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(Application ID: 382613 CCFA Partners Research Proposal)

Application Title:

A Survey of Inflammatory Bowel Disease Patients on Health Insurance Satisfaction

Average Score: No Average Score is saved for this application.

Admin Summary:

No Admin Summary Statement has been entered for this proposal.

Critiques

Reviewer: 212973 Reviewer Score: 2.00

Critique Text: Outstanding proposal likely to have significant impact in the future for patients

with IBD Future studies should incorporate pediatric patients and their families

Critique Questions:

Question 1: Does the proposal address a significant knowledge gap in basic or clinical understanding of IBD? Does the proposal contain patient-based studies which are likely to lead to significant gains?

Score: 2.00

Answer: Highly significant and likely to lead to gains in the future. Assessing IBD patient satisfaction with US healthcare insurance—perform survey of IBD patients on their experience with health insurance medication coverage -pt fxs affecting satisfx w/ insurx -insurance fxs affecting satisfx w/ insurx -multivariate analyses to ID covariates affecting satisfx Eventual goal: ID insurx fxs affecting pt satisfx w/ insurx after controlling for pt fxs -info will help IBD pts select health insurx best suited for their needs Secondary goal: provide feedback to insurx companies that will potentially induce changes in insurance policy and coverage to benefit IBD pts in long-run -Rate insurance plans for IBD pts in a way that will also give effective feedback to insurers?could lead to improvements for health insurance plans for pts with ibd and w other chronic diseases

Question 2: Does the application propose novel concepts, approaches or methodologies, aimed at improved clinical and/or translational research in IBD?

Score: 2.00

Answer: originated on Twitter now proposing to survey pts on CCFA Partners

Question 3: Include a comment as to whether the proposed work is appropriate in scope and the methods are feasible.

Score: 3.00

Answer: Feasible Should include specific power calculation

Question 4: Is this an experienced IBD investigator with a track record of high quality productivity and collaboration in the field? If a junior investigator, do they have a mentor with the appropriate qualifications to supervise the work?

Score: 3.00

Answer: Outstanding lead investigator Biosketches not provided for remaining team members so unable to assess

Question 5: Is the proposed study free of excessive overlap with current or previously approved work?

Score: 1.00 Answer: Yes

Question 6: Is the proposed study well suited to be carried out in conjunction with CCFA Partners? Is the respondent burden minimum enough so as not to compete with the other aims of

CCFA Partners?
Score: 1.00
Answer: Yes

Reviewer: 213949 Reviewer Score: 2.00

Critique Text: Overall, this is a novel area, with a collaboration between a seasoned investigator and a patient, to investigate the role of health insurance and medication compliance. While we are not given the specific aims for the survey within CCFA partners, the pilot aims are provided, and excellent pilot data are provided. The investigators can work with the DMC to further develop the survey. While this would need to be approved by the DMC, given the questions on the example survey already performed, I do not think that the final survey would need to come back to the full committee for approval. Conditions for launching the survey would need to be an approved final version, with concrete specific aims and analysis plan. The only drawback to the current proposal is the lack of development of the approach, which will be informed by the final survey.

Critique Questions:

Question 1: Does the proposal address a significant knowledge gap in basic or clinical understanding of IBD? Does the proposal contain patient-based studies which are likely to lead to significant gains?

Score: 2.00

Answer: This is a collaboration between a patient and IBD faculty to better understand the role of health insurance costs/high deductibles, the prior authorization and renewal process, and whether this leads to delays or changes in treatment. This is a highly relevant area for patients.

Question 2: Does the application propose novel concepts, approaches or methodologies, aimed at improved clinical and/or translational research in IBD?

Score: 2.00

Answer: Clear plan to expand the pilot phase survey and implement within larger groups within CCFA partners in a staged process.

Question 3: Include a comment as to whether the proposed work is appropriate in scope and the methods are feasible.

Score: 6.00

Answer: Excellent preliminary data, the aims specifically are not provided, the investigator want to work with the DMC to develop the final instrument based on the pilot data. While we are not given the exact specific aims for the new survey, it is clear that the investigators have listed several aspects of insurance that they feel need a better understanding - particularly the frequency with which insurance complications lead to non compliance.

Question 4: Is this an experienced IBD investigator with a track record of high quality productivity and collaboration in the field? If a junior investigator, do they have a mentor with the appropriate qualifications to supervise the work?

Score: 1.00

Answer: Exceptional mentor, and patient researcher combination. Mentor is Peter Higgins from Michigan, excellent track record in IBD research.

Question 5: Is the proposed study free of excessive overlap with current or previously approved work?

Score: 1.00

Answer: No overlap with current work.

Question 6: Is the proposed study well suited to be carried out in conjunction with CCFA Partners? Is the respondent burden minimum enough so as not to compete with the other aims of CCFA Partners?

Score: 2.00

Answer: Well suited for partners. There is the possibility of selection bias in our sample, given the nature of the cohort, but this would still yield important information about access to care.

Reviewer: 311829 Reviewer Score: 2.00

Critique Text: This is a major area of concern for patients. Having the results on how patients are interacting with insurance companies and their level of satisfaction can inform the individual behavior of patients seeking insurance, as well as advocacy efforts to improve access and coverage. The methodology of iteratively developing a survey instrument is appropriate to develop a robust survey instrument, and they already have a good beginning with their Google forms survey. It is an excellent use of the CCFA Partners database and doesn't impose a major burden on the patients to complete the questions.

Critique Questions:

Question 1: Does the proposal address a significant knowledge gap in basic or clinical understanding of IBD? Does the proposal contain patient-based studies which are likely to lead to significant gains?

Score: 2.00

Answer: This issue is of major concern to patients. And the knowledge will also help CCFA in its advocacy efforts.

Question 2: Does the application propose novel concepts, approaches or methodologies, aimed

at improved clinical and/or translational research in IBD?

Score: 3.00

Answer: The iterative approach to survey development based on pilot testing with the target patients makes a lot of sense in getting to a very useful survey that will achieve the objective.

Question 3: Include a comment as to whether the proposed work is appropriate in scope and the methods are feasible.

Score: 3.00

Answer: Definitely is in scope and the methods are feasible. However, it will require a lot of interaction with CCFA Partners faculty and staff to develop the survey iteratively.

Question 4: Is this an experienced IBD investigator with a track record of high quality productivity and collaboration in the field? If a junior investigator, do they have a mentor with the appropriate qualifications to supervise the work?

Score: 2.00

Answer: no information is provided on the track record of the investigators. But I know Dr. Higgins and his experience with clinical research.

Question 5: Is the proposed study free of excessive overlap with current or previously approved work?

Score: 2.00

Answer: they do not mention a search of the literature, but there doesn't seem to be similar information available.

Question 6: Is the proposed study well suited to be carried out in conjunction with CCFA Partners? Is the respondent burden minimum enough so as not to compete with the other aims of CCFA Partners?

Score: 1.00

Answer: This seems to be a particularly appropriate use of the CCFA Partners database