

TRENDS IN PHARMACEUTICAL RESEARCH AND DEVELOPMENT

Data Report: The State of the Drug Development Industry

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METHODOLOGY & PROFILE





Participants were heavily screened to ensure they met the following criteria:

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Industry: Pharma, biopharma, or biotech company



Level: Have drug development decision-making responsibility and be director-level or above



Role: Work in a role related to drug development



Company: Have at least one compound in development

Geography: US/Canada, Europe, Asia, Australia, or Middle East/India 152 participants were surveyed in April 2022

Survey was conducted on behalf of PPD, part of Thermo Fisher Scientific, by Industry Standard Research (ISR), using ISR's proprietary Health Panel. Participants were provided an honorarium for their time.



Statistical Differences

Data were analyzed using statistical crosstabs to check for any statistically significant differences across demographic segments, including:



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Geography

US/Canada (n=75)

Europe (n=46)

Asia/Pacific (n=31)



Small: Annual R&D Spend < \$100M (n=42)

Mid: Annual revenue \$100M - \$999M (n=41)

Large: Annual R&D Spend ≥ \$1B (n=69)



Director (n=95)

VP/C-Suite (n=57)

Statistically significant differences between segments at a 95% confidence level are shown in callout boxes throughout the report with the data for each segment in parentheses.

Small (57%) vs. Mid (22%) and Large (15%)

In the example above, the data from respondents from small companies is significantly higher than that of respondents at mid-size and large companies.





RESPONDENTS WERE SURVEYED FROM:





Respondent Profile

RESPONDENTS WERE SURVEYED FROM:











EXECUTIVE SUMMARY





Survey participants reported that **Oncology and Hematology** (59%), **Rare Diseases** (39%), and **Immunology and Rheumatology** (38%) are the therapeutic areas leading their drug development pipeline



Challenges with **patient recruitment** in clinical trials (e.g., patient retention, population diversity) (55%) and **increasing complexity of clinical trials** (51%) are the biggest pain points for respondents' organizations



The largest proportion of survey participants consider **greater use of RWD/RWE** to complement data from clinical trials (45%) and **leveraging new technologies** in drug development (e.g., mRNA, drug discovery platforms) (44%) to be the greatest opportunity areas in drug development in clinical trials



Top 5 Opportunities



There is **wide adoption of new innovations, strategies, and technologies** at respondents' companies, with over half of respondents reporting their organization currently utilizes **adaptive trial design** (64%), **digitalization** (e.g., cloud computing, APIs, digital platforms) (62%), **RWD/RWE** (59%), and **big data and analytics** (data science) (53%). Nearly half of survey participants reported that the average timeline to produce a drug moves more slowly than it did two years ago (48%), while one-quarter of respondents noted a faster drug development timeline (24%).





The COVID-19 pandemic has encouraged respondents to **decentralize trials,** or work with partners that can do so (51%) and identify areas for process improvements to **increase speed to market** (49%).



Among respondents who reported that their organization currently utilizes decentralized trials, the average proportion of trials conducted in this manner **has increased by 11 percentage points over the last year** and is expected to increase another 13 percentage points over the next two years.



Survey participants who do not currently use decentralized trials expect that, on average, roughly one-quarter of their clinical trials (27%) will employ this strategy by 2024.

EXPERT TAKE

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"DCTs are a solution to the biggest challenges [reported in this survey, patient recruitment and enrollment]. Making it easier for people to participate in studies will solve that challenge."

Mariah Baltezegar, VP Specialized Solutions, PPD, part of Thermo Fisher Scientific





Respondents recently involved with outsourcing at their organization indicated, on average, that the largest proportion of clinical development work is **outsourced using a full-service, trial by trial** (32%) model, followed by hybrid full-service/FSP (16%) model and in-house employees (15%). With more than half of survey participants providing ratings of "Very Likely" to "Extremely Likely," **clinical laboratory diagnostic services** (80%), **data management** (74%), **clinical trial management** (63%), and **biostatistical analyses** (58%) are the activities reported as most likely to be outsourced at respondents' organizations.







One-third of survey participants reported that their company became more likely to outsource **all of a trial** (35%) over the past two years, while roughly half said the same for outsourcing a **portion of a trial** (47%).

Patient recruitment is an important area among respondents: Difficulties related to patient recruitment tops the list of challenges and the ability to better recruit and engage patients via digital/DCT featured among respondents' top three opportunity areas.

When asked to describe their current outlook on patient recruitment compared to two years ago, **two out of five respondents expressed a negative outlook for patient recruitment** (42%).

Common themes for being less optimistic include patients delaying care/avoiding hospitals and trials

centers due to COVID-19, increased competition for patients, and the impact of COVID restrictions on hospitals/sites.

One-quarter of survey participants are more optimistic regarding patient recruitment for clinical trials (26%).

Many respondents cited patients being motivated by the pandemic to participate in trials, decentralized trials, and new recruitment methods/technology as sources of their positive outlook.



EXPERT TAKE

"Studies are extremely specific and very narrow to prevent failure, but it's counterintuitive, as it limits the number of patients eligible for the study."

Rodrigo Garcia, MD, MS, VP Sites and Patients Center of Excellence, PPD, part of Thermo Fisher Scientific





DRUG DEVELOPMENT



Therapeutic Areas

Q1. Which therapeutic areas/therapeutics are leading your organization's drug development pipeline today? Please choose up to 5. (n=152)



'Other' responses include: Neuromuscular, Nutrition

- Nearly three out of five respondents reported that Oncology and Hematology (59%) is one of the therapeutic areas leading their company's drug development pipeline.
- Rare Diseases and Immunology and Rheumatology were among the top five therapeutic areas for 39% and 38% of survey participants, respectively.

Challenges

Q2. What are the biggest challenges your organization is currently facing? Please choose up to 5. (n=152)



Other' responses include: Local expertise, Market access, Pricing and access, Staff burnout, Unintended value transfer to stakeholders, War in Ukraine

- More than half of respondents said that their organization is facing challenges with patient recruitment in clinical trials (55%) and increasing complexity of clinical trials (51%).
- + Some interesting differences between company sizes emerged:
 - Trial complexity is more frequently noted as a challenge among respondents at large organizations.
 - Respondents at small organizations report more trouble with funding and elongated study startup times.

Opportunity Areas

Q3. What do you consider to be the greatest opportunity areas in drug development in clinical trials? Please choose 3. (n=152)



'Other' responses include: Use of biomarkers as endpoint

- The largest proportion of respondents consider greater use of RWD/RWE and leveraging new technologies as the greatest opportunity areas in clinical trials (44-45%).
- More than one out of three respondents consider improved patient recruitment via digital and decentralized trials as an opportunity, tying back to recruitment being considered a top challenge.
- Fewer than 15% of respondents included influx of investment in the industry or renewed public interest as a result of COVID-19 as opportunity areas in drug development.

Use of New Innovations, Strategies, and Technologies

Q4. Is your organization currently using any of the following innovations, strategies, and/or technologies? (n=133)



- Nearly two-thirds of respondents reported that their organizations are currently using adaptive trial design (64%) and digitalization (62%).
- The smallest proportion of respondents are currently using artificial intelligence (33%) at their companies, with those at large organizations being more likely to report use of AI than those at mid-size or small companies.

Drug Production Timeline

Q5. Compared to two years ago, how has the average timeline to produce a drug (from first-in-human trials through market approval) changed at your organization? (n=152)



- Half of respondents reported that that the average timeline to produce a drug is longer now than it was two years ago (48%), compared to one-quarter reporting a faster timeline (24%).
 - Respondents at large organizations more frequently selected one of the "more quickly" response options, while those as small or mid-size companies were more likely to select "more slowly."
 - Small companies experiencing timeline difficulty was also seen in their higher frequency of reporting challenges with elongated study startup times.

COVID-19 Impact

Q6. How has the COVID-19 pandemic altered your organization's drug development strategy? Please select all that apply. (n=152)



- Half of survey participants said the COVID-19 pandemic encouraged us to decentralize trials (51%) and identified areas for process improvements that will increase speed to market (49%).
 - Respondents at large organizations were more likely to identify process improvements than those at small companies.
- Two out of five participants surveyed reported that the COVID-19 pandemic motivated greater collaboration in drug development across entities.
- Only one in ten respondents indicated the pandemic **did not alter** our drug development strategy (11%).



DECENTRALIZED TRIALS



Decentralized Trials - One Year Ago to Currently

- **Q7.** One year ago, what percentage of your company's clinical trials would you estimate were conducted as decentralized trials? (n=61, excludes respondents who do not currently use decentralized trials and those unable to answer)
- **Q8.** What percentage of your company's current clinical trials would you estimate are being conducted as decentralized trials? (n=63, excludes respondents who do not currently use decentralized trials and those unable to answer)



- Respondents who reported that their organization uses decentralized trials said that one-fifth of their clinical trials were conducted in this manner one year ago.
- The same survey participants estimate an 11-percentage point increase in the proportion of decentralized trials conducted today (31% on average).

Q9. What percentage of your company's clinical trials would you estimate will be conducted as decentralized trials in two years (2024)? (n=118, excludes respondents unable to answer)



- Among the 63 respondents currently using decentralized trials, the proportion of trials conducted in this manner is expected to increase by an estimated 13 percentage points, on average, over the next two years (44% of trials).
- Survey participants who reported that their organizations do not currently use decentralized trials project that approximately one-quarter of their trials will be decentralized in 2024, on average (27%).



EXPERT TAKE

"The more you have people participate and you can bring the study to them, the fewer dropouts you'll have. Ideally it will reduce timeline and reduce overall cost."

Decentralized Trials

While the previous two pages highlighted the mean percentage of clinical trials conducted as decentralized trials, the data below shows how the reported percentages were distributed using the following buckets: 5% or fewer of trials decentralized, 6 to 10% of trials decentralized, 11 to 25% of trials decentralized, 26 to 50% of trials decentralized, and more than 50% of trials decentralized.



+ One year ago, most organizations that used DCTs did so for 10% or fewer of their clinical trials (55%).

- One-fourth of respondents whose companies utilize DCTs predict that more than half of their organization's clinical trials will employ this strategy by 2024 (27%).
- Respondents who do not currently use decentralized trials expect the prevalence of DCTs in two years' time to roughly mirror the proportions reported by respondents using DCTs today.





OUTSOURCING



Q10. In the past 18 months, have you been involved with outsourcing part or all of a clinical trial? (n=152)



 Three-quarters of respondents have recently been involved with outsourcing part or all of a clinical trial (76%).



Q11. For the areas in your company with which you are familiar, what percent of the clinical development work is accomplished via the following models? Your best estimates are fine but values must sum to 100%. (n=115, respondents not recently involved with outsourcing excluded)



Among those who outsource, the full-service, trial-by-trial model accounts for the highest proportion
of outsourced clinical development work (32% on average). The next nearest models are used for half
as much work as the full-service model.



Q12. Using the scale provided, please indicate how likely your company is to outsource each of the below drug development activities. (n=115, respondents not recently involved with outsourcing excluded)



- Most respondents reported that their organizations are "extremely likely" or "very likely" to outsource clinical laboratory and diagnostic services (80%) and data management (74%).
- Study design is the least likely drug development activity to be outsourced 33% of respondents said it was "not at all likely."
- Across nearly all included activities, respondents from small companies indicate a statistically higher likelihood of outsourcing compared to those at mid-size or large organizations.

Outsourcing Trends

- **Q13.** Over the past two years, has your company become more or less likely to outsource all of a trial? (n=115, respondents not recently involved with outsourcing excluded)
- **Q14.** Over the past two years, has your company become more or less likely to outsource a portion of a trial? (n=115, respondents not recently involved with outsourcing excluded)



- Over the past two years, roughly one-third of respondents indicated that their company has become more likely to outsource all of a trial (35%), while nearly half said the same for outsourcing part of a trial (47%).
- Greater likelihood of outsourcing could perhaps be in response to talent shortages (4th on the list of respondents' biggest challenges).
- + Approximately half of survey participants noted no change in outsourcing rates at their organization.



PATIENT RECRUITMENT



Patient Recruitment Outlook

Q15. How would you describe your outlook regarding patient recruitment for clinical trials compared to two years ago? (n=115, respondents not recently involved with outsourcing excluded)



- The largest proportion of survey participants are less optimistic about patient recruitment for clinical trials compared to two years ago (42%).
 - Respondents at mid-size organizations more frequently expressed a negative outlook than those at large companies.
- + One-quarter of respondents expressed optimism about patient recruitment (26%), with respondents from US/Canada showing more optimism compared to those in Europe.

Q16. Why do you feel less optimistic about patient recruitment compared to two years ago? (n=48)



SELECT VERBATIM RESPONSES: LESS OPTIMISTIC

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"COVID has diverted specialized medical and support resources from clinics in Europe and Asia to support primary COVID care. **Patients (at risk due to underlying disease) are unwilling to participate in trials requiring non-essential medical clinic visits.**"

"In general, clinical **studies tend to become larger, longer and more complex**, e.g., in order to allow appropriate stratification, power subgroups, include different active comparators, etc. This development is leading to **increased competition for study centers and individual patients**."



"Not sure the reason, but it seems that **trial logistics in general are increasing** leading to lower patient recruitment. This may be due to **not (yet) using the appropriate technologies to increase patient recruitment consistently**. We also experience increasing CRO challenges, largely related to **quality of / qualified staff** — believe this is a general result of the war on talent."

Please see appendix for full list of responses.

Q17. Why do you feel more optimistic about patient recruitment compared to two years ago? (n=30)



SELECT VERBATIM RESPONSES: MORE OPTIMISTIC



"It is a story of both quality and quantity. I feel the **pandemic has increased awareness** about the importance of the clinical trial process and data integrity and completeness. This may help with **motivation for patients to not only participate but to comply with protocols** and complete data collections."



"The industry has opened new ways to recruit patients in an effort to ensure **more diversity and inclusiveness that is a better reflection of society** and this has opened up new avenues for patient recruitment. In addition, due to COVID and earlier adoption of technology, there is more **digital/decentralized trials which make it easier for patient retention and recruitment** — thus my optimism!"



"Greater **availability of big data to find patient populations**, and higher engagement of patient advocacy groups."

Please see appendix for full list of responses.





Appendix

OPEN-ENDED RESPONSES: PATIENT RECRUITMENT



Patient Recruitment - Less Optimistic

Q16. Why do you feel less optimistic about patient recruitment compared to two years ago? (n=48)

A lot of competition for patients make this a money business. Entry of new specialized patient recruitment companies with dodgy business processes. Legal and compliance hot spot

Because it's becoming harder to find treatment naive patients that satisfy the protocol inclusion and exclusion criteria

Because of pandemic

Challenge due to what seems to be an increase in companies developing drugs for rare diseases

COVID decimated trial infrastructure

COVID has diverted specialized medical and support resources from clinics in Europe and Asia to support primary COVID care. Patients (at risk due to underlying disease) are unwilling to participate in trials requiring nonessential medical clinic visits

COVID has slowed recruitment in our trials for a variety of reasons. That may or may not return to normal levels in the future COVID increases the complexity to a new dimension. A new wave of COVID comes along and the recruitment drops, in-house restrictions increase, dropouts also increase. We need to budget for higher dropouts against the typical 15% being provided in earlier trials. This has an escalating effect

COVID pandemic has made it difficult to recruit patients due to more frequent monitoring required in clinical trials

COVID pandemic has made patients more worrisome about coming into research offices and has created some mistrust with drug development for some

COVID restrictions (loss of centers), world politics restricting access to previously high-recruiting areas (Ukraine, Russia, Belarus)

COVID restrictions at study sites, patient fear

COVID still providing obstacles for patient contact. Patients appearing at trial centers COVID-19 has changed patient priorities and they are less likely to participate or prioritize a clinical trial

Despite the news related to the development of the COVID vaccines that showed the importance of getting subjects into clinical trials for some therapeutic areas, it will not cause more subjects to consider trials in oncology. In the therapeutic area of oncology there is a lot of competition for patients from all the companies developing therapies

Due to COVID restrictions and because people are more afraid of contamination if they go out from their homes. Then you have an increased risk to lose patients during the clinical trial if they get infected with COVID

Due to COVID there is greater cost to access hospital site testing for patient monitoring

During my current Phase II trial, I have experienced how patients (especially elderly) stay at home and hardly come out to visit a doctor, as a consequence they can not be informed about clinical trials that are currently running. If they are informed, they are very hesitant to participate

Patient Recruitment - Less Optimistic (cont.)

Q16. Why do you feel less optimistic about patient recruitment compared to two years ago? (n=48)

Evolving patient landscape, available options outside the study, complicated protocol with excessive demands on subjects etc.

Finding the right patients, increasing competition from other trials, decreasing quality of site staff due to COVID burnout

Greater difficulty to get people to travel and participate in external activities if not of immediate benefit. Definitely a higher level of disinterest and apathy in participating in trials, unless they are COVID or vaccine-related

Higher burden for patients to come to clinical trial site and get poked and prodded in the post-COVID world

Impact of COVID (and associated hospital practices), regulatory environment and financial constraints on our hospital-based clinical work In general, clinical studies tend to become larger, longer and more complex, e.g. in order to allow appropriate stratification, power subgroups, include different active comparators, etc. This development is leading to increased competition for study centers and individual patients

It is more difficult to get patients into studies. They are not coming to the hospital and waiting longer for routine or diagnostic visits. They are also reluctant to enter a clinical trial that has many visits to the hospital or clinic. COVID has especially frightened older people

It's harder for CROs to keep skilled personnel to maintain the personal attention that is needed to work with the sites to foster efficient patient recruitment

Lack of patients going through the system and non-availability of the correct caliber of staff

Luck of trust in Pharma industries

More compounds in development, especially in the Onco and Immuno Onco field More difficult to find suitable cohorts, more emphasis on diversity

More drugs and trials chasing the same patients

Need to increase diversity within our patient population, which places additional stress on identifying clinical sites and their ability to recruit and enroll ethnically diverse patients who qualify and may benefit from the study drug

Not sure the reason, but it seems that trial logistics in general are increasing leading to lower patient recruitment. This may be due to not (yet) using the appropriate technologies to increase patient recruitment consistently. We also experience increasing CRO challenges, largely related to quality of / qualified staff — believe this is a general result of the war on talent

Pandemic has influenced rate of enrollment

Patient recruitment for challenging indications, especially in the USA region, is a bottleneck in terms of cost and timeline

Patient Recruitment - Less Optimistic (cont.)

Q16. Why do you feel less optimistic about patient recruitment compared to two years ago? (n=48)

Patients are less willing to travel long distances for study sites, and there is a very competitive landscape for the appropriate patients. Companies that have shifted to DCT approaches more than ours have a competitive recruitment advantage

Patients are reluctant to attend onsite visits at hospitals. Patients may be more careful in selecting which study they participate in after all the communication on the vaccine development, fear of new products and credibility of the pharmaceutical companies

Recruitment challenges especially in rare diseases

Recruitment is getting harder each year. Regardless of the therapeutic area

Reduced investigator-patient impact

Reliability after Corona

Slow recruitment rate and difficulty in recruitment due to COVID-related testing and sample handling

The pandemic situation has grossly affected recruitment — suspension and delay are everywhere. Investigators are being reassigned to more COVIDrelated studies. Subjects are also decreasing due to associated concern on either after COVID infection side effects or on-going COVID vaccination process specially in field of neuroscience and dermatology

There is great impact by COVID-19, less patients are interested in participating clinical trials

Ukraine war as well as COVID limits patient recruitment in China as well as in Russia and Ukraine which are very important regions for us Very difficult to recruit in a number of countries currently because KEE's [Key External Expert] are exhausted, patients more reluctant to take part in studies, and health services are occupied doing catch up chronic care

War in Ukraine and sanctions for Russia

With increased investment in new drug development as well as more focusing on hot therapeutic area



Patient Recruitment - More Optimistic

Q17. Why do you feel more optimistic about patient recruitment compared to two years ago? (n=30)

Al-based platforms are being used for patient recruitment which helps in identifying and preselecting the patients

Appropriate education of participating subjects about clinical trial, simpler trial design, and implementation of innovative and effective strategies focusing on recruitment of appropriate subjects

As decentralized trials and the use of digital technologies in study designs increase, patient recruitment becomes easier as we are meeting patients where they are instead of making them come to us

Because of increased communication due to digitalization

Better access after COVID, improved medical care

Better healthcare infrastructure and awareness

Changes in the COVID-19 situation

COVID pandemic increased public willingness and knowledge about clinical trials. Adaptive designs and new safer technologies for unmet needs will increase patient willingness to participate. New data capturing technologies (e.g. wearable devices) also ease patient recruitment

Decentralized/virtual clinical trial providers have opened up a range of recruitment sources

Due to COVID, patients are more aware of the importance of clinical trials and their objectives and are willing to take part in an effort that will benefit humanity as a whole

General positive sentiment towards the drug industry due to COVID vaccine development

Greater availability of big data to find patient populations, and higher engagement of patient advocacy groups

Greater awareness throughout the general public about the need to participate in clinical trials. This should stimulate more willingness to enroll as a clinical trial participant Hope there will be less difficulty in the recruitment challenges of patients since the common man acquired the knowledge of the clinical research process during the COVID-19 pandemic

I am expecting going forward patient recruitment will be higher and expected to overcome challenges related to patient recruitments such as complexity of study protocol, lack of awareness about clinical trials in patients and sociocultural issues related to trial participation. Specially after COVID-19 we can expect much faster patient recruitments based on new technology advancements which allows us even remote trial participation etc.

Improved patient reach through (social) media channels. More awareness of patients towards the importance of clinical trials due to COVID-19 experience. Improving large data sets on availability of patients with a certain disease

Improved treatment databases to identify subjects, increased trial decentralization to improve the clinical trial subject experience

Increase in diversity and inclusion practices



Patient Recruitment - More Optimistic (cont.)

Q17. Why do you feel more optimistic about patient recruitment compared to two years ago? (n=30)

It is a story of both quality and quantity. I feel the pandemic has increased awareness about the importance of the clinical trial process and data integrity and completeness. This may help with motivation for patients to not only participate but to comply with protocols and complete data collections

Recruitment to clinical studies is often challenging, and there has been increasing focus on developing strategies to promote participant recruitment. Post COVID pandemic, the recruitment of participants to non-COVID-19-related clinical studies has been negatively impacted by issues including prioritization of COVID-19 research due to change in the research staff priorities. Majority of the ongoing trials had been paused during the pandemic but now with DCT and virtual trials, it is now easier to get patients enrolled globally as they don't have to spend any time for a site visit or transit times which itself enhances the recruitment. compliance and retention of the patients. With the DCT trials on rise, bringing trials to patients, having their concerns/voices heard in the early trial phase plus focusing on QOL - all has a positive impact on patient's recruitment as now they can be recruited globally, transmit their data via electronic or mobile devices, get study procedures done locally or by their GP/PCP and direct shipment of drugs to patients plays an important role for recruitment

Increase in patient awareness

Optimistic about this because higher participation and motivation of doctors to join the clinical trials as collaborators or collaborating research sites are very common

Pandemic effects

The benefits of data-driven, clinical trial patient recruitment are finally coming to fruition. The quantity of high quality, real-world data has improved dramatically over the past few years. For example, we can now leverage historic treatment patterns at specific sites of care to identify the best clinical trial sites

More regular patient follow up at clinical sites — less interruptions due to COVID

More awareness among patients especially poc/underserved The industry has opened new ways to recruit patients in an effort to ensure more diversity and inclusiveness that is a better reflection of society and this has opened up new avenues for patient recruitment. In addition, due to COVID and earlier adoption of technology, there is more digital/decentralized trials which make it easier for patient retention and recruitment — thus my optimism!

Using a combination of RWD, DCTS, and other DHTS to facilitate a "last mile" strategy when it comes to clinical trial diversity, equity, and participation access It is a story of both quality and quantity. I feel the pandemic has increased awareness about the importance of the clinical trial process and data integrity and completeness. This may help with motivation for patients to not only participate but to comply with protocols and complete data collections

More use of digital tools to recruit and capitalize on COVID trial inclusion

New technology is helping us a lot, the pandemic has also motivated many potential subjects to take part in trials



Appendix

SCREENING QUESTIONS/DEMOGRAPHICS









Decision-Making Responsibility



Please select your **primary area** of decision-making responsibility. Please **select one**. (n=152)



Please select your **area(s)** of decision-making responsibility. Please **select all that apply**. (n=152)









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