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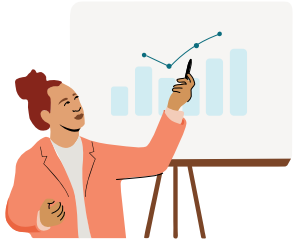
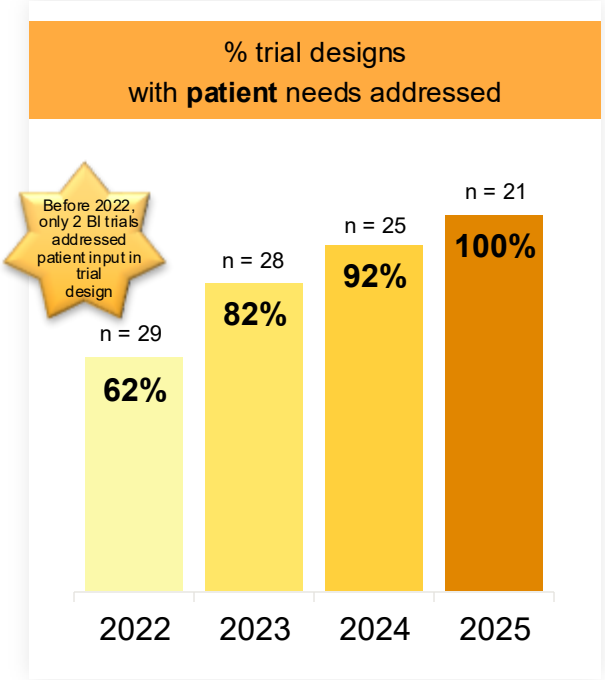
in Clinical Research

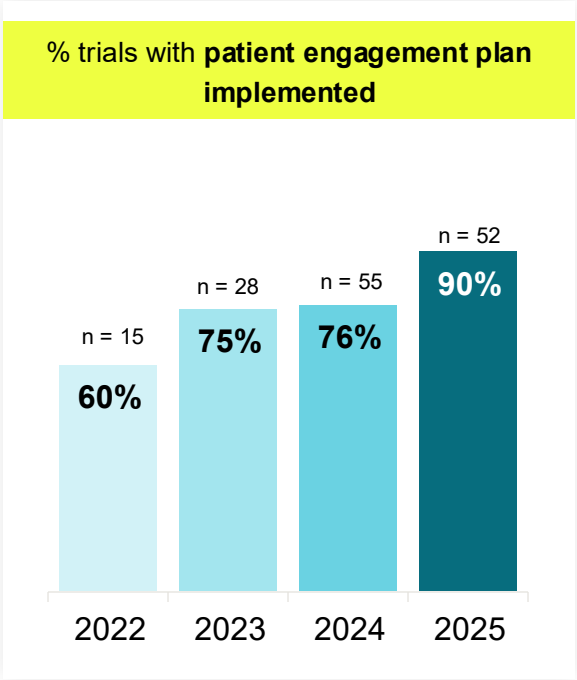
How Boehringer Ingelheim Turned Patient Input into Measurable Trial Success: *Faster Enrollment, Higher Retention, Better Experience*

Kisha Bush
Director of Patient and Site Engagement
Boehringer Ingelheim

Embedding the Patient Voice: Our Journey from Ad-Hoc to Systematic Input in Clinical Trial Design







From Assumptions to Accountability: Our Four Key Lessons Learned in Patient-Centric Trial Design

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Don’t make assumptions

In one of our trials, the trial team wanted reduce the patient burden by offering home nursing. They spend a lot of time and budget on implementing home nursing in the trial, and in the end no patient used this service.

Start Early

In a patient ad board, we asked patients about a pain endpoint we wanted to use in a trial. They said the endpoint is not meaningful for them. However, since this happened only 3 months before the trial start, we could not make any changes. Because of this experience, we have made it mandatory to understand patient needs and address these in the trial design before the trial design is frozen.

Make it everyone’s business

In the past, patient feedback was often not incorporated because the engagement was done by people who were not designing the trials. Now, the accountability for addressing patient needs in the trial design sits with the people designing the trials.

Strong senior management commitment

Before 2021, there was no strong senior management commitment, and the implementation status was low. After senior leaders started putting patient-centricity in their goals and talking about the value of patient engagement in R&D, we saw a steep increase in colleagues wanting to engage with patients for trial design.

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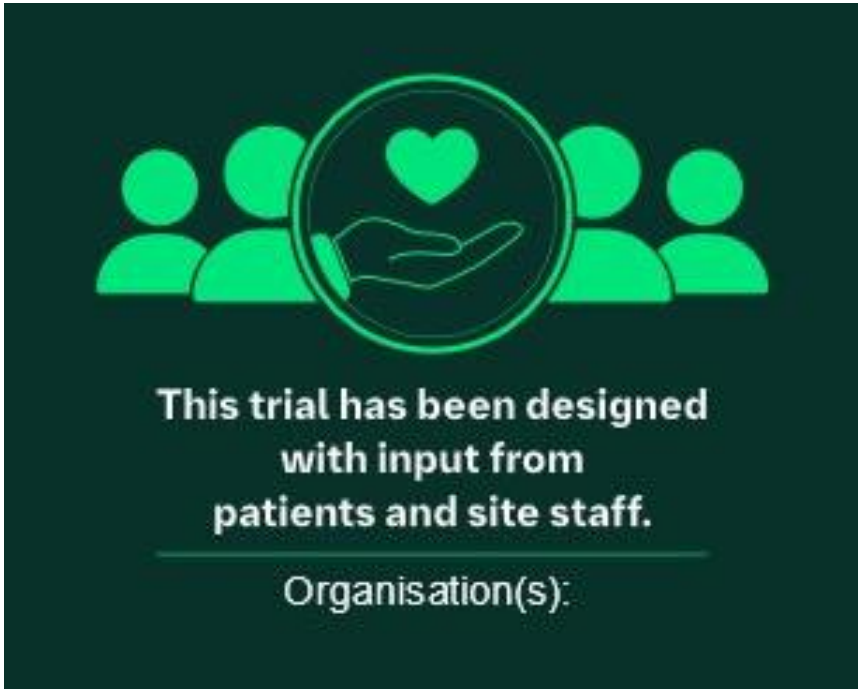
What have we done?

- Embedded stamps on our Patient Materials
- Established core criteria for Patient & Site Engagement Plans.
- Assess the Patient Journey during Trial Design
- Establish global vendor partnerships to obtain site and patient insights.



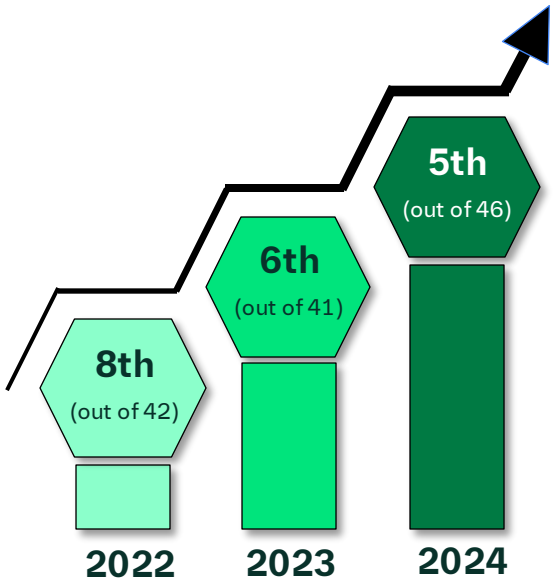
Patient Input that Pays Off: 220 Days Faster, Fewer Amendments, $35M Potential Savings per Trial

Boehringer trials with patient input:

- Recruited on average **30% (220 days) faster**
- Had on average **one global amendment less**

Enabling estimated potential **savings of $35M per trial**

Growing Trust, Growing Impact: Our Climb in External Patient-Engagement Rankings



Patient View ranking for engaging with patients in (R&D)

Case Study

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We know the disease - but not the lived experience

- Large Phase III trial in Pulmonary Fibrosis
- Patients with Pulmonary Fibrosis have difficulty breathing and face many physical challenges
- Long trial duration (1–2 years), demanding onsite visits, and complex procedures could make participation challenging
- **Trial simulations during trial design to understand challenges and implement solutions**

44 countries

573 sites

2,355 patients enrolled

≥52 weeks

Physical and logistical burden

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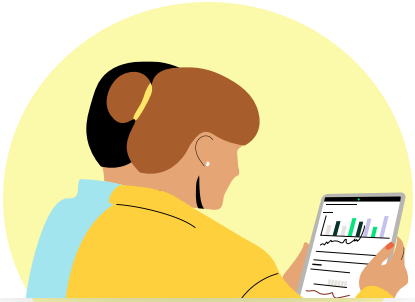
Insight	Impact on clinical study
Overall trial duration and time commitment will be burdensome for someone living with pulmonary fibrosis	More flexibility for time window allowed between visits and the time of day for a visit Moved PRO assessments to optional home assessments
Due to shortness of breath and oxygen devices, it can be difficult to travel to the site and walk distances from the car park to the clinic	Travel assistance and concierge services provided to ease transportation and logistics for patients and their caregivers
Consider reimbursement for travel expenses and time	Caregiver's travel expenses were reimbursed where allowed

Recruitment success

- **Study 1:** 4 months ahead of time
- **Study 2:** On time

High participant and site satisfaction

Outcomes



Retention targets achieved

- **Study 1**: 87%
- **Study 2**: 84%