Inviting patients as equal partners in the **drug development process**

Greater patient engagement in rare disease drug trials is not just a 'nice to have.'

Naomi Litchfield, Global Patient Advocacy Lead at contract research organisation Bionical Emas, who specialise in facilitating clinical development of new treatments for rare diseases, says: "Positive patient engagement is a crucial part of the drug development process."

Creating connections

As a former Senior Clinical Research Nurse at Great Ormond Street Hospital, Naomi cared for rare disease patients participating in clinical trials and early access programmes and has seen the impact investigational drugs can have. Now, she and her team are enabling partnerships between pharmaceutical companies and patient advocacy groups throughout the drug development process.

Early, often, transparent

"Patient engagement must be early, often, and transparent," says Naomi.

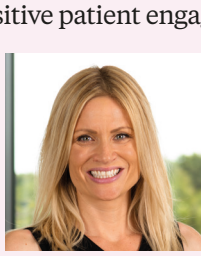
The process starts at the drug development preclinical stage, with the creation of an access policy and a patient communication plan. "Companies need to understand the patient's condition, and that means listening," she says. Naomi and her team create materials to support the patients, from education materials about clinical trials and early access programmes to communication templates and frequently asked questions documents.

Communication between parties

At the clinical development stage, the team looks to reduce patient burden as much as possible. Considering the patient perspective early in clinical development supports the choice of clinically meaningful endpoints, which can be particularly challenging in rare diseases.

Patient engagement with payers such as the NHS or health insurers can also be really valuable. A clear understanding of patients' needs here can create efficiencies and accelerate timelines — especially important in rare diseases," says Naomi. "Many are progressive and hard to diagnose, so after a long diagnostic journey, patients and families may not have much time."

Once a new drug is commercialised, the team helps plan communications — where their relationships with patient groups can help — and provides feedback from trial participants for future clinical development. "Feedback to patients is also vital," she says. "Many take part in clinical trials; not just for early access to new treatments but to help future generations. Positive patient engagement benefits all parties."



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