

Clinical Evidence for Genomic Medicine Sustainability

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IGNITE

- IGNITE network collectively has documented genomic medicine implementation:
 - Feasibility in multiple settings
 - Inpatient/outpatient
 - AMC, urban, rural, private practice, VA etc
 - Challenges and barriers
- Sustainability and widespread adoption into clinical practice requires increased focus on evidence base:
 - Clinical utility, including impact on clinical outcomes
 - Economic impact

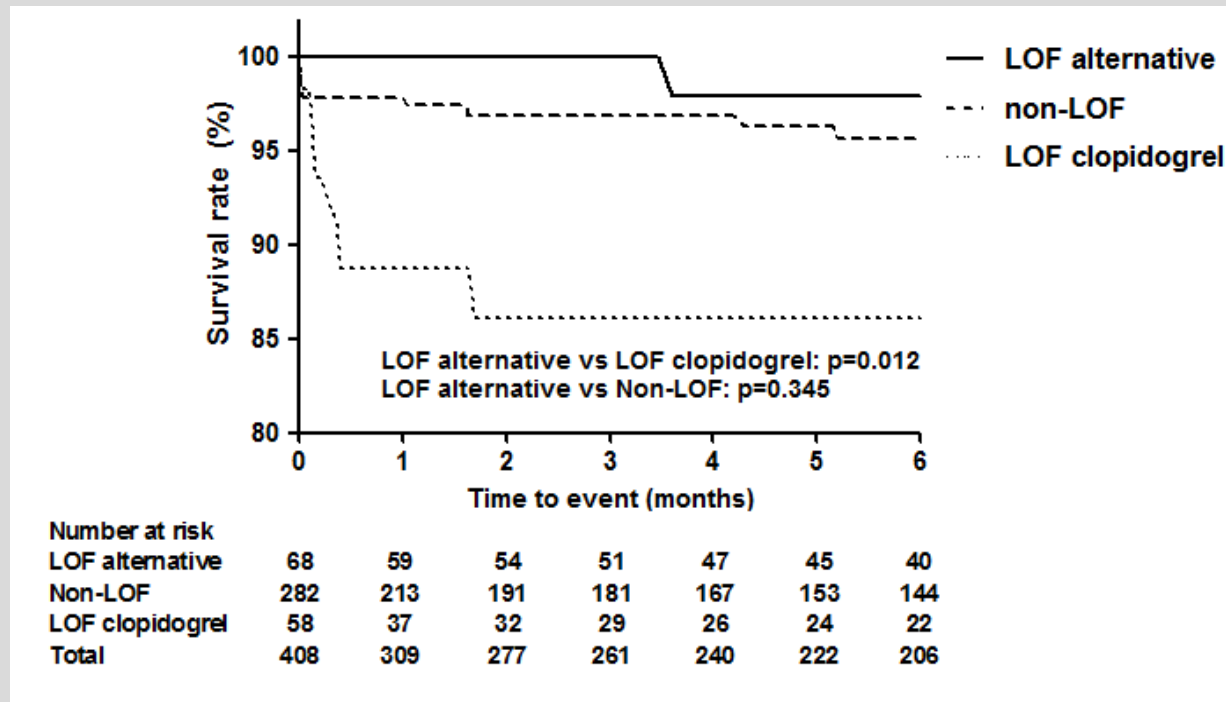
Clinical evidence generation in IGNITE –



Pharmacogenetics examples

- Pharmacogenetics

- UF group documented positive impact on clinical outcomes in 400+ patients with *CYP2C19* genotype-guided antiplatelet therapy post PCI



Clinical evidence generation in IGNITE – Pharmacogenetics examples



- Pharmacogenetics
 - IGNITE Pharmacogenetics Interest Group effort *CYP2C19* genotype-guided antiplatelet therapy project
 - 9 sites, 4,477 patients
 - Outcomes data accepted for presentation in high profile “hot clinical science” session at American Heart Association Scientific Sessions in November
 - Data embargoed
 - Goal is simultaneous publication in high impact journal
 - Outcomes data in 400+ not likely to change practice; data in 4,400+ may
- Economics (pharmacogenetics)
 - Analysis ongoing for *CYP2C19*-clopidogrel outcomes data
 - Broader economic implications of pharmacogenetic testing the focus of Indiana University’s project

Clinical evidence generation in IGNITE – Disease genetics examples



- All examples, primary focus is documenting the approaches, barriers and challenges to clinical implementation
- Monogenic diabetes
 - Seek to document changes in diagnosis, treatment, glycemic and related variables, hypoglycemic episodes, visit frequency, hospitalizations, patient-reported outcomes
- *APOL1* and in hypertensive African Americans
 - Primary clinical outcome is BP control
- Family history
 - Evaluating psychosocial impact, changes in lifestyle and risk management by patient, clinical care by provider; secondary analysis on cost-effectiveness

Sustainability and widespread clinical adoption



- IGNITE network suggests that greatest barrier moving forward is clinical evidence
- Clinical evidence gaps influence willingness of:
 - Clinicians to adopt into clinical practice
 - Payors to pay
- Future efforts should focus more specifically on clinical evidence generation to ensure wide-spread adoption
- Network-wide efforts have power to document clinical utility, clinical outcomes and economic implications in a manner not possible with a single site

Clinical Evidence: Summary and Recommendations



- IGNITE network has documented across multiple clinical settings and scenarios the feasibility of clinical implementation of genomic medicine
- Clinical evidence gap is critical need moving forward
- IGNITE-2 could be structured in a manner more similar to traditional NIH networks, where common projects are selected for implementation across the network, to enable building evidence base for sustainable genomic medicine initiatives