Andrew 0:06

Hello and welcome again to another episode of "In The loop." Today Rasmus is coming back to have another chat about blockchain, but this time taking the basics and layering on something relating to pharma. We are going to dive a little bit into pharma and to understand how blockchain is applied. Look at some names, case studies, points of reference, so that we can go a little bit further. Then a little bit on the COVID situation, Corona times, also what's actually holding back pharma at this time. So, first things first, Rasmus. Hello, great to see you again. How are you?

Rasmus 0:54

I'm very good. Thank you for inviting me again and I'm very happy to be here today.

Andrew 0:59

Brilliant. So, let's start pharma, over to you

Rasmus 1:05

Well, you can say pharma, let us do a couple of definitions first, because we're going to talk much deeper about actual applying blockchain in pharma.

Pharma sometimes it is important also, to define it a little bit, you have pharma and healthcare.

Healthcare is where we go to the doctor. It's where we go to a hospital and that part where it interacts with it happens inside the hospital. The other definition of pharma is what happens outside the hospital. That's from defining drugs and doing the research and development to trials the production and then supplying the actual drug to the healthcare provider.

First, it's important because the blockchain actually covers both sides and people often see that as pharma. On top of that, we do need to also think of three different parties in this discussion, there are the consumers, you and I buying the actual drug or getting it on a prescription. There is the pharma company, or the healthcare provider that provides it to us, as you know, also produces it. Then finally, we have the government because it is something we eat, we put into our mouth and in that way it's also important to have something like the US FDA approval.

Andrew 2:18

So in that case, we've got three pillars, or three points of the triangle, and for pharma, is it something they really have to get involved with? Could they not just wait like everybody else seems to be doing?

Rasmus 2:33

Well, if we go into this, and then also why I mean, it might be actually a good reason for having blockchain for pharma, which some people actually may or may not have heard about that in the COVID-19 discussion here. But let's just talk in very simple words to why is actually a blockchain relevant for pharma. In the other podcast, we discussed what it is. So I'm not going into that. But I will try to give some examples and dial a little bit more into it.

Andrew 3:02

Right. And with regards to sort of FDA approvals and other government bodies, do they specify that you need blockchain now?

Rasmus 3:11

No, they don't specify, but they do have a vague definition that you need to have an interoperable model where you actually can track and trace your drugs. So, what is not to like about that, it is that people have a free definition. But many people have actually turned to the many companies, and that could be like Merck, Pfizer, Novartis and other large pharmaceutical companies, for blockchain then say, Okay, this might actually be the wrong way we solve this and have gone with technical providers on that.

Andrew 3:47

And with that, with regards to the sort of, let's say, the tracing side of things, what about the actual financial implications? Is there any value for pharmaceuticals?

Rasmus 3:57

I want to dial back a little bit, because just to be sure that people see why it is relevant for pharma.

It's something about the general part on friction between the vaccine participants. There is today a company that produces the drugs, but not the same one that did the research on it, and eventually, the one that is distributing it is not the same company. So that means we now have a lot of parties that have to communicate and have to have a track of where this drug is. And, make sure it's not counterfeit, unfortunately.

The WHO says that around 8% of the drugs that we actually consume worldwide is counterfeit. That means it wouldn't have the effect and that's actually very sad.

So, you can even have malpractices that way around. The friction, the speed, let's say we go to the discussion on a trial for a pharma company in the time of development. They need to have a lot of patience and that's quite expensive, depending on its phase one, two, or three. FDA estimates that a phase three trial means that we now need to put around $20 million in for that, to have enough variance, enough people in it, that's a lot of money.

So you want to make sure when you do this, you can actually both have proof that it actually worked or not, but also have an easier way of having people to verify it, meaning FDA goes in and then says it's correct. People are looking at it, that is one way you could have the frictions between the actual three parties. I am talking about the patient, me being part of a trial, the government and the actual producer of it.

Andrew 5:42

Would you see that one benefit being possibly with these trials, because they are expensive, and we had Corona times, and everybody's saying, I'm going to get a vaccine in months, somebody says “Not on your life” or whatever. If blockchain was about, would that help in any way in terms of the speed of that process, the validation and things like this for the trials?

Rasmus 6:02

Yeah, I mean, we haven't seen the COVID-19 vaccine yet. But what is important is that it's going to go through the same channels as any other drug. So if we put that into a more of a fast track, or speed that process up because we have the data available, it is very likely that they will actually approve it faster, meaning that we could save more lives. It has a positive effect both on economy and on health.

On top of that, let's just take the case that a vaccine comes, the distribution of that vaccine is equally important that we now inject the product or the actual drug that we are supposed to do. We don't inject something that might not be the product.

On top is the actual supply chain. That's the other part we're saying as we're looking into a blockchain, we now have a ledger, which is distributed to a lot of places and you cannot put something on that which is not correct.

If you now follow the right procedure, that means that some somebody is past the point where you actually don't do trials, you're now distributing and you know that drug is originating from this factory, because probably there is going to be more factories producing it like the N 95 masks in the US.

That was a hundred and ten million dollars that was put up by the government in the US and everyone could supply it, because it was so hot in demand. Everyone could buy it, but the tracing of where that mask came from, if it was really the right mask with anyone who could stamp N95 on mask. Those things could not be traced because it went through very tangled supply chains.

Going forward, that's one of the things that some of the larger companies are coming back to in the examples as they actually try to get that particular be it medical devices or drugs more streamlined.

I will know exactly what I'm buying from where it was produced and which part or parties was involved.

Andrew 8:12

So, with regards to blockchain with pharma, do we have a couple of case studies or real-life situations where these sorts of things are happening at the moment?

Rasmus 8:21

Yes, we do have and one of them is also what you can read and some of the articles that are on the Internet we will put in the show notes on the latest articles on this show.

One specific example is the return of drugs once they have been supplied to the end, to the pharmacies. Now they want to return it because it is a perfectly usable drug, but it's not just being sold by this partner. So, if you now need to return that in the US, to the distributor, you need to know exactly where it has been.

It needs to have a barcode on it so you can identify down to this single batch of that drug and that today is a huge administrative task. When you put it on a blockchain as you move it out, and then take it back, you know exactly that it was in this pharmacy in this county in this city, that part was there. Then you can start saying, okay, it is legitimate.

But more important, if somebody tries to tamper with it, you can mark that batch as suspicious, not saying it's wrong yet, but you can at least identify the bad apples faster. For us as a consumer, if they do this in the supply, we all know it's the actual drug that we're getting, when it comes back. This is not a small business. This is around seven to ten billion dollars a year in just returned drugs that need to be distributed to other countries, or for that state, or other parts of the same country.

It's a lot of money. If you can't do it, you may have to simply take it out of the chain and say, this needs to go to destruction. We don't take this, don't deliver it to people even when it is a perfectly fine drug.

In that perspective, there is something and it's already called MediLedger. They are probably the first and most forefront part on this, because it's actually in work today,

Andrew 10:25

Right, I've not actually heard about this.

Rasmus 10:28

So, in 2013, the FDA made a Security Act and the EU made a directive about false medicines. The consequence of that is that now since 2013, within 10 years, you now need to keep track of your drug the whole way through from when it's produced, to actually distributed and also handled. That inter operational system they demanded is to be in place in 2023.

Now we are in 2020 and we see the first initial part here, but the track and trace part, which is coming before the return part is where they are working right now. For those companies that are part of this larger MediLedger, they will be able to actually prove how it's actually gone from the initial production all the way into the pharmacy and if something is returned, so it is a real life example.

Andrew 11:25

Regards to this, you've got to be FDA compliant. What are the other cases? Are they on the supply chain? Or have we got just the MediLedger? What other things could be out there?

Rasmus 11:37

A couple of things. I'll try to explain here that given that we are talking about pharma and healthcare, you can say that we talked about the trials.

The other part is the patient data. FDA and the Center for Disease Control in the US talks about electronic medical records, or for that sake, an electronic health record. The main purpose is to actually have the patient data securely stored, so it's not open for everyone.

You can have it for the trial purposes. So, I can see that it was you that was in this trial, but your record and your life and the whole sickness part will stay secure. Because that's one of the concerns by FDA is that when you do these trials, you're often handing it over to a clinical trial as a company, and they would then also need to keep those records secure.

That is one where blockchain is also coming. Another part is, of course, I said, this is the whole part on the supply chain, where the analysis even goes further down, where you make sure that counterfeit is out.

You take the claims that might be there, you can't claim the same thing twice at different places, because it was claimed already and was also paid out.

Today, that's a lot of paperwork that nobody does and if you do have two insurance companies, they don't see that there was a claim maybe on one side and on the other side. Those companies are interested in having a claim and that is why insurance is interested and moving towards that use.

Andrew 13:23

It is, but it's also people like the NHS, where people decide they're going to go on holiday. So, they stack up on some drugs and then pretend to their GP that, unfortunately I do know somebody that did this in the UK before they emigrated. They claimed they were lost and therefore got another three months' supply because they didn't want to pay for the drugs abroad. For me, it's one of these things where I can see the savings. I can see the legal aspect, as well. But we've mentioned MediLedger, what other companies do we have?

Rasmus 14:00

Let's take something some examples right.

Andrew 14:02

Something I can understand.

Rasmus 14:04

Yeah, so first of all, you know, in order to kind of grasp this, there is also a working group, the group is called the clinical supply blockchain working group which Biogen, Pfizer, GlaxoSmithKline, Merck, AstraZeneca and Deloitte working towards having some kind of industry standards.

It is because whenever we have this, like the MediLedger, there are some conventions, what do we actually put on this? How do we do it, you also have European vendors like SAP trying to support these people.

Many of the pharmaceutical companies have this as the underlying their ERP system, the enterprise resource planning system. Then on top you have IBM which is very much a partner that now has blockchain as a product that you can pull down from the shelf. They will say okay, how do we support you now? In this initiative and actually get you there.

And maybe I should also tell another part, which because we talked about MediLedger, I should talk about what is MediLedger? What is the underlying technology and there we go back to the last discussion on blockchain?

It runs on what is called Ethereum, which is the actual company that has the blocks. This was possible to start up in 2017, that's three years ago, before IBM had a ready to use ledger. And now it's running on a ledger that is purposed for keeping something of value, and distributed to what it is today, around 15,000 different places the same storage of the same data.

So, this is about around the world, you now have records running on a ledger, which is used already. And not to forget from the last discussion as well on the smart contract. If something happens, let's say a drug is suspicious, a smart contract can mean that then that company won't get a return fee, or they won't get the remuneration that they are actually allowed to get because they couldn't prove that the drug is okay, or has actually been in their hands all the way. So now we have technology, which is invented years ago or some years ago, supporting and moving forward in a different industry than it was originally designed for as a technology.

Andrew 16:32

Now, when we go to look at the pharma companies. We have got this alliance, but have they done anything? Or are they still talking and still trying to work standards

Rasmus 16:45

I think this is continuous basis, right? I mean, right now, what you have now is the MediLedger that is defined. But you can say there's still a lot of other places you could have even more definitions on it. The MediLedger runs on a technology, which is not proprietary for the pharma industry. They use the Ethereum, nowadays blockchains looks at like IBM wants to make a medic co block token or a blockchain. That would be the next level again, so you are now in a situation where you can actually have consortiums going together and saying, All right, we definitely want this information to be **stored so we** can show others, it could be the FDA or the actual consumer, at one point of time, we are in control of this, and everyone else is having the same record so we cannot do fraudulent information.

Andrew 17:39

Will this end up being each will have, according to an industry standard, the Merck versus the Biogen versus the whatever? Or will they all be together in some way?

Rasmus 17:52

That is where you can say that the industry drive this much more. The reason is why blockchain does not work, it is all about adoption, you need a lot of people on it. Or you need at least the important and relevant players to go on to it.

That was the history back in the transportation where you had the world's largest transportation company, and the technology provider having a blockchain, but nobody was on it and then it didn't work.

Now, they did change that in the pharma where they now have the right people, the right code, the right participants and are expanding.

So, let's take the simple thing by Walmart, KPMG, Merck and IBM. They did this around food, they made a blockchain called food trust, one to see how your product travels from its production to the store and how it was kept at a certain degree of temperature to ensure quality. So, it was not, perishable goods left in the sun, right?

That's the thing, you would have information that shows that this is edible, or at least okay and secure. That is the same purpose that you see in the drugs case, I will give an example, some vaccines need to be kept at a certain temperature in order to be valuable when you actually administer it to a person.

That is now where the blockchain can travel along and say, when it was here, it was at this temperature and when it was the next place it will be the next temperature. When you're going to use it, is it still valid or safe to use? So, it has the safety part.

Andrew 19:43

Now I understand that one. In your opinion, what's actually holding pharma back on using blockchain?

Rasmus 19:55

It's the collaboration. It's people wanting to own it.

Now, we are more mature, but in 2017 there was some bad news on investing money because it's not free, they had to set up the blockchain on MediLedger and now we're having more people on board.

Everyone was probably because let's face it, pharma is a very conservative industry. You do not move things unless it's really safe, or at least it provides a valid sound business case in it.

On top of that, if you do **this, am I** actually meeting the regulatory requirements as it is not only me, as we are now back in the triangle. Do I benefit? FDA or EU? From showing just because it was on a blockchain, I saved some of the documentation along the way.

You also have people that are scared, it's a lot of millions they have invested. What if I use blockchain and it didn't give the value? They would have to do the whole trial again.

Well, that won't work, so people have been holding back on that. Now. We are seeing improvements and we are seeing that the adoption is there. More companies in pharmaceutical want to be on the same blockchain, not a Pfizer and Merck individual blockchain, they will be on a joint one, because it served a purpose for all those participants.

Andrew 21:20

Right. So it's almost going to be like an open standards, in terms of the definition, but it's specific for that application in that industry.

Rasmus 21:28

Yes, and again, this is about the adoption of it and the collaboration part. The infrastructure is there then probably it will be even cheaper to build infrastructure for this, but it's also about being first and having something that actually runs on the MediLedger if you're talking about drugs. Lastly, for the collaboration, the concerns are what's holding the blockchain back.

Andrew 21:55

Right, interesting. And, in your opinion, what do you think will be the next thing that you'll see in pharma, where they will actually adopt it?

Rasmus 22:10

Once we solve the fact that this actually is safe to use, and we take out these middlemen that may actually or may not introduce counterfeit, I think there will be like a new standard, that will be the way you actually do it.

You also need to have the FDA changing their mind saying it is okay, especially when those have been in pharma. I'm not signing with the pen on a piece of paper anymore to show that this is actually correctly tested and so on.

We are digitizing this journey now for the FDA as well and that is one of the challenges. I think that's where you see them, they have pushed for legislation and directives. Now they also need to live up to that and be able to audit or approve based on that level.

Andrew 23:01

It's interesting, because as we know, it's a government body. And that could be another little game in itself.

Rasmus 23:07

I can make the connection back because that's actually where you have the COVID-19 discussion, it pushes CDC, FDA EU to say how can we actually fast track things. That will push the digitalization as it has pushed even normal corporates to do digitalization.

Andrew 23:30

So, Rasmus? That's great, a good overview on pharma. From my side, thank you, again, for popping back to have a chat about blockchain. What we'll do as well going forward, if you don't mind is maybe look at another industry, and if you're listening to this and you'd like him to dig a little bit into a particular topic area regarding blockchain, or a subject or an industry, could be automotive, renewable energies or something like this. Then I'm sure Rasmus would like the homework. In all seriousness, thank you very much for turning up. It's been brilliant. Thanks.

Rasmus 24:15

Thank you very much.

Episode Tags: Blockchain, Pharma track and trace, Rasmus Schioenning, Andrew Travers, EU - Falsified Medicines Legislation and Directives, FDA - Food and Drug Supply Act – 2013, Mediledger, Food Trust