Sustainability Planning for ISCC

Summary

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Agenda

- **Executive summary**
- **ISCC activities**
- **Resource requirements**
- **Funding sources**
- **Organizational structure**
- **Budget**
- **Discussion**

There is solid support for sustaining the ISCC

ISCC participants want to continue the initiative

- **Strong interest in sustaining most existing ISCC activities**
- **Preference for federal, philanthropic and industry grants as the main funding source, with minor funding from dues, licensing, fee-for-service**
- **No clear consensus on preferred organizational structure**

Prospective stakeholders from industry express an encouraging level of interest in participation and potential funding

- **Health plans/PBMs interested in clinical decision support for testing and prescribing based on evidence-based guidelines**
- **Pharmaceutical companies interested in how genomics can influence prescribing patterns and improve outcomes**
- **Genetic testing companies interested in increasing awareness of opportunities to use genomics**
- **Some players will want to be actively engaged in the work of the ISCC; others may be more hands-off**

Prospective stakeholders will need more clarity and a specific request from the ISCC to move forward

Summary of sustainability proposal (I)

- **Maintain current ISCC mission:**
  - **Improve genomic literacy of physicians and other practitioners**
  - **Enhance the practice of genomic medicine through sharing of educational approaches and joint identification of educational needs**
- **Sustain most current ISCC activities and consider expansion into new areas over the next three to five years**
- **Establish basic infrastructure to administer the ISCC, either within NHGRI, as part of an existing organization, or with a fiscal sponsor**
- **Institute a simple, transparent governance structure**

Summary of sustainability proposal (II)

- **Diversify funding**
  - **Maintain NHGRI funding and involvement to the degree practical**
  - **Open membership to industry –with appropriate safeguards– to benefit from their expertise and financial resources**
  - **Institute modest dues from specialty societies**
  - **Seek philanthropic foundation grants that match ISCC mission**
  - **Consider applying for NIH grants, possibly in collaboration with others, e.g., Pharmacogenetics Research Network**

- **Next steps**
  - **Discuss proposal with ISCC members (today)**
  - **Begin business development for new funders**
  - **Select a permanent home for the ISCC**

Activities to be sustained (I)

Activity	Explanation
Convening	• Act as a neutral convener for genomic issues in clinical practice • Convene all interested stakeholders (medical societies, academia, government, and industry participants) to promote clinical education in genomics and to share best practices
Use case (and competency/EPA) development	<u>Use cases</u> • Develop and maintain general and specialty use cases in genetics • Evaluate disseminated use cases for relevance and utility • Identify and develop materials to support use cases • Review existing competencies and explore how to translate into use cases that support competency achievement <u>Competencies / Entrustable Professional Activities</u> • Determine what competencies fit into current clinical practice • Review existing competencies in genomic medicine education and existing guidelines in the use of genomics • Maintain/update competencies/EPAs over time

Activities to be sustained (II)

Activity	Explanation
Educational product and use case curation/ marketing	• Circulate use cases through ISCC dissemination efforts • Collect existing educational products from ISCC representatives • Identify relevant federally-funded resources and initiatives to assist genomics education efforts and clinical practice • Work with use cases group to identify areas of emphasis for educational products (e.g. ordering of genetic tests, counseling, return of results)
Consulting to societies	• Determine the extent to which medical societies have genomics in their clinical guidelines • Identify gaps and develop recommendations for professional societies to implement genomics education into clinical practice • Reach out to specialty boards about integrating genomics into exams
Research	• Pursue NIH and foundation research grant opportunities to promote implementation of evidence-based genomic guidelines in clinical practice alone or in partnership

ISCC could expand its role over time; However, there is less consensus on certain activities among ISCC participants

Potential activity	Explanation
Create content	Create original educational products, in addition to curating existing educational products developed by third-parties (e.g., medical societies)
Advocate for payer coverage	Promoting evidence-based guidelines to encourage reimbursement for genomic testing by public and private payers
Practice workflow redesign	Redesign practice workflow (e.g., EMR modification); may be addressed by other NIH initiatives such as IGNITE
Consumer/public education	Inform consumers and the broader public about the use of genetic testing

Resource requirements – Ballpark estimates (I)

Activity	Description	FTE and type of resource	Other resource	Comments
Convening	Regular calls, periodic conferences and webinars	½ FTE for conference planning, logistics support- $50K	$250K budget for space, logistics, speakers	Conference expense ~$2K per person for ~125 attendees
Use case development	Developing genomic competencies and use cases	½-1½ FTE project management $50-150K; voluntary/in-kind staff time	n/a	May be able to tap into existing use cases from industry
Educational product curation/ marketing	Creating, curating and promoting a central repository of educational products	1 FTE for curation, relationship management with societies - $100K	Website development/ maintenance/ hosting - $50K	Initially will leverage G-2-C-2 infrastructure
Consulting to societies	Review educational products, identify gaps, and make recommendations on integration of genomics into practice	Cost: 16 hours * $100/hour/society. Insufficient scale to sustain dedicated staff. Most work could be contracted out and billed on cost-plus basis	n/a	Societies will be reluctant to pay and would prefer to use member volunteers

Resource requirements – Ballpark estimates (II)

Activity	Description	FTE and type of resource	Other resource	Comments
Research	Pursue NIH and foundation research grant opportunities to promote implementation of evidence-based genomic guidelines in clinical practice	Direct staff to be determined by grant requirements	Grant writing resources to be provided by ISCC or grant partner/co-applicant	Grant likely to cover direct cost with small overhead. Would likely need to partner/sub-contract
Logistics	Coordination and management support, meeting logistics	Suggest finding partner organization	n/a	Related to convening activities above
Administration	Responsibility for all legal, taxation, and regulatory issues for projects (e.g., financial/ audit management, HR/payroll)	Suggest finding partner organization or fiscal sponsor to achieve operational synergies	Fee is often calculated as up to 15% of total expenses	n/a

Potential funders: Examples and motivation

Funder category	Examples	Motivation
Genetic testing companies	Illumina	Increase awareness of opportunities to use genomics
Pharma companies	Amgen	Promote use of genomics to influence prescribing patterns and improve outcomes
Payer/PBM companies	CVS Caremark	Provide clinical decision support for testing and prescribing based on evidence-based guidelines
Specialty societies	ACOG, ACCME, ASHG, ACMG, AMP	Promote educational products; support existing members; enhance society value to new members
Government	NIH, CMS	Promote the translation of science into clinical practice Promote the use of evidence-based clinical guidelines
Academia and research institutes	Scripps Institute	Support genomic educational initiatives for undergraduate and graduate medical schools as residency and fellowship programs
Providers	El Camino Hospital (Genomic Medicine Institute)	Support educational initiatives within the provider organization for clinicians of all types (e.g., physician, nurse, pharmacist, genetic counselor)
Foundations	Robert Wood Johnson Foundation, Commonwealth Fund	Promote use of genomics in order to improve health care quality and clinical/cost outcomes, and reduce disparities
Nonprofit organizations	American Association for Cancer Research, Personalized Medicine Coalition	Promote use of genomics in clinical practice in order to improve clinical outcomes

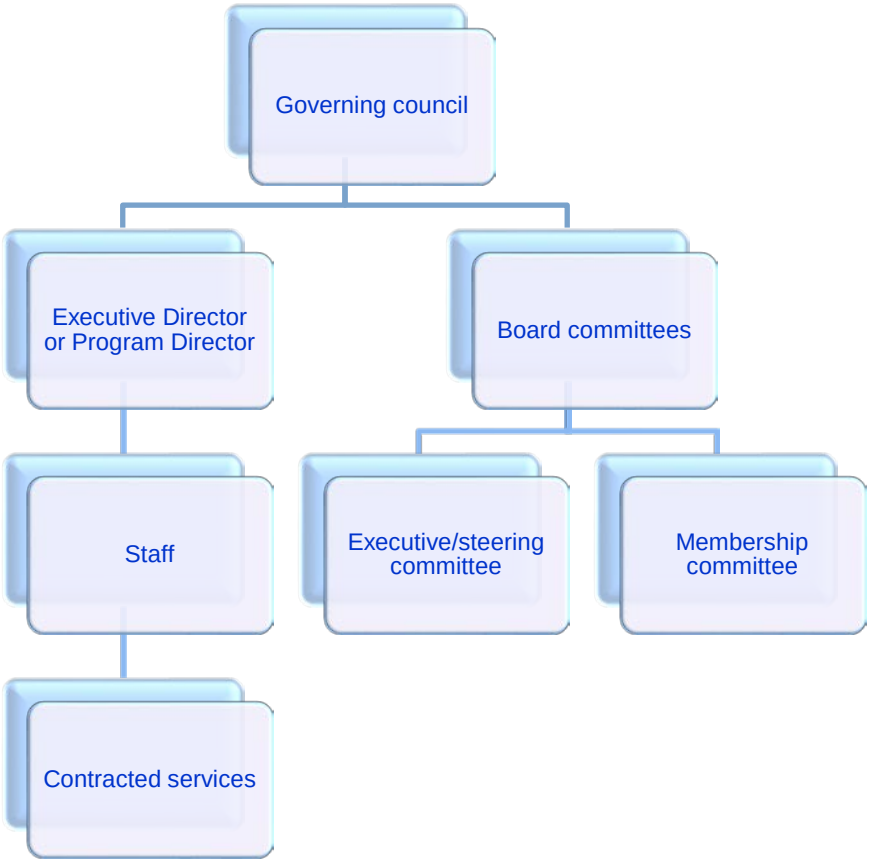
Potential funders: Interest by activity

Funder category	Activities of interest					Number of entities
	Use cases	Educational product curation/ marketing	Convening	Consulting	Research	
Genetic testing companies	x	x	x			>100
Pharma companies	x	x	x			50-100
Payer/PBM companies			x			>100
Specialty societies	x	x	x	x	x	>100
Government agencies	x	x	x		x	>5
Academia and research institutes	x	x	x			50-100
Providers	x	x	x		x	>3000
Foundations			x		x	10-30
Nonprofit organizations			x			5-10

Approximate revenue potential from new funders: Industry represents largest opportunity

Funder category	Funding per organization per year	# of potential funders within 3 years	Approximate funding potential
Genetic testing companies	$20-50K; tiered based on FTEs or revenue Additional program funding:$10-150K	10-20	$500K- $1M
Pharma companies			
Payer/PBM companies			
Specialty society – convening only	$5K dues	20-40	$50-100K
Specialty society – convening and product distribution	$15-20K dues, royalties	5-10	$100K
Academia and research institutes	$5K dues	5-10	$35K
Providers	$5K dues; Tiered based on number of relevant providers in an organization	10-20	$75K
Foundations	$25-150K grants	1-2	$50K
Nonprofit organizations	$1-20K dues; tiered based on capacity	3-5	$25K
TOTAL		~50-100	$1-2M

Structure: Components



Host: Options and considerations

Potential host	Description	Pros	Cons	Attractiveness
Standalone	Independent organization with dedicated staffing	• Ensure dedicated staffing to achieve objectives • Enhance accountability	• Redundant effort • Increased expense • Hard to recruit staff	Low
NHGRI	Existing ISCC oversight	• Independence, neutral, trusted	• Limited resources • Skill set mismatch	Medium
For-profit company	Commercial medical education provider	• Expertise in clinician education, product marketing, etc.	• Concern about conflict of interest and staying true to mission	Low
Not-for-profit organization	ACGME, ACMG, AMA	• Operational synergies • Existing subject matter expertise	• Main focus likely to be on existing constituent base	Medium
Fiscal sponsor/foundation	TIDES, Resources for Human Development	• Operational synergies • Alignment with mission	• ~10-15% of operational expenses	High

Pro forma income statement: Preliminary

($K)	2015	2016	2017	Comments
Revenue				
Membership	250	500	750	Covers base operations
Program funds	-	100	250	For named projects, convenings
Total revenue	250	600	1,000	
Costs				
Curation	100	150	200	Volume of materials increases over time
Project management	75	100	150	To take on additional projects
Website	25	50	75	Initially with G-2-C-2
Convening	150	250	400	Assumes some convenings w/dedicated funds
Logistics	-	25	50	
Administration	53	86	131	@ 15% of operating costs
Total costs	403	661	1,006	
Surplus/Deficit	(153)	(61)	(6)	Possibly covered by NHGRI?

Discussion