# Submission Form

Please complete all details, provide all documents, and send your request to [clinicaltrialdatarequest@ultragenyx.com](file:///C%3A/Users/Cwoods/Box%20Sync/Desktop/Clinical%20Trial%20Data%20Requests%20Research/clinicaltrialdatarequest%40ultragenyx.com). Incomplete forms will not be considered and returned to the requestor. Proposals must be completed in English and will not be reviewed until all information is provided. If a proposal is approved, all parties that will have access to the data per the proposal must sign a data access and use agreement to gain access to the data.

## Section 1: Requestor Information

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| **Date of Original Submission** |  |
| **Has this proposal already been submitted?** | No | Yes |
| If yes, please provide the date of prior submission and summarize how you have amended the proposal in response to initial denial:   |

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| **Primary Researcher information** |
| First Name Last Name: |  |
| Title: |  |
| Institution: |  |
| Address: |  |
| City: |  |
| State/Province: |  | Post/Zip Code: |  |
| Country: |  | Email: |  |
| Phone: |  | Fax: |  |
| Conflict of Interest (please refer to section 8 for list of potential COI)  |  |
| **Statistician Information**  |
| Name: |  |
| Title & Current Position: |  |
| Employer, Company, Research Institution or Affiliation: |  |
| Phone |  |
| Email |  |
| Conflict of Interest (please refer to section 8 for list of potential COI) |  |
| **Additional team members who will have access to the data (please include all team members who will access the data)** |
| Name: |  |
| Title & Current Position: |  |
| Employer, Company, Research Institution or Affiliation: |  |
| Phone  |  |
| Email |  |
| Conflict of Interest (please refer to section 8 for list of potential COI) |  |
| Name: |  |
| Title & Current Position: |  |
| Employer, Company, Research Institution or Affiliation: |  |
| Phone |  |
| Email |  |
| Conflict of Interest (please refer to section 8 for list of potential COI) |  |

**Please add additional rows for each team member with access to the data**

Please submit the curriculum vitae for yourself and all team members with your proposal.

## Section 2: Research Proposal

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| **Research Title** *(Limit to 200 characters)* |
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| **Research background/rationale emphasizing why the research needs to be conducted now and how the research will add to the field** *(Limit to 3000 characters, please include abbreviated references when applicable)*  |
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| **Research Design** *(Limit to 3000 characters, please include abbreviated references when applicable)* |
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| **Research hypothesis** |
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| **Please provide full citation of references used above**  |
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## Section 3: Data Requested

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| **Please indicate the data or information requested, listening the specific studies, subsets, data fields, and time points being requested** |
| **NCT # or Protocol Title** | **Enrollment (N=#)** | **Data Fields or Variables** | **Time Points** |
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| **Please provide the reason(s) why you have selected these studies and data fields for your proposed research** |
| **NCT # or Protocol Title** | **Study Population** | **Justification for selecting this study(ies) and data fields** |
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## Section 4: Statistical Analysis Plan

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| **Please outline your statistical analysis plan (SAP)** *This summary should include, but is not limited to, the following information:** *Primary, secondary, and any additional endpoints*
* *Effect measure of interest (eg, for inferential studies: risk or rate ratio, risk or rate difference, absolute difference; for descriptive studies: rate with confidence intervals)*
* *Description of the population to be analyzed*
* *Methods to control for bias (eg, restriction, matching, stratification, covariate adjustment)*
* *Assumptions and any planned adjustments for covariates or meta-regression or modeling of covariates*
* *The statistical approach (eg, Bayesian or frequentist (classical), fixed or random effects)*
* *Meta-analysis approach where applicable (eg, random effects meta-analysis, stratified meta-analysis)*
* *Statistical tests and methods (eg, Fisher's exact test, Kaplan-Meier curves, log-rank test to compare group) and adjustment for multiple comparisons*
* *Power to detect an effect, or the precision of the effect estimate given the sample size available*
* *Statistical power calculations and levels of significance*
* *Model fit tests, sensitivity or heterogeneity analyses (eg, Chi-Squared Test, I squared statistic)*
* *Analysis of subgroups (eg, by age, disease state, ethnicity, presence or absence of comorbidities); different types of intervention*
* *Handling of missing data*
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## Section 5: Ethical Considerations

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| **Does the proposed research require an Ethics Committee or Institutional Review Board (IRB) approval? Please provide additional details if the answer is yes or no.**  |
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## Section 6: Data Sharing Plan

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| **Please provide your plan, including estimated timelines, for how you intend to share the results.** *Please note the data use and agreement form required to access the data upon approval requires that results be shared with Ultragenyx Pharmaceutical Inc.*  |
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## Section 7: Research Proposal Funding

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| **Please indicate how this research plan will be funded** |
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## Section 8: Example Conflicts of Interest

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| **Please indicate if any of the potential conflicts of interest apply to any of the researchers included in this proposal. Please provide your results in section 1 for each individual team member who will have access to the data.** * *I currently work for a pharmaceutical company, or have done so in the last 3 years*
* *I was involved in the study(ies) that the data is requested for in this request or other Ultragenyx study(ies)*
* *I work for a contract research and development company, or have done so in the last 3 years*
* *I provide expert advice (consulting) to a pharmaceutical company, or have done so in the last 3 years*
* *I participate in a strategic advisory role on an Advisory Board / Steering Committee that drives the strategic direction of a pharmaceutical company, or have done so in the last 3 years*
* *I earn an honorarium from a pharmaceutical company*
* *I hold a patent (planned, pending, or issued) relating to a pharmaceutical product.*
* *I earn royalties relating to a pharmaceutical product*
* *I am a principal investigator, or have been in the last 3 years, for an industry-sponsored clinical trial*
* *I am an investigator, or have been in the last 3 years, for an industry-sponsored clinical trial*
* *My organization currently receives funding/a grant, or has funding/a grant pending, from a pharmaceutical company*
* *Someone in my household (spouse/partner, minor children) works for a pharmaceutical company*
* *I personally own shares (including options) in a pharmaceutical company*
* *Someone in my household (spouse/partner, minor children) owns shares in a pharmaceutical company*
* *I am involved in a law suit as an expert witness related to the pharmaceutical industry or for a drug*
* *None*
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