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Clinical Trial Supply: Executive Viewpoints on Challenges and Orchestration Opportunities

Supply chain digitalization can provide enhanced visibility and intelligence in the clinical supply environment, much like it does in the commercial supply chain. In this video, you will learn about the current and emerging opportunities for the digitalization of clinical supply transactions and how tighter orchestration of the network ensures precision and resiliency in this highly dynamic environment.

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Jitendra Kumar: Good morning, everyone. I'm Jitendra Kumar from Thermo Fisher Scientific. I've been with Thermo Fisher now 23 years, over 2 decades. Two countries I've lived in, US and now in Switzerland.

What you'll see is the challenges that in the pharma clinical supply chain the companies face to bring that drug to the market and how the solution providers are part of that challenge and can also be part of the solution, and with me is also...

Tereance Puryear: Hi, Tereance Puryear, Solution Consultant TraceLink. You guys may have heard me speak yesterday, and I see some visitors from yesterday's track as well. I'm going to let this meet more about Jitendra's experience, and I'll follow his talk track and support the conversation a bit.

Jitendra: The session is sort of focusing on in the clinical supply chain, digitization and network can improve the speed, transparency, and enhance the quality and the intelligence of the decision that are needed similar to the commercial supply chain.
In the clinical supply chain, there is a lot of different stakeholders, the pharma companies, the trial sponsors, the CROs, the CMO logistic providers, and everybody trying to orchestrate and work together to bring that life saving therapy to the patient, and how a network can actually enable and get that drug to the market faster.

Before we kick off the session, I'm just coming from the US, had a business trip, and met a really good close friend of mine for 20 years. We were having a dinner, and he shared that his mother-in-law was recently diagnosed with a late stage cancer. True story. I'm not making this up.

They've looked at different options. Looking at now clinical trials, is there a therapy that might help the mom? Just keep that in the mind as we look at the session. Now, imagine that a pharma does have a drug that could help this woman. However, the way the clinical trial runs, what might happen.

Clinical trial go through from R&D preclinical to phase 1, 2, 3 before a first prescription written, and any money is made. With that, let's look at how the clinical trials are run and some of the numbers.

30 percent average dropout rate across all clinical trial. When you're recruiting the patients, at least 30 percent of those patients will drop out in the clinical trial. They will not continue to take the medication. $35,000 plus takes daily operational clinical cost to run a clinical trial, everyday cost to run a clinical trial.

85 percent of clinical trial fail to retain enough patients. Once you find the patients, it's hard to find the patients, 85 percent of the clinical trial fail to retain those patients. 10 to 15 years on average, it takes from the finding the molecule to get that drug to the market so that the prescription can be written for a patient to get that medication, 10 to 15 years.

3 to 9 months at a minimum for companies who know how to do this, at a minimum. That's how much time they take to connect what we call point-to-point, system to system integrations. 12 to 15 different IT systems are used in running clinical supplies. Only 1 out of the 10 drug ever gets to see the market. They go through phase 1.

Lots of drugs drop out in the phase 1. Phase 2, phase 3, they don't get through the approval process. And ladies and gentlemen, $2.6 billion is what it takes for a pharma to get that drug to the market. Before in the commercial supply chain, before in the commercial, you can get that drug produced and start sending it to distribution center, this is the state of the clinical trial.

Just think of this lady that depending on where the drug that might be, and if IT

systems you were connecting took 3 to 9 months to do that point-to-point indications, or you might decide to do it all manual because you don't have the time, 12 to 15 systems, what is the hope for this woman?

Just a very brief overview of how clinical trial, different systems, different stakeholders, and a lot of disconnected systems in the industry from the sponsors themselves, ERP systems, the CRO who's managing the clinical trial, their clinical trial management system, the CDMOs, drug development, ERP, MRP.

A packaging company would have their own ERP, MRP. IRT where the patients are randomized and decided which drug is given to what patient. 3PL, 4PL, their systems.

Then a lot of new systems are coming in from the clinical space, electronic trial master file, electronic requirement, patient recruitment system, patient adherence, a lot of different systems are coming in. They're all best in class, but they don't speak to each other very well.

All these different stakeholders and the China challenges you can imagine is disconnected data and supply chain, lack of visibilities. Everybody is trying to do their job, trying to figure out where the drug is, lack of visibility.

Decision-making delays, and imagine an order was placed for this lady to say, "Hey, can we pack that drug and ship that drug to this?" An email was sent out. All of us are guilty to...I'll get to that email.

A lot of decision-making delays, then a lot of other thing that also apply for demand planning, drug wastage because we produce sometime too much. We ship it to a country where we don't have the patients, patient recruitment problem, low retention, patient adherence.

Patients don't always remember to take the drug, and lot of the admin burden, paper, all the stuff that's happening on paper, yielding to ultimately the high cost

of bringing that drug to the market.

These were some of the things that how the clinical trial supply runs using emails and portals. Point-to-point proprietary system integrations. A lot of the system in the clinical supply space are not the commercial systems. SAPs and Oracles of the world, they are catching up, but not quite there yet.

Lack of data standards and adoption. Can you believe in the clinical supply, every item, any every SKU, there are no standards for how do you define it? Industry actually did work together, so we were part of our industry consortium to develop those standards with GS 1.

So standards are there, but there's still a lack of adoption because everything has been running the way it's been for 30 years. Then, again, taking 3 to 9 months to connect those systems. Just imagine this phase 2 trial.

Now you're connecting with maybe a new provider, a new IRT system, a new order management system, and you have to make a decision. Do you spend the time and the money, 3 to 9 months and the money to make those point-to-point connections, or do you choose to go the classic all the way? We'll just work with the email, some SharePoint team site, and we'll send the information. That's the current state.

At Thermo Fisher, we run 7,000 plus clinical trials annually. Almost every drug, every other drug that comes to the market runs through Thermo Fisher somehow, somewhere, whether we manage the drug development or the supply chain. We really work with a lot of our customers. If there's a customer in the pharma, we probably work with them.

Providers, logistic provider, 40 different logistic providers to make sure the drug arrives on time to that patient in the country where it's needed. The speed is paramount in the clinical supply because it's not like, oh, 6 to 9 months later, the patient would need the drug. Once the patient is recruited, you want to get that

drug to the patient as quickly as possible.

The speed here is you need a 100 times faster than in the commercial supply chain because that patient may not have any other hope. There's no other the reason they're in a clinical trial generally is because there's nothing else available for them. That's sort of the way the operation has been.

Future state. Let's say 2024, 2025, where the industry needs to go, where we are trying to get industry to move forward to, is adopt the data sharing standards. Don't build your own IT systems where you are not able to share the standard. Of course, you can't replace the systems overnight. How about maybe what Shabeel has mentioned earlier?

I met Shabeel a year or so ago, and when I heard him first speak about this integrate once, I was like, man, we spend so much time and money in trying to connect with all our solution providers. I'm like, yes. Why don't we connect once to be able to share that information?

This is a vision for us, and, hopefully, with the help of TraceLink, we would be able to get there. Connect once and be able to benefit whether it's the clinical or the commercial. If you're in the cell and gene therapy space, the speed is even paramount. Imagine a patient cell are taken out in autologous therapy.

In 20-, 40-, 48-hour, that drug that that cell need to go to manufacturing, be modified, that therapy need to be maintained at temperature, and go back to that patient in matter of couple of days. The speed is paramount, and to be able to share all that information and ensure that the patient is going to get the right therapy.

It's imperative for the industry to adopt something that is going to move this industry forward, especially in the clinical supply space. I'm sure commercial also benefit from it. Like I said, in the cell and gene therapy, clinical to commercial, it's a much faster changeover. You're not talking about, "Oh, it takes 1, 2 year to set

up the supply chain."

Oftentimes, what we are learning is the clinical supply chain becomes your commercial supply chain in cell and gene therapy until you get at much larger in different countries and globally.

I'm going to pass over to Tereance to share some of the things that what's happening on the network side.

Tereance: Before I let Jitendra go, I want to go back to this slide quickly. What are the conversations like when you get down to the concept of connecting to new partners and new systems outside of your four walls to get started? How does that conversation typically go?

Jitendra: The truth is the first thing would be, well, what system, what data, and share us the requirement. I'll be honest with you, I've spent a lot of my time in the IT sitting in the business now, and I was one of those person. What are the requirements? Have they been signed? Sign those requirements. Are you sure these are the requirements you want us to build?

Then you'll work with sharing those requirements with your partner, and they'll say, "Well, it will take us time. This is not the priority right now. We don't have the budget." A lot of time is spent in those requirements and signing them off and getting the funding for, can we do this integration in time for the supply to be ready?

It's a lot of requirements and IT spend and who's going to pay for it. Those are the conversation that takes place oftentimes connecting to the solution providers.

Tereance: Is it a conversation too of we've always done it this way or this is the way we prefer because it's easier? Is it a resistance to the outside of the dollars?

Jitendra: The challenge is that's what industry falls back to is that's what we have

done in the clinical supply space in the clinical trial. Introducing something new, which may be a risk, is the last thing anybody wants.

They always fall back to, well, it works that way, why change it? Because creating a risk in the clinical supply could mean patient may not get the drug on time, could also mean some quality issues. The challenge always is, do I want to introduce that risk in my supply chain by doing something different? However, it does not need to be that way.

Tereance: OK. Then I think my last one for you is, how do you think industry can overcome the risk? How do I get started? I want to do this, but I want to avoid the risk as much as possible. What could we look to do to get around that uncomfortable space?

Jitendra: This question comes up almost in everything we do in the clinical supply. How do you make the change from the current process to the new process? Even though I would love to say, "Hey, this technology and the solution is proven and tested, it's gone through the validation and qualification." However, what we found works best is run the processes in parallel.

Run your the process that you have currently, and then add the new process to it to prove that the new process does not create the risk from the quality perspective and will show you the benefit. That's generally what you found is that for almost in any situation, running the process in parallel allows you to be able to adopt it. Sometime you run a pilot for a non real trial.

However, often that's not always possible. The other option that works is to run those team in parallel to be able to prove that the new process, the new solution will work, will not reduce this quality, and is going to be better than your current processes.

Audience Member: I was intrigued by the high percentage of dropouts in the clinical trial. Can you speak to some of why that is and what's the impact on the

timelines? Because I understand the supply chain challenges and how to overcome those. Patients. Can you speak to that one a little bit?

Jitendra: One of the common one is when you're looking for a patient, you have a certain criteria to say, I will need to recruit a patient who meets this objective. Finding those patients, depending on, again, what disease you're looking for, they may be in the remote area. If your hospital is in the city, just imagine a hospital in Barcelona, and people are 100, 200 miles away from here.

They'll sign up because they feel like this is their hope. They'll sign up, but people are busy. They have busy lives. Often what happens is they cannot handle the burden of having to travel for the visits to the hospital every month or whatever the schedule is. That's one of the challenge where locations are too far and patients that you find are not able to keep that commitment. That's one of the challenge we found.

The second challenge often is the burden it creates on the life overall. Having to come to the sites, taking the drug, remembering to take the drug, filling out whole bunch of paper diaries, believe it or not, when you take a drug in the clinical trial, you're required to maintain, did you take the drug as prescribed or not?

The classic example is there's a paper diary. Can you fill that one up? Or there's a e-diary that you can record to say, "Yep, I took the drug and whatnot." The burden it creates on the patients.

Then many other times, sometimes the cost of the patient themselves, like having to travel, is the sponsor, the CRO who's going to pay for it. Those are some of the key challenge that we found which causes the patient to drop out from a clinical trial. There's many more, but these are some of the ones that we've had to figure out and find solutions for them so that the patients can stay in the clinical trial.

Audience Member: Is the dropout rate correlated to the timeline? Does it like...do you have...?

Jitendra: Yes, it does. Initially, patients, you will start out, and this is where you will recruit probably sometime 200 plus percent always for the patient because patient will drop out. The longer the trial goes, if you do not have the right solutions, the more patients will drop off. Like, generally, after 3 to 6 months, you'll see a more patient dropout rate in the clinical trial as it goes.

Tereance: How many people in here are actually in the clinical trial space actively or looking to or wanting to learn?

With MINT, what we're looking to do, I think, initially is impact the complete supply chain, but that average 3 to 9 month for enabling IT system integration is where MINT really will shine and support, I think, even improving the clinical trials process by just getting the system squared away.

I like to look at it as the practitioners can actually do their job more efficient and faster. The conversation I'm going to quickly go over is what you've heard yesterday and earlier today is we're looking to connect the entities in the supply chain for the various systems we admit. As Jitendra mentioned, there's 12 to 15 systems. How many of you guys deal with that in your normal supply chain today?

It's not 12, it probably may not be 12 to 15 total, but it's still a higher number where you're having to connect the dots and figure that out. I think the burdensome conversation is, how do we get started? I've done this before, and I've been burned by another provider. I've tried this before, and it was it didn't work. It cost too much.

The ROI dips after a few months of investing dollars to connect 1 or 2 partners. It's a challenge. In this space of clinical trial, it's more advantageous to look at how to mitigate the risk as opposed to looking at it as a challenge to not moving the needle to improve it.

When we look at the studies that we've done internally from our product team, our research group around clinical supply, working with partners, obviously, like,

Jitendra, understanding what all goes into the communication that's happened over email today.

I think we mentioned yesterday GS 1 is starting to do some standards around some of these transactions, but I'd argue that the industry practitioners have a longer list and they're outpacing GS 1 because they want to get to a standard they can use at least across most of their supply chain.

The transactions you see here, some of these are very similar to what you see in common supply chain today. Jitendra, from your point, of these transactions, what area is the most challenging when it comes to if we just had a digital solution, this will make a life a lot easier?

Jitendra: I would say in the supply chain, a pharma drug, when it moves to for packaging purpose, whether you're filling in the bottles or making blisters and whatnot, getting that information that the drug is coming, you need to receive it and go to the quality inspection to approve. It's all email-based.

At our dock, drug shows up. Our customers, we've been working with them for 20, 30 years, drug shows up. Do we have enough people in the plant to be able to receive it all?

Imagine that drug is minus 20. It cannot sit on a receiving dock. It has to move. Imagine if that information was flowing in through an ASN to say, "Hey, we're getting now 20 shipment today with minus 20 drug. Make sure we have enough resources and enough space to be able to store it." That's one of the key challenge.

Then once we've done the packaging, a lot of the production order batch record, it's all back and forth email because to get that information to make sure we're going to package it as is required for that clinical trial. Every clinical trial, that recipe is different. Imagine clinical trial is not like, "I'm going to run a batch of this for a 100,000 packs." It's all small batches, and you're running those.

Every batch record goes to our quality approval, the pharma quality, and approving those, a lot of email. Finally, the one that makes the most challenge is that order to ship to that patient. We get so many orders.

Believe it or not, every single one, doesn't matter whether it's for a small pharma that has just 10 patients in a clinical trial, and that one shipment is as important as maybe if Novartis or Bayer who have large pipeline and large customers for Thermo Fisher. In the clinical trial, every single one of the order for us and for a patient is as important, and making sure that those orders don't slip through the cracks.

Imagine an email...so we have, like, SLAs. An order coming in before 10:00 AM, if needed, we will ship it the same day so the patient can get the drug next day. Imagine a patient's flowing into the hospital. At 10:00 AM, they have an appointment, and we promised the customer, we will get the drug there before 10:00 AM tomorrow. Email came in. People didn't read that email, did not act on it.

Getting that distribution order to make sure that the order flows into our ERP so that it can be picked, packed, and shipped and be on its way to the patient, that's the last one that really makes the difference impacting the patient life. That's the most critical one, I would say, in the distribution space.

Tereance: OK. One more. When we think about we talked about the system to system approach. That's the pinnacle. Two systems speaking to each other, less human interaction, more working in the systems doing their role.

In the system to person or using a UI, I know there are a lot of systems from our conversations, but others, is there a role or a space for collaboration where shipping request came in? Something's wrong. There's something we all never know what it is, but you have to collaborate. Is defaulting back to email safer or a collaborative space?

Jitendra: Again, everybody loves email. An order came in. Something is not right

with the order. Sometimes we are collaborating back and forth with our pharma sponsor to say, "Hey, this order, you're asking it to ship this, but that kit was already shipped to a different location." Is that the right one? So, yes, we collaborate, unfortunately, via emails.

In some cases, we have the SharePoint or the Teams portal, but often with the 3PL. The shipment left us. It's stuck in the customs. Or, imagine that shipment is going through the US, and it's sitting at the Phoenix, Arizona at the tarmac. Why the temperature is rising? I mean, the clinical trial drug, every single one of the shipment is temperature monitored because there's not a lot of stable data.

We are collaborating with the 3PL to say, "Why is this there? Why is it delayed?" There's a lot of collaboration that happens, and today, it's a lot of them is via email. A lot of noise.

Audience Member: Is Thermo client of TraceLink or...?

Jitendra: Yes. No. No. We have...So we use Thermo, sorry, TraceLink solution for our commercial supply chain as well. We do a lot of the commercial drug and socialization and all, and we're looking at the clinical supply to address this solution.

In the commercial, we already have been using all of our facilities where we're doing the drug manufacturing. Commercial drug runs it on TraceLink crystallization solution.

Audience Member: The value of it.

Jitendra: Yeah. Definitely. Yes.

Tereance: To that point, I won't share too much. Through our conversations, again, learning the number of systems, and I think it's you guys have a lot of work to do internally. There's a lot of work system wise. Again, that idea of do I want to

hire a full scale IT project off my management office to run internal and external systems?

Do I want to expand that, or do I want to have these IT professionals who know this space focus on the internal systems that need to work to get the information in, synthesized, used by the various parties, and pushed out to the entities it needs to go to?
I think most of us would argue to say we don't want to invest additional dollars to hire more IT people to learn the space to connect the dots while you're building an internal ecosystem to improve your own shop.

That's how I look at the actual idea for many. Some of the thing I'm not going to go over the whole slide, but the themes are repetitive because it's the same idea. Integrate once, interoperate with everyone.

We understand the standards and we're the ones we are learning, we're learning very fast and working with strong partners to understand what's the best way today that we can implement this. We're agile enough to shift around, move, improve to make it work in the space because this is very dynamic and time is of the essence.

Unlike most parts of the supply chain, time may not be the biggest factor. Here, time is a huge factor, and you don't want to delay simply because you were risk adverse to improving your systems because of any number of reasons why it was a challenge in your prior roles or experience.

In the interest of time, I call this a messy slide. It gives that view of what it really takes and what it looks like. The dashed lines are ones where copy transactions want to go back to an entity for their own record keeping purposes. The solid lines are where actual data needs to flow. You can go top down, and you can read through this. We're going to, of course, share slides afterwards.
But imagine the idea again of what Jitendra verbally said, this is done over email,

but now look at it trying to be done over email. I'm downloading data from a system, PDFing it, Excel sheet, SharePoint portal. Name the list. Google Sheets. We've heard, I think, my colleague, Moiz, when you talk about some companies using WhatsApp to share information.

Again, where you got everyone's attempting to do something different, but there's a better way and approach to take it. But everyone clearly wants to do something beyond email portals and spreadsheets. We're going to close on just a few bullet points. Again, this is a reoccurring thing. We tailor this to the clinical space, but the real time exchange of data, I think we just hit on why real time matters.

The simple delay that hits every part of supply chain, I didn't see the email, we couldn't receive the order properly, I couldn't process a request. It's very simple. It's every day, but in certain spaces, it resonates a lot more.

Consistent, predictable notice. How many people want consistent, predictable notice, in any part of their supply chain? I think we all would argue everyone would desire and love to have that. It'll make our lives easier.

Chasing order and delivery status. If I don't know, I can't make business decisions. We mentioned that the other day. If you don't know in clinical trial, you can't move product to its next phase of its life cycle.

Reduce time to commercialization. I'll let Jitendra tag on this one a bit more because this is an interesting space where the idea we've done this, and now we're going to try to commercialize. What is it?

Jitendra: Let me just give you an example. I shared the story about this mom. Not only her life could be saved, but the benefit, the pharma. Imagine that drug that was going through did not take 10 to 12 years.

The integrations did not take through the 9 month. Some of the blockbuster drug...I was just looking at one of the drug, Humira. When it went blockbuster in

2011, the annual revenue was $8 billion, 2 years ago, $22 billion revenue for that one single product. It comes to about $21 million a day. One day revenue for the pharma for this drug was $21 million when it was in 2011.

The benefit even the pharma sponsor who's putting a lot of money reduce the time to market by days, by weeks, and months, and you're talking about a lot of saving, which will translate into the lower cost of the drug. Because if you're spending $2.5 billion to make the drug, of course, the price of the drug will be higher as well.

If you can reduce that time, not only the pharma, their revenue increases, it would also bring down some of the cost of the drug that the patients have to pay. Clinical to commercial speed, it's just amazing what can be done and what industry can actually help with the patients and the sponsors both.

Tereance: Awesome. Single multimodal integration. I will tell you when I did a lot of reading about IRT systems and how they vary so much, and you read some publications that they are, I guess, outdated older technology. However, if you don't want to cause any risk in your supply chain, you use it.

Not that I think they work well, but the challenge is connecting to them in the various modes and models they come in through all the trials.

Jitendra: Until a few years ago, every trial would have their own separate IRT system, separate database, separate interface. Literally, it's like creating a copy. If you're running 10 trial, 10 different IRT system, and you have to integrate with each one of them.

Tereance: That's just the IRT. Remember the slide we showed, 12 to 15 systems. Now you got 14 more left. The scale, and I see some of our IT professionals in here. That's scary. I mean, again, time is not on your side when getting this done. With the CDMOs and 3PLs partners benefit from using MINT. I guess the tagline here.

Again, they're integrating once. They're exchanging that data. I often say that the

partners face the same challenges as the clinical drug manufacturers. They have the same problems. They're getting a bunch of emails and requests to do something. They gotta get it out fast as someone's going to get a bunch of emails and have to do something.

It's a very, very...I don't want to overcomplicate this. It's very simple. It's efficiency. Everyone's facing the same challenges. Thermos's not 3PL's only customer they have to work with. They have tons.

Jitendra: I mean, the other thing I'll just add here is, in some of the trials, we ship the drug to the patient's home directly. We have to share the address of the patient where they live with the 3PL. Imagine that going over an email. From the HIPAA GDPR perspective, that is not allowed. You cannot be sharing patient information in an unsecure manner.

The challenges that are there from even data privacy perspective using these old antiquity methods is just imagine, you'll be able to use a network where communication is encrypted, and you don't need to share information over and over and over via emails and whatnot.

I mean, this to me is a no brainer for industry to get behind and try to bring it to the market to ensure that you can speed up the drug to the market faster.

Audience Member: Is the data collection for submission to the government body that's going to ultimately approve the trial, is that a challenge as well with the disparate systems and the email?

Jitendra: It is. EMA, just this year, they rolled out a new clinical trial information system. Generally, when everything is done, all the data is sent to the EMA or US FDA in a format that people are looking, and it takes time to review that data. Actually, in Europe, I'm not aware of the US yet, but in Europe, they have now created a format.

You can send the data from your system to the EMA for them to review it and to be able to approve. Imagine something, the trial finished, all the data you compile, which takes time, and now you submit it to the EMA or FDA. It could take months for them to review it and to be able to give you approval or not.

Imagine a while where all this can be sent electronically in a way that they need to see it. Those standards are already actually established by EMA. I hope that submission data would also go through this integrate once methodology.

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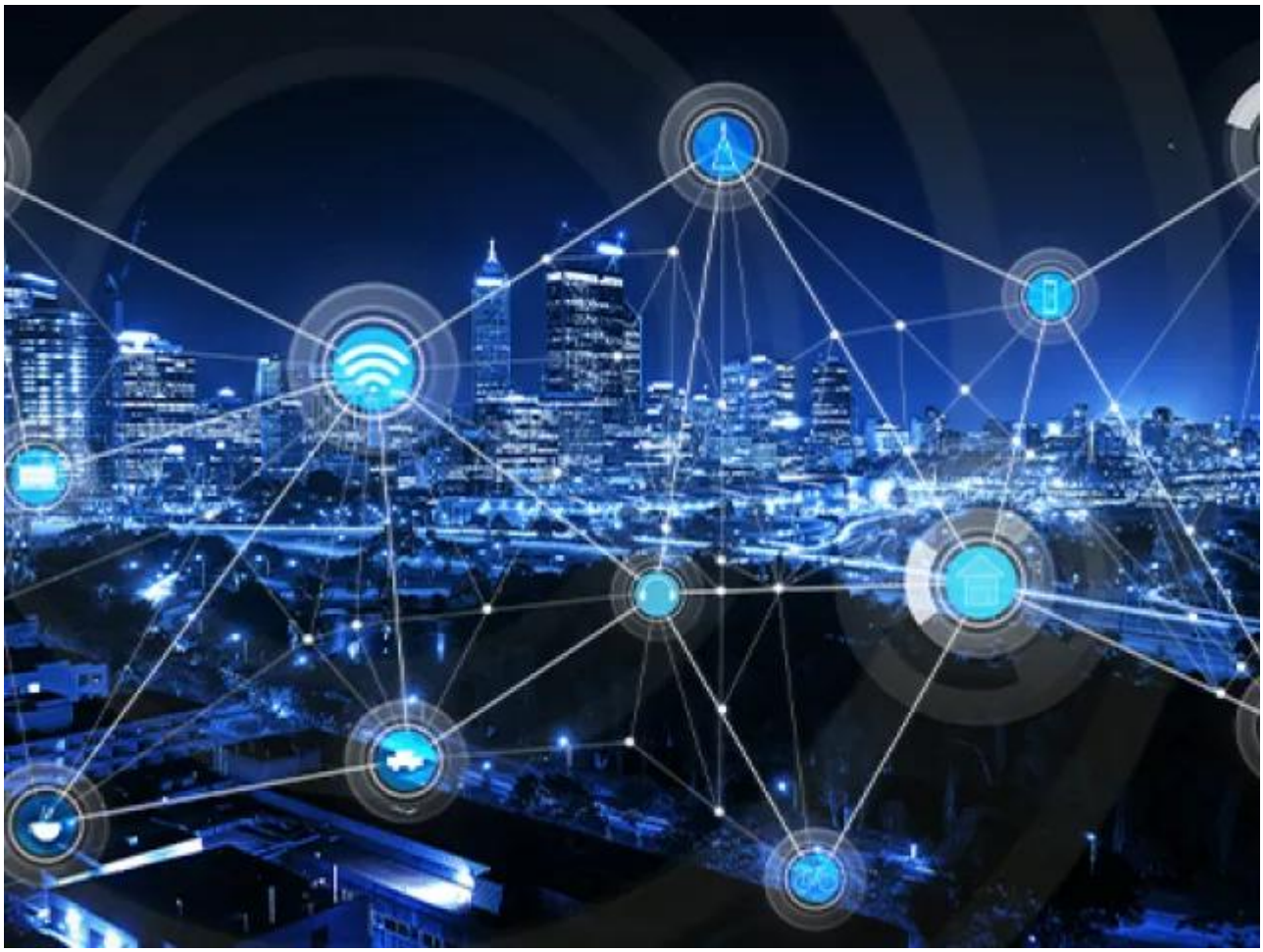

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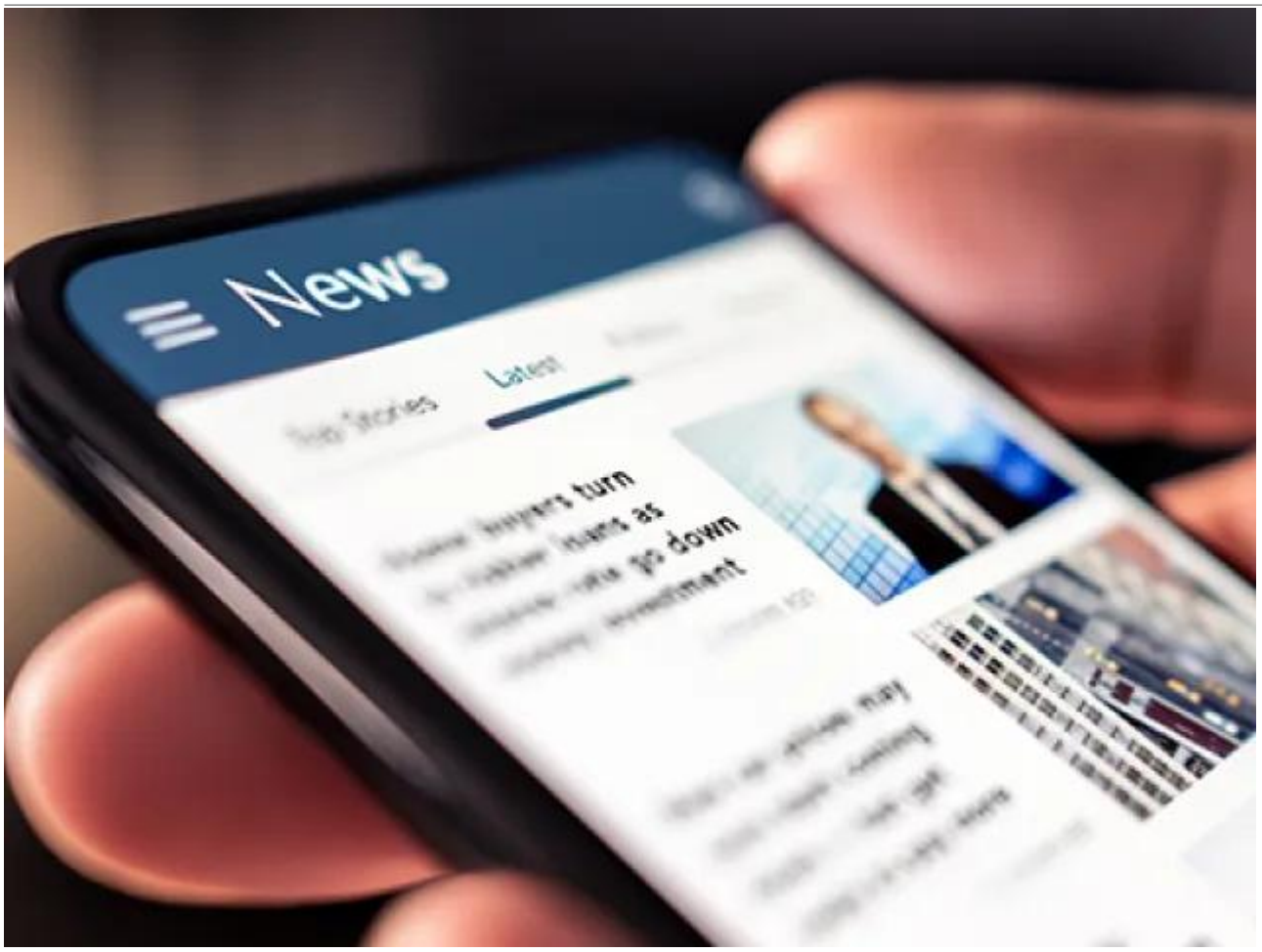

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