CLINICAL TRIALS TRANSFORMATION INITIATIVE

Tool 3. Assessment of Patient Group External Relationships: Other Patient Groups

Assessment of Patient Group External Relationships	YES	NO	NA	Notes
Relationships with Other patient groups: Does the patient group engage collaboratively with other patient groups of interest?				
Does the patient group collaborate with other patient groups in advocating for policy and budget initiatives beneficial for their public and private partners (patients, NIH, FDA, academia, industry)?				
Does the patient group collaborate with other patient groups in cofunding research of mutual interest?				
Does the patient group collaborate with other patient groups in organizing or participating in meetings/conferences focused on best practices, lessons learned and insights gained in areas of mutual interest?				
Relationships with Academia: Does the patient group engage collaboratively with academic and other research institutions, centers of excellence, etc.?				
Does the patient group collaborate with such institutions in funding research projects supportive of the patient group mission?				
Does the patient group collaborate with such institutions in keeping academic investigators informed of funding opportunities of government agencies and other patient groups?				
Does the patient group collaborate with such institutions in supporting academic investigators' grant applications to these other funding sources?				
Does the patient group collaborate with such institutions in encouraging and facilitating scientific collaborations?				
Relationships with Industry: Does the patient group engage collaboratively with industry partners?				
Does the patient group facilitate discussions between industry and academic "discovery" scientists?				

Assessment of Patient Group External Relationships	YES	NO	NA	Notes
Does the patient group have and make available assets needed to assist industry partners throughout the development cycle (e.g., registry, natural history, translational tools, key opinion leaders)?				
Does the patient group help de-risk early-stage development by funding or cofunding discovery, translational and clinical work?				
Does the patient group educate, motivate and recruit patients so that clinical trial enrollment, compliance and retention are optimal?				
Relationships with Patients: Does the patient group's relationship with patients and their families enable the patient group to:				
Communicate effectively with the patient population?				
Obtain robust registration in a patient registry?				
Motivate patients to participate in a natural history study?				
Obtain sufficient patient biosamples to assist in preclinical studies?				
Educate, motivate, and engage patients so that clinical trial enrollment, compliance and retention are optimal?				
Assist in post market surveillance?				
Relationships with the NIH: Does the patient group engage collaboratively with NIH institutes and centers (e.g., disease-specific institute and NCATS)?				
Does the patient group maintain dialogue with program officer and appropriate offices of special interest (e.g., translational or clinical staff, Office of Rare Disease Research, TRND, BrIDGs)?				
Does the patient group maintain two-way communication between NIH and the patient group's other stakeholders (e.g., keeping NIH staff informed of the status of research and needs of the disease community, keeping the patient group's academic and industry partners aware of NIH opportunities, submitting letters of support for NIH applications, participating as co-applicant for NIH programs when appropriate)?				
Does the patient group participate in the functions of the National Advisory Councils of the NIH institutes and centers of interest?				
Relationships with the FDA: Does the patient group engage collaboratively with the appropriate centers and offices of the FDA (e.g., CDER, CBER, and CDHR review divisions, Office of Orphan Product Development, Rare Disease Program)?				

Assessment of Patient Group External Relationships	YES	NO	NA	Notes
Does the patient group help educate these FDA personnel regarding the disease, its unmet medical needs, benefit risk evaluations, etc. (e.g., include FDA personnel in the patient group's scientific conferences, brief FDA personnel at FDA workshops and symposia)?				
Does the patient group work with its academic and industry partners in preparing IND submissions, participating in pre-IND and other milestone meetings?				
Does the patient group have patient representatives designated as FDA special government employees ready to serve on FDA Advisory Committees and as members of the FDA teams at milestone meetings with industry sponsors?				
Relationships with Congress: Does the patient group engage congressional representatives regarding issues of key interest to its patient community?				
Does the patient group encourage its community members to engage their elected representatives in support of legislation beneficial to them (e.g., more robust budgets for the NIH and FDA, policy provisions intended to benefit and improve NIH and FDA operations, newborn screening)?				
Does the patient group collaborate with other patient groups in organizations aimed at concerted efforts to work with Congress in support of beneficial NIH and FDA budgets and policies (e.g., Research America, Alliance for a Stronger FDA)?				

Abbreviations: BrIDGS=Bridging Interventional Development Gaps; CBER=Center for Biologics Evaluation and Research; CDER= Center for Drug Evaluation and Research; CDRH=Center for Devices and Radiological Health; FDA=Food and Drug Administration; IND=investigational new drug; NCATS=National Center for Advancing Translational Sciences; NIH=National Institutes of Health; TRND=Therapeutics for Rare and Neglected Diseases

To learn more about CTTI's Patient Group Engagement work, please visit https://ctti-clinicaltrials.org/our-work/patient-engagement/patients-groups-clinical-trials/