too much more of your time, but I wanted to just ask a few more broader questions before we finish. And one is just the type of clients that you take on. Is Quintiles—is it generally just big pharma? Do you do work for say smaller, more virtual companies? And how has that changed over time?

GILLINGS: Funny enough, that has changed less than one might think. In the early days, it was always assumed that we only did work for small pharma companies or biotech, and big pharma was self-contained, or there's nothing further from the truth. All my early programs came from big pharma, every single one of them. And I don't think I particularly dealt with a small company until at least five years—the company was five years old. On balance, I would say slightly more of our work has been with one of the top twenty-five pharma companies, so 50 to 60 percent of our revenues have tended to come from the larger of large pharma. I'm not actually sure what the percentage is today, but I wouldn't think it has changed that much.

We are, though—one trend is happening. We are getting more larger partnerships with midsized pharma companies. So if you take over everything that a midsized pharma company does, you know, you do get a big contract.

DICK: Right.

GILLINGS: For a midsized company that wouldn't have been on the horizon ten or twelve years ago, because they would have outsourced some things, but wouldn't say, **<T: 110 min>** okay, you're my partner here. You have more skills than we do, and therefore, you do it. So I would say that's probably the biggest change. Some of that partnering may well be moving up to the big pharma. I'm expecting huge partnerships with big pharma companies that will be the next era.

Now the biotech companies, it's always been a moderate part of our business. And with biotech capital now coming along again—

DICK: Yeah.

GILLINGS: —you know, it's been speeding up this past year. But there's much more capital now in the biotech industry than there was three or four years ago. That is providing a market, again. But that does oscillate a lot with the financial markets. If investors are putting money in biotech companies, they have to spend it, and if they're not, they don't have anything to spend.

DICK: Yeah.

GILLINGS: So our business there is a little more up and down, according to more the financial markets as a whole.

DICK: I see. Now I also wanted to ask about this I guess globalization of the company, or becoming a global company, and—and perhaps discussing some specific cases in terms of moving into Asia or China or Europe and so on. How was it—I guess what would have been—what have you had to deal with in terms of I guess there's different cultures, there's different regulatory structures, and so on. How have you managed that in terms of interesting these global markets?

GILLINGS: Well, what—I always made a point—I mean, I try to keep up with current affairs, and so—and probably more so coming from the UK, maybe more so than an average American. So, you know, that's point number one. I always tried to visit the countries I thought I wanted to do business in before even doing business. So I'd travel there, talk to the regulators, talk to some professors, talk to some customers. If I could identify any, talk to some potential employees.

Sometimes talk to accountants and lawyers, just to make sure I'd spoken across the board. So I would do that all the time.

And then as a result of that, form a view, well, particularly if I located a good person to lead the company in that country, because I tend to like a locally led person, if I could locate such a person, I'd bring them to head office or over to London in the UK, and we'd give them a lot of orientation and training, and then obviously, hopefully, if it was a leader, they would be knowledgeable about things in the first place. But typically, then, it was the first company of its type in that country, so there wasn't a cadre of people that did all this. So that was my sort of formula. And then once I'd got a sense of the size of the market, I would then try to guesstimate, well, you know, what's the size of the market? I would try to guesstimate, is there any local competitor at all? Because there's always some company buried that does some similar. Then is this market going to grow? Will our customers in America or Europe, will they do business with us in that country?

Once I'd got feedback on all that, and sometimes I had to make a spirited guess, because I'd often get the feedback they wouldn't do the business there, but then I'd try to figure, well, we can do it a little cheaper. Maybe it's a better business model. One could find—but then sometimes people would change their mind, and they would do business there.

So as I weighed all this up, typically about a year later I'd start it up, and then what I'd do, I'd try to visit it as frequently as I could. So what I then developed was going around the world four times a year, so go all the way around the world, and make the ports of call, so plan that whole round the world trip. And that would then—four times a year, and that would enable me to be face to face with all the startup organizations that we had.

DICK: Wow.

GILLINGS: So that was my general strategy, anyway.

DICK: Mm-hmm.

GILLINGS: Quite grueling. I mean—

DICK: Yeah. I would **<T: 115 min>** imagine.

GILLINGS: Yeah.

DICK: The move towards global markets, is this a general trend within the CRO industry?

GILLINGS: Yes, it is. But we've lead that I would say by far, particularly in Asia. And that has enabled us to build an expertise. You know, we have a lot of physicians, and quite experienced people now in Asia.

DICK: Mm-hmm.

GILLINGS: Which you may find if you dug deep would not be the case with all our competitors—with any of our competitors. And you'd probably find our drug development knowledge was pretty deep relative to anyone, you know, big pharma company notwithstanding, in the industry. Because remember, our clinical group is much bigger than any other clinical group anywhere in the world. It's probably twice the size of the biggest in the pharma industry.

DICK: Wow.

GILLINGS: So that expertise, you don't build it overnight. You go through a period where you might get a leader. Then you've got to get a lot of junior people. You've got to get the business moving in. You've got to get the quality standards and all the systems in place. And then you attract a few more senior people at the same time as you're building the business. And all this time, you're losing money. [Laughs] And then it comes of age when it can stand on its own. It can make a profit. And the managers are experienced enough to participate in a global management team.

And what I did, I set up three geographical management structures, which I call management boards, of the Americas, Europe, Middle East, and Africa, and Asia and Asia Pacific, so that we had the regions were linked up to a management board that was sensitive to the geographic demands. And then, of course, functionally, we had the lines of business globally managing things. But what to me had was the functional lines reporting, and the geographic views of whether, oh, this decision in the head office now is bad for Asia. It might be good for Europe. And you're not taking account—like for example, business is a little slower, you don't grow jobs so much. Well, then, now Asia can't employ people. Well, they're growing at the same rate anyway, and maybe Europe is dead flat. Well, you can't have the same rules apply from one to the other. So making the company much more sophisticated on all these things became the order of the day.

DICK: I see. Do you know what's driving this sort of globalization or setting up CROs in different regions of the world?

GILLINGS: Well, basically, more economies are moving into the, what, greater than three thousand [dollars] or four thousand [dollars] of GDP per head, per capita, which tends to be the point at which you spend more money on health care, wherever it may come from.

DICK: Uh-huh.

GILLINGS: And therefore, more money gets spent on pharmaceuticals, and therefore, there's more interest in that local market. And as a drug is on the market with more sales in a particular country, there's more desire—the government of that country wants to know more about it, and say may demand, well, we have more studies that are in this country, and so forth.

DICK: I see.

GILLINGS: So you get that cycle that really is economically driven originally, and once enough money gets made, it moves into the health care framework, but it's sort of like, boom, and then it starts moving, you know. So it's really a step process.

DICK: A qualitative shift.

GILLINGS: There is a qualitative shift. Now Asia has been—you know, if you look at the, what, per capita GDP across Asian countries, you'll see they're—let's [inaudible] for a one thousand [dollar] to five thousand [dollar] range and beyond. Countries have been moving into this range. So their health care expenditures have been accelerating. And so now the demand is all the way down the system. They're setting up regulators, looking at things. And there's much more interest for big studies to have patients in those places where you're going to sell the product.

The other side of it is also as products are sold globally, there's a lot of competition. **<T: 120 min>** You need to recruit enough patients to do the studies in the first place. And sometimes, you need the global capability to recruit the numbers of patients you need. There wouldn't be enough patients in the United States to satisfy all the drugs that are being developed. So that has definitely become the case the last twenty years, whereas previously, no, there wasn't the amount of patients that needed to be put on these drugs. And so you didn't really need the globalness.

DICK: Great.

GILLINGS: Some diseases also are more Asian. So there, you do get the patients. Hepatitis, for example. I mean, you can study it outside of Asia, but you get a lot more patients if you go to Asia.

DICK: It just makes more sense—

GILLINGS: Yeah.

DICK: —to have that. Yeah, I guess to kind of conclude our talk here, I was wondering if you could maybe reflect on I guess the CRO industry that you've in many ways built up here, and how it's changed over time, you know, emerging kind of in the early eighties, and—

GILLINGS: Sure. The big change, the big shift has been it's gone from a tactical decision to outsource to a more strategic decision. It's part of the business model moving forward. I would say that is the big shift that's taken place.

If you really go back more, I'd say in the eighties it was more consulting. In the nineties, it was more we've got too much work and we've got to get it done. And then more recently, it's, well, we won't be successful on being an efficient industry unless we take a lot more notice of what the resources we need and what the cost of those resources are, how much we partner and outsource, and so how we really restructure that biopharmaceutical business development model. And that's what I'm calling strategic, that last bit.

So we've moved from tactical to strategic, and then the tactical, it went through the shift of more being a consulting exercise to being an overflow exercise, and then becoming a strategic infrastructure exercise now. I would say that's the big picture.

Now that carries with it certain things, because of the scale that a company like ours have reached. I mean, we may in many regards now have better systems, or more software, or more, you know, viable software across the whole industry than even our big customers, notwithstanding how many they spend. We probably still now spend more money than any one of our customers on IT. But it was the case once where we were far outspent, but nevertheless, not really outstripped in capability. But the spending was so much more, because they were such bigger companies.

I don't think IT expenditures in the pharma industry would be their best gold star. I don't think they'd get any stars at all. I think research and inventiveness, and then—on the one hand, in the eighties and nineties, and now marketing products, more recently, would be the A star that would be given. And some of these things now are gravitating towards our industry, and particularly ourselves, where I think we're changing the processes and the way some of these

things are done because of the business demands being made on us to be more efficient. So that now is a very healthy industry, because competition is forcing better processes, more efficient processes. And so now that we're strategic, we're then changing the way things are actually done, which is the way it should be, you know, because now we have the greatest skills, certainly in the logistics of drug development.

DICK: Yeah.

GILLINGS: I mean, there's no doubt about that. If you took out all the CROs, then nothing very much would get done.

DICK: [Laughs]

GILLINGS: There's another thing that's important here, and that is I think the biotech **<T: 125 min>** industry could never have grown up without that infrastructure, because if you take the early biotech companies, you know, they did build their own infrastructure, but you can't have thousands of companies, or at least hundreds, all building an Amgen or a Genentech.

DICK: Yeah.

GILLINGS: I mean, it won't work.

DICK: And many of those are working out of university labs, and—

GILLINGS: That's right.

DICK: —when they started up—

GILLINGS: But you can have thousands of companies on a virtual system. And the sharp change that's taking place is now you can do anything virtually. And so that opened up the capabilities of the inventiveness of scientists anywhere to exploit it much, much more, and, you know, that's exhibited as you go from the middle nineties onwards, and I would say about the middle nineties, it was clear that was starting to take place. You could be much more virtual.

You know, the huge number of biotech companies you've seen being developed, or HUYA is an example here, many of those would have had a lot more difficulty, because they couldn't have grown virtually. So I think it's really helped push the more inventive side of the research part of the industry as a whole.

DICK: Where then they can focus on that, and then farm out or outsource the—

GILLINGS: That's right.

DICK: —the other needs. Did you see the virtual pharmaceutical model being taken up more, now that it seems like there's infrastructure in place where it can be done, or could potentially be done?

GILLINGS: No question. And I see more partnering, because I've got a sort of a fund vehicle that we're partner with things. That's distinct from Quintiles. But I think you'll find that the tasks that get done, the day-to-day operational tasks, outsourced more and more. But there's more business partnering on the decision of where to put the risk investments. So now the revolution is taking place, partly because it's so expensive to develop a drug, and partly because if you spread your risk a little bit, you know, take half a return on each of two products, and as long as one of them win, you win, instead of its all or nothing.

DICK: Yeah.

GILLINGS: That sort of mentality. And then I think there's been a tendency in big pharma companies to have an investment decision that's more based internally, on the internal dynamics of the science, and the decision making about that science, which has an inherent bias towards something invented in one's own shop, right? Oh, we invented it. We know more about it. Therefore, it must be good. Oh, that guy, that's nowhere near as good as ours.

I think the pharma industry needs to continue to move, and it is beginning to move, more to a real evidence-based, risk-based, return on investment-based modeling of investing in products, and may the best man win. When you put this objective data to state—on the table, and you're not driven by this more subjective data, ah, you know, we're going to back this, so that is slowly taking shape, partly because of the partnering. You know, if there's another funding mechanisms, that funding mechanism doesn't just cough up money without the substance and support that that money will show a return. So I think there's that side of the virtualness. On the business side, it's becoming a little more virtual, as well as, you know, on the day to day operational side.

I think that bodes well. I mean, one can think of, you know, more open-source type systems developing in the future, too. **<T: 130 min>** More digital patient networks. The whole business will change quite a lot. You know, the first Facebook trial we talk about a lot. And we're in a position to do all of that. We've got our own digital patient business unit, a lot of systems that could do all that. So the whole landscape, you know, the social networking, the internet, is moving in, and the internet more on the data, because now we can move data around.

DICK: Yeah.

GILLINGS: So you build the processes to enable it to be valid and reliable. But the other side is the studies and the patients, you know. Now that through social network types of things can be made much more efficient.

DICK: Great. Well, I think this is a good place to conclude here. Thank you very much for sitting down and chatting. It's—

GILLINGS: Did you get what you wanted?

DICK: Certainly. Certainly. You know, I think it's a great story, so really appreciate it.

GILLINGS: Excellent.

DICK: Great.

GILLINGS: Well, I enjoyed it very much. Yes, you know, I'm having to think back a little bit there.

[END OF AUDIO, FILE 1.1]

[END OF INTERVIEW]