CITELINE AWARDS

ENTRY GUIDE

ENTRY DEADLINE: FRIDAY, FEBRUARY 23, 2024

WEDNESDAY, MAY 8, 2024

THE WESTIN BOSTON SEAPORT DISTRICT HOTEL, BOSTON

ENTRY AND GENERAL INQUIRIES:

Jo Kirkpatrick

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www.citeline.com/awards/citelineawards

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THE AWARDS

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THE CITELINE AWARDS

Now in their 8th year, The Awards champions the individuals, teams and companies revolutionizing the research and development of new products in the pharmaceutical industry, globally.

On Wednesday, May 8, 2024, these highly respected Awards bring together leaders from around the world, to shine a light on the brilliant work, and success stories, which often operate under the radar. Join us for an evening of networking and celebration, to toast the inspirational work and tireless commitment, shown by the brightest minds in the industry. The Awards night is dedicated to recognizing and celebrating clinical achievements in the pharmaceutical industry.

We have an array of categories for 2024 to suit the whole life-cycle of the clinical R&D industry:

CATEGORIES:

1. Excellence in Rare Disease Drug Development — SOLD TRIALWIRE™
2. Best Use of Artificial Intelligence in Clinical Trials
3. Excellence in Patient Recruitment and Engagement
4. Best Patient-facing Technology Initiative
5. Best Sponsor-facing Technology Initiative
6. Most Successful Early Phase Research (Preclinical & Phase I)
7. Champion of Diversity & Inclusion in Clinical Research
8. Clinical Partnership of the Year
9. Most Innovative Start-up Company
10. Clinical Research Team of the Year
11. Excellence in Use of Real-World Data/Evidence
12. Clinical Trial Result of the Year

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WHY ENTER

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NOW IN ITS 8TH YEAR, THE CITELINE AWARDS REPRESENT THE GOLD STANDARD OF ACHIEVEMENT IN CLINICAL R&D

Share your accomplishments with our highly-esteemed judging panel and enter for a chance to win.

If you are shortlisted you will benefit from a host of promotional and networking opportunities:

- **Gain global recognition** for your company's innovations
- **Showcase your capabilities** to your prospects, customers and partners
- **Generate powerful publicity** for your company through our Citeline Awards global marketing campaign
- **Be seen** by the most influential names on our expert judging panel
- **Experience** a top-level networking opportunity with hundreds of high achieving industry executives at the Awards ceremony in May.

There is an entry fee to enter the Citeline Awards. Entries are charged at $99 per entry (for those submitted before February 23, 2024). For any late submissions after the deadline, entries will be charged at $199. The entry fee goes towards your attendance at the event when purchasing a minimum of 3 seats. You can enter as many relevant categories as you wish.

HOW TO ENTER:

VISIT – www.citeline.com/awards/citelineawards

CREATE – your online account.

SELECT – your category or categories.

COMPLETE – your online entry form(s) explaining why you or your company should be considered a winner this year. Please refer to the category criteria as a guide.

SUBMIT – your entry and you will receive an automated submission receipt and an invoice will be sent to you shortly after your submission.

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1 EXCELLENCE IN RARE DISEASE DRUG DEVELOPMENT

SPONSORED BY

TRIALWIRE™

The attempt to combat rare diseases is a challenging task that exemplifies how the pharmaceutical industry addresses unmet medical needs. This Award will recognize the efforts of an individual, team, or company that demonstrated excellence while developing a drug intended to treat rare diseases. The judges will be looking for a drug development program or trial with the largest potential impact in the rare disease space. Outstanding patient centric processes and innovation in study conduct to overcome the various obstacles of rare disease drug development will also earn high marks.

To be eligible, drug development activities must have taken place between January 2023 – February 2024. Entrants must have played a role in drug development and/or trial conduct, and all joint parties must be disclosed in the application.

To enter this category, please provide the following:

- The name of the individual, team, or company, including an outline of their role(s).
- Details of the drug development program or clinical trial, i.e., rare disease(s) being targeted, name of drug(s), trial name(s) (title, protocol ID, trial identifier), phase, patient segment(s) studied, and sponsor(s).
- Provide evidence of the impact that the drug has had, or potentially could have, on the patient population and addressing unmet medical needs.
- Describe any unique strategies used to ensure successful study execution within this challenging space, such as trial design, patient centric processes (e.g. close engagement of patient advocacy groups), innovative patient recruitment methods in identifying potential trial participants, use of synthetic controls, or study planning strategies (e.g. use of surrogate markers or original tools and approaches to gather key clinical data).
- If available, please provide documentation (URL) in support of the achievements described.

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2 BEST USE OF ARTIFICIAL INTELLIGENCE IN CLINICAL TRIALS

Artificial intelligence (AI) is revolutionizing healthcare and its application in Pharma is gaining momentum. AI technology provides new opportunities to improve drug discovery, clinical development, and commercial adoption of new medicines. This Award will recognize the efforts of an individual, team, or company in leveraging artificial intelligence to improve a clinical trial process, or to support the successful operations of a clinical trial.

The judges will be looking for innovative uses of AI that provide a meaningful impact on protocol design, trial execution, or other related activities. To be eligible, activities must have taken place between January 2023 – February 2024. Entrants must have played a role in the design, implementation or application of the AI tool, and all joint parties must be disclosed in the application.

To enter this category, please provide the following:

- The name of the individual, team, or company, including an outline of their role(s).
- Details of the clinical trial or drug development program, i.e., disease(s) being targeted, name of drug(s), trial name(s) (title, protocol ID, trial identifier), phase, patient segment(s) studied, and sponsor(s).
- Describe the utilization of artificial intelligence in the context of the trial/drug development program; if machine learning (ML) is involved, be sure to describe how ML is used. AI/ML to support any stage of the clinical trial journey may be submitted, including but not limited to:
  - Protocol development, including identification/ refinement of study population and entry criteria, study design, endpoint selection
  - Patient recruitment or retention
  - Trial monitoring practices, including safety monitoring
  - Clinical data management
- Evidence of the impact the use of artificial intelligence had (or is having) on the trial/drug development program.
- Describe how the use of AI has improved the trial(s) or trial process. Provide relevant details on how AI has helped reduce costs, improve quality and/or save time.
- If available, please provide documentation (URL) in support of the achievements described.

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3 EXCELLENCE IN PATIENT RECRUITMENT & ENGAGEMENT

Sponsors and drug development teams are increasingly adopting novel recruitment strategies and technologies to actively engage patients in the clinical trial journey. To support successful enrolment and to better understand the perspective of the patient, fundamentals of consumer and behavioural science are being applied in the clinical research arena. This Award will recognize the efforts of an individual, team, or company in bringing innovative approaches to support patient-consumer engagement in clinical trial recruitment. The judges will be looking for creative initiatives that fostered connection with the patient community and delivered a positive and meaningful impact on trial enrolment.

To be eligible, clinical trial recruitment activities must have taken place between January 2023 – February 2024. Entrants must have played a role in the design or implementation of the study recruitment strategy, and all joint parties must be disclosed in the application.

To enter this category, please provide the following:

- The name of the individual, team, or company, including an outline of their role(s).
- Details of the clinical trial or drug development program, i.e., disease(s) being targeted, name of drug(s), trial name(s) (title, protocol ID, trial identifier), phase, patient segment(s) studied, and sponsor(s).
- Describe the initiatives undertaken to support patient recruitment and engagement for the trial/drug development program. Activities to support any phase of the clinical trial journey may be submitted, including but not limited to:
  - Protocol development, including elements of inclusion/exclusion, study design, endpoint collection
  - Patient centric recruitment activities and campaigns
  - Caregiver engagement
  - Initiatives to enhance patient convenience and encourage enrolment
- Evidence of the impact the activity had on the trial's recruitment/retention; if available, please provide documentation (URL) in support of the achievements described.

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4 BEST PATIENT-FACING TECHNOLOGY INITIATIVE

This Award recognizes the promising and disruptive role that digital health technology is currently playing in clinical trials. Technological innovators are discovering novel ways to gather high quality patient data using an array of digital tools. Advances in development of smartphone apps, mobile health devices, and a host of other products are revolutionizing the way patients participate in clinical trials. The judges will be looking for the product that represents the best advance in improving patient data collection and/or the patient experience in clinical trials. Those considered may include electronic patient diaries, mobile health devices or any other digital tools that support, encourage, or aid the patient's participation in the clinical trial.

All recently launched or significantly updated technologies are eligible to enter if they were used in at least one clinical trial between January 2023 – February 2024. Companies wishing to enter must have played a role in the development and/or use of the nominated technology, and all parties to any joint development agreements must be disclosed in the application. Both technology companies and trial sponsors utilizing the technology are eligible to enter, individually or jointly.

To enter this category, please provide the following:

- The name of all companies involved in the product development (and use/implementation in the clinical trial(s), as applicable), including an outline of their role(s).
- Specify the date and market of the technology's first launch, if applicable.
- Outline the key features and benefits of the technology, and how it supports the patient's clinical trial journey.
- What problems does this product solve and what is novel about it?
- What is the single most significant benefit of the entrant's technology to users?
- If possible, please provide a link to a product demo (product webpage, YouTube video, etc.).

> **"This Award recognizes the promising and disruptive role that digital health technology is currently playing in clinical trials."**

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5 BEST SPONSOR-FACING TECHNOLOGY INITIATIVE

This Award recognizes the vital importance of using the most sophisticated platforms to catalyse and optimize data gathered during clinical trials. Advances in software and applications have a pivotal role to play at all stages of the trial process, assisting sponsors in effective management of study logistics, monitoring, risk mitigation and timely data collection and analysis. The judges will be looking for the product or suite of products that help study teams better manage and oversee clinical trial activities.

All recently launched or significantly updated technologies are eligible to enter if they were used in at least one clinical trial between January 2023 – February 2024. Companies wishing to enter must have played a role in the development of the nominated technology, and all parties to any joint development agreements must be disclosed in the application.

To enter this category, please provide the following:

- The name of all companies involved in the product development, including an outline of their role(s).
- Specify the date and market of the technology's first launch, if applicable.
- Outline the key features and benefits of the technology, and how they support the clinical trial process. Where benefits include cost or time savings, please provide supportive data.
- What problems does this product solve and what is novel about it?
- What is the single most significant benefit of the entrant's technology to users?
- If possible, please provide a link to a product demo (product webpage, YouTube video, etc.).

> **"This Award recognizes the vital importance of using the most sophisticated platforms to catalyse and optimize data gathered during clinical trials."**

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6 MOST SUCCESSFUL EARLY PHASE RESEARCH (PRECLINICAL & PHASE I)

This Award will recognize an early phase research project that met or surpassed its objectives on a range of key performance indicators. The entrant should show that the successful completion of the program was material in enabling the sponsor to advance its drug to the next development phase either on or ahead of schedule and/or keeping within its development budget.

To be eligible, results for the study or program under nomination must have been released between January 2023 – February 2024. Entrants must have played a role in the early phase research, and all joint parties must be disclosed in the application.

Photo: Last years winners Avidity Biosciences

To enter this category, please provide the following:

- Full details of the project; i.e. project name (i.e. name of drug candidate or trial title), phase of development, target indication and population studied (if applicable), sponsor(s), and the primary drug(s) tested.
- Summarize the major findings of the study, such as in vitro/in vivo results or primary/co-primary and main secondary endpoints.
- What were the main milestones and deadlines for the preclinical or Phase I study? Please supply evidence of how these were met or surpassed.
- How did this study enable advancement of the drug to the next development stage?
- If available, please provide documentation (URL) of trial results; i.e. press release, investor presentation, conference abstract/presentation, clinical study report synopsis or other publication.

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7 CHAMPION OF DIVERSITY AND INCLUSION IN CLINICAL TRIALS

Enhancing the diversity of clinical trial populations is critical to achieving equity in healthcare and improving health outcomes in our most vulnerable populations. Historically, clinical trial populations have been rather homogenous, and treatment effect and patient outcomes observed in a trial setting may have limited applicability to the larger 'real world' population.

This Award will recognize a company, team or individual who has demonstrated exceptional initiative in promoting diversity and inclusion of underrepresented populations within a clinical trial or drug development program. The entrant should describe the activities/strategies implemented and the impact they had on patient enrolment. Activities ranging from patient-focused study design, use of technology, awareness and recruitment campaigns, or other creative and innovative approaches will be considered. Evidence of the impact these activities/strategies had on recruitment should also be included.

> **"Enhancing the diversity of clinical trial populations is critical to achieving equity in healthcare and improving health outcomes in our most vulnerable populations."**

To be eligible, the initiatives undertaken must have been activated between January 2023 – February 2024. Entrants must have played a role in the design, launch or execution of the plans, and all joint parties must be disclosed in the application.

To enter this category, please provide the following:

- Full details of the project, i.e., project name (i.e., name of drug candidate or trial title), phase of development, target indication and population studied (if applicable), sponsor(s), and the primary drug(s) tested.
- What specific strategies/activities were undertaken? At what point in the study were they deployed?
- Describe the impact the strategies/activities had on study recruitment. Please share any relevant metrics used for measuring impact.
- If available, please provide documentation (URL) of trial recruitment campaign or any other publicly available sources that illustrate the strategies/activities undertaken.

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8 CLINICAL PARTNERSHIP OF THE YEAR

This Award will be presented to two or more organizations who have set a new benchmark in partnering through collaborative clinical trial activity that took place in 2023/24. Partnerships could take place between multiple pharmaceutical and/or biotech companies or between a pharmaceutical and/or biotech company and a contract research organization, research institute, non-profit, or cooperative group.

To be eligible, the collaborative clinical trial activity in question must be ongoing or completed between January 2023 – February 2024. Entrants must have played a role in the collaborative clinical trial activity, and all joint parties must be disclosed in the application.

To enter this category, please provide the following:

- Provide the names of organizations involved and basic details of the partnership.
- Why was the partnership novel?
- How does this partnership set a new benchmark for other deals?
- How has partnership achieved an outcome that would not have been possible if partnership had not been created?
- If available, please provide documentation (URL) in support of the achievements described.

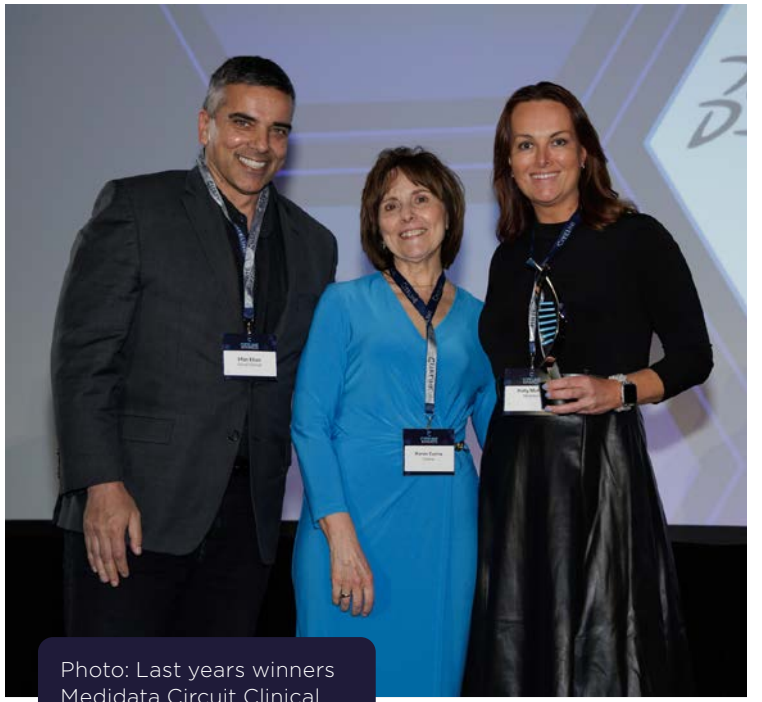

Photo: Last years winners Medidata Circuit Clinical

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9 MOST INNOVATIVE START-UP COMPANY

Clinical trials are high risk, expensive, resource-intense undertakings that present significant challenges to early-stage companies with limited financial and human capital. This award will recognize a start-up pharma/biotech company that has developed creative and innovative approaches to the formidable challenges that clinical trials present to small organizations. Solutions may include innovations in designing team structures, resourcing solutions, technology, or process/workflow efficiencies around any clinical trial related activity. Solutions must be those developed or applied between January 2023 – February 2024.

Start-up pharma/biotech companies wishing to enter must have designed, delivered, and launched the innovation (alone or with a partner), and all parties to any joint development activities must be disclosed in the application.

To enter this category, please provide the following:

- The name of the company and the innovative solution
- Specify the date of first implementation
- Outline the key features and benefits of the innovation, and the impact it had on the study timeline, costs, or quality. Where applicable, include cost and/or time savings data to support any claims.
- What problems does this innovative approach solve and what is novel about it?
- If possible, please provide additional supporting documentation (process flow chart, Vimeo/YouTube video, etc.).

Photo: Last years winners Electra Therapeutics

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10 CLINICAL RESEARCH TEAM OF THE YEAR

This Award will recognize the clinical research team who has made significant contributions in advancing a new therapy through one or more clinical phases. The judges will be looking to reward the high performing team that has been most successful in reaching its goals, adopted effective working practices, achieved major milestones within expected timelines, and contributed to the advancement of new therapies.

To be eligible, the core project for the nominated team must be ongoing or completed between January 2023 – February 2024. Entrants must have played a role in the core project for the product.

Photo: Last years winners George Clinical

To enter this category, please provide the following:

- The company's name, the team being entered and basic details of its core project.
- What was the greatest achievement of the team during the qualifying period?
- How did all members/functions of the team work together to achieve its goals?
- How does the achievement contribute to advancing new therapies to market?
- What work practices has the team adopted to support the success of the product's development?
- If you believe that this team is particularly outstanding, but for reasons not covered in the questions above, please give relevant details.

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11 EXCELLENCE IN USE OF REAL-WORLD DATA/EVIDENCE

Fuelled by the digital revolution in healthcare data, clinical research teams are increasingly advancing drug development through use of real-world data (RWD) and real-world evidence (RWE). Both can have many tactical applications throughout the clinical development lifecycle. From study design to site selection and patient recruitment, to safety monitoring and post-market surveillance, RWD represents an efficient and powerful tool to drive insights and optimize clinical research. And RWE, when fit for purpose, can play a pivotal role in drug approvals, as acknowledged in recent regulatory guidance documents.

This Award will recognize the efforts of an individual, team, or company that demonstrates excellence in applying RWD/RWE to support drug development. The use of RWD/RWE could occur as early as development of the protocol concept, through trial completion and/or regulatory application submission. The judges will be looking for creative and innovative uses of RWD/RWE to support a drug's clinical development journey.

To be eligible, clinical research activities must have initiated, progressed, or completed between January 2023 – February 2024. Entrants must have played a role in the design, implementation or application of RWD/RWE, and all joint parties must be disclosed in the application.

To enter this category, please provide the following:

- The name of the individual, team, or company, including an outline of their role(s)
- Details of the use case – disease(s) being targeted, name of drug(s), trial name(s) (title, protocol ID, trial identifier), phase (if applicable), patient population studied, and sponsor(s).
- Describe the key objective that the RWD/RWE supported – what and how it was done
- If available, please provide documentation (URL) in support of the achievements described

Photo: Last years winners COTA

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12 CLINICAL TRIAL RESULT OF THE YEAR (OPEN TO PHARMA & BIOTECH COMPANIES ONLY)

This Award will recognize the clinical trial which reported results that had the greatest impact and is expected to lead to an advance in healthcare. The judges will be looking to reward the clinical trial with the largest commercial impact, highest impact on patient population, the greatest disruption in a market, or the advancement of clinical trial design. This might include the first demonstration of a clear clinical effect for a new drug in an area of unmet medical need, a pivotal study of a new drug with a breakthrough mechanism of action, or a major study of a potential new or expanded indication for an already marketed product.

To be eligible, results for the study under nomination must have been presented in the public domain between January 2023 – February 2024. Entrants must have played a role in the clinical study, and all joint parties must be disclosed in the application.

To enter this category, please provide the following:

- Full details of the study; i.e. trial name (title, protocol ID, trial identifier), phase, disease type and patient segment(s) studied, sponsor(s), and the primary drug(s) tested.
- Summarize the major findings of the study, including all primary/co-primary and main secondary endpoints, and safety endpoints.
- Provide evidence supporting uniqueness and advancement of knowledge in an area of unmet medical need or clinical trial design.
- How do these findings represent a potential leap forward in therapy?
- Documentation (URL) of publicly available trial results required; i.e. press release, conference abstract/presentation, clinical study report synopsis or other publication.

> **"The judges will be looking to reward the clinical trial with the largest commercial impact, highest impact on patient population."**

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JUDGING PROCESS

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THE CITELINE AWARDS

Prides itself on its judging panel, comprised of independent, senior industry experts from around the world, each chosen for their knowledge, objectivity and credibility.

The judges separately consider entries from those categories that are relevant to their particular areas of specialist knowledge, expertise and experience, ensuring a considered response to every individual submission. Each category is reviewed by at least three judges. The judges mark each entry against the published criteria for its category, giving a score out of ten for each. These are then collated by the Awards team to determine which entries are included in the shortlist, and the ultimate winner. The chair of the Judging Panel reserves the right to cast any deciding vote, should the need arise.

The judges' decision is final and neither the organizers nor the Judging Panel will enter into any correspondence about the results. The winner's details are strictly embargoed until the night of the Awards.

The shortlisted entries will be listed on the Awards website: **www.citeline.com/awards/citelineawards**

ENTRY DEADLINE:
FRIDAY FEB 23 2024

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WHO CAN ENTER

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THE CITELINE AWARDS ARE OPEN TO ANY RESEARCH BASED PHARMACEUTICAL OR BIOTECH COMPANY

Open to any research based pharmaceutical or biotech company operating anywhere around the world, as well as to some third-party or partner companies that supply services to the pharmaceutical industry.

Entries are charged at $99 per entry – you can enter as many relevant categories as you wish.

THE RULES

All entries must be written in English.

- Limit your entry to 1000 words or less.
- All entries must be accompanied by a 100-word synopsis of the entry as you would like it to appear on all publicity material (this is in addition to the 1000 words or less entry).
- All entries must be submitted via our online system
- All entries must be based on activities undertaken between January 2023 – February 2024.
- Companies may enter more than one category, provided that each entry has been specifically written to address the relevant criteria and is accompanied by a separate 100-word synopsis.

CONFIDENTIALITY

- The organizer of the Citeline Awards, recognizes and respects the sensitive nature of the information submitted in the entries. We ensure that this recognition is shared by our Judging Panel. We therefore require each judge to sign a confidentiality agreement before they are appointed.
- Entries are not disclosed or discussed outside the judging process.
- Once an entry is shortlisted, extracts from the entry summary only will be sourced for inclusion in the Awards ceremony and any subsequent editorial coverage.
- Please ensure your entry summary contains no confidential or sensitive information. The Judging Panel for each Award is selected to avoid any conflict of interest.

HOW TO ENTER

SELECT – your category.

COMPLETE – the online entry form explaining in 1000 words or less, why you or your company should be considered a winner this year. Please refer to the category criteria as a guide.

SUBMIT – your entry and you will receive an automated submission receipt and an invoice will be sent to you shortly after your submission.

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FAQ's

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Q. How do I enter?

A. It's very simple. Ensure you have read the entry guidelines and category criteria. Decide which category or categories you wish to enter. Create an account on our entry system which allows you to save and amend your entry until you are ready to submit your application. Answer the questions and criteria relevant to your chosen category.

When your entry is complete, don't forget to click submit! You can look at and review your submitted entries up until the entry deadline on Friday, February 23, 2024.

Q. How much does it cost to enter?

A. Entries are charged at $99 per entry, when entering by February 23, 2024. Any entries submitted after the deadline will be charged at $199 per entry.

There is no entry fee for the Most Innovative Start Up Company category.

The entry fee goes towards your attendance at the event when purchasing a minimum of 3 seats. An invoice for any entry fees will be sent to you shortly after the entry deadline.

Terms of the entry fee:

- The entry fee is per entry. (2 entries in the same category would be 2 entry fees.)
- 1 entry fee is redeemable per 3 seats in a single booking.
- A maximum of 3 entry fees (from an individual company) can be used towards a table booking. (of 10 places)
- It is not permitted to combine entry fees with other entrants – entries must have been submitted by the same registered person in a company

Q. When is the entry deadline?

A. The entry deadline is Friday, February 23, 2024.

Q. I am not sure which category our entry would fit into?

A. If you are not sure which category your entry fits into, please contact Jo Kirkpatrick at jo.kirkpatrick@citeline.com for further assistance.

Q. Can I enter the same submission into more than one category?

A. We encourage entries in more than one category per individual or company, where appropriate; please ensure to review the category criteria and tailor your entry accordingly. Each entry is charged at $99.

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Q. I am a sponsor of the Awards. Am I still able to enter?

A. Yes, of course! You are welcome to enter any category, except the one you are sponsoring.

Q. How will I know whether my submission has been received?

A. All submissions will be acknowledged by an automated email once you have submitted your entry. Our Awards team will also get in touch with you again shortly after the entry deadline. If you have any concerns please contact Jo Kirkpatrick at jo.kirkpatrick@citeline.com

Q. How will I know if my submission has been successful?

A. Following the judging all companies and individuals will be notified by email. Finalists will be announced on our website: www.citeline.com/awards/citelineawards

Q. What do I get if I win?

A. The Citeline Awards are highly regarded within the industry and winning an award marks you out as a leader in your field. The winners will be announced at the Awards ceremony on Wednesday, May 8, 2024; they will also receive a trophy and certificate of recognition, social media banners and inclusion in a press release.

Q. How can I ensure I'm at the networking ceremony?

A. It's essential to book your place at the event. For more information, please contact christopher.keeling@citeline.com or jo.kirkpatrick@citeline.com.

Q. Are there other ways I can get involved in the Awards?

A. Yes, there are many sponsorship opportunities available. For more information, please contact christopher.keeling@citeline.com or jo.kirkpatrick@citeline.com.

ENTRY AND GENERAL INQUIRIES:
Jo Kirkpatrick • Tel: +44 (0) 7917 555 986 • Email: jo.kirkpatrick@citeline.com

CITELINE AWARDS

WEDNESDAY, MAY 8, 2024
THE WESTIN BOSTON SEAPORT DISTRICT HOTEL, BOSTON

ENTRY AND GENERAL INQUIRIES

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SPONSORSHIP AND ATTENDANCE INQUIRIES

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