Massachusetts Institute of Technology

MIT CBI Center for Biomedical Innovation

MIT CBI NEWDIGS Design Lab

Financing and Reimbursement of Cures in the U.S. (FoCUS)

White paper: Healthcare leaders convene: take next step towards developing and modeling new financing mechanisms for cures

Executive Summary

NEWDIGS (NEW Drug Development ParadIGmS), an initiative led by the MIT Center for Biomedical Innovation (CBI), seeks to re-engineer biomedical innovation to more reliably deliver new, affordable treatments to the right patients faster. Their latest project, FoCUS (Financing and Reimbursement of Curative Therapies in the US) convenes bio/pharmaceutical development stakeholders (including biopharma companies, patient advocates, investors, payers, physicians, and policymakers, among others) to co-design and prepare pilot ready scalable solutions to the complex challenges of product financing and reimbursement. Project collaborators benefit from pre-competitive knowledge sharing and help to shape best practices for the years to come.

On October 27, 2016, MIT NEWDIGS hosted a FoCUS Strategic Planning Design Lab with a diverse group of healthcare leaders from the stakeholder set. The group built on the work begun in the May 3, 2016 FoCUS kick-off meeting. In May, FoCUS began developing a design toolkit and sought participant input and interest level in moving a financing and reimbursement project forward. The output from this strategic planning meeting includes the establishment of targeted disease area works groups which will be known as TAGs: gene therapies, durable oncology treatments, and antibiotics were nominated areas of interest. The project goals will be to prototype and refine financing and reimbursement models, using the integrated understanding developed by each TAG of the cure characteristics, payer segmentation, and financing tools specific to its target areas. Outputs will include work on the initial cures characterization framework for each TAG which will be presented in the next Design Lab in April 2017 and enhancements to the "toolkit" used to make those characterizations. Following framework acceptance will be modeling and simulation exercises leading to fully vetted and rigorously tested financing pilot designs which may be run by FoCUS implementation partners. Pilots are expected to be designed to encompass scalable financing innovations for specific classes of biomedical breakthroughs.

This brief provides more context on the project progress, including background on the cure characteristics, payer segmentation, and financing tools development work done to date; project phases; and the **next steps** and **action items** for each TAG.

Introduction: Moving FoCUS Forward

Background

The MIT NEWDIGS FoCUS Design Lab conducted on May 3 produced a consensus among a diverse group of healthcare leaders to move forward on FoCUS objectives and laid down a foundation for the next stage of development. Participants in the lab established a framework for characterizing curative therapies that could serve as the basis for the design of financing models. They then generated eight candidate-financing methods that could best match with one or more cure characteristics. These exercises confirmed that different forms of cures will exist for different treatments and that they will require different financing mechanisms. This work is described in the May 3rd White Paper published and distributed to the attendees, and also served to set the stage for this strategic planning design lab held on October 27, 2016 and described here

Objectives for October 27 Design Lab

1. Consider and refine FoCUS strategic goals and approach
2. Review and refine evolving "tools" in the FoCUS design toolkit
3. Discuss project structure and implementation plan
4. Examine issues that are expected to be common across target areas and that may warrant *ad hoc* teams and activities
5. Lay the foundation for the launch of target area groups (TAGs) in first-quarter 2017, including gene therapies, durable oncology treatments, and antibiotics

Stakeholder Perspectives Represented

Health care insurance carriers
Pharmacy benefit management
Financial risk-bearing provider organizations
Pharmaceutical manufacturers
Investment community
Health technology assessment organizations (HTAs)
Clinical practitioners
Life science research organizations
**Patient perspective-while advocacy groups did not attend there is an ongoing conscious effort to include this perspective in this and subsequent events*

The October 27 Design Lab was a strategic planning session which also served to bring together the stakeholder groups interested in each of the therapeutic area groups. It started with a review of the overall aims of FoCUS, objectives for the session, and a call for assets to consider for case study reviews that could inform modeling and simulation of financing options and eventually lead to project pilots. After a review of the FoCUS toolkit participants separated into three target area groups for in depth discussions on the proposed TAGS of gene therapies, durable oncology treatments, and antibiotics, examining specifics on how pilot financing models could be structured and executed in each domain. Participants raised these general considerations for the initiative:

- Discussions about pricing specifics could produce anti-trust issues. Therefore, it was determined that pricing discussions are out of scope for FoCUS. The value of treatments to various constituents (e.g., patients, providers, payers, and developers) is assumed to have been applied to pricing already which will be taken as a "given" in modeling. Values of High, Medium and Low will be utilized.
- Broad implications of proposed payment methods must be considered, such as consequences related to laws, regulations, coverage policies, contracts, and transaction processes.
- Financing mechanisms selected should be scalable for most payer segments and transaction systems should be capable of processing them. Further, any tools needed to make a finance mechanism acceptable and workable should be part of the development process.
- Financing mechanisms for antibiotics may need to account for R&D incentives to a much greater degree than for the other FoCUS target groups – gene therapies and durable oncology treatments.
- In the development of models, the assumptions used are that financing mechanisms to be developed are for treatments that are past regulatory approval for clinical use, within the scope of most health care coverage policies, and have negotiated prices.

FoCUS Toolkit

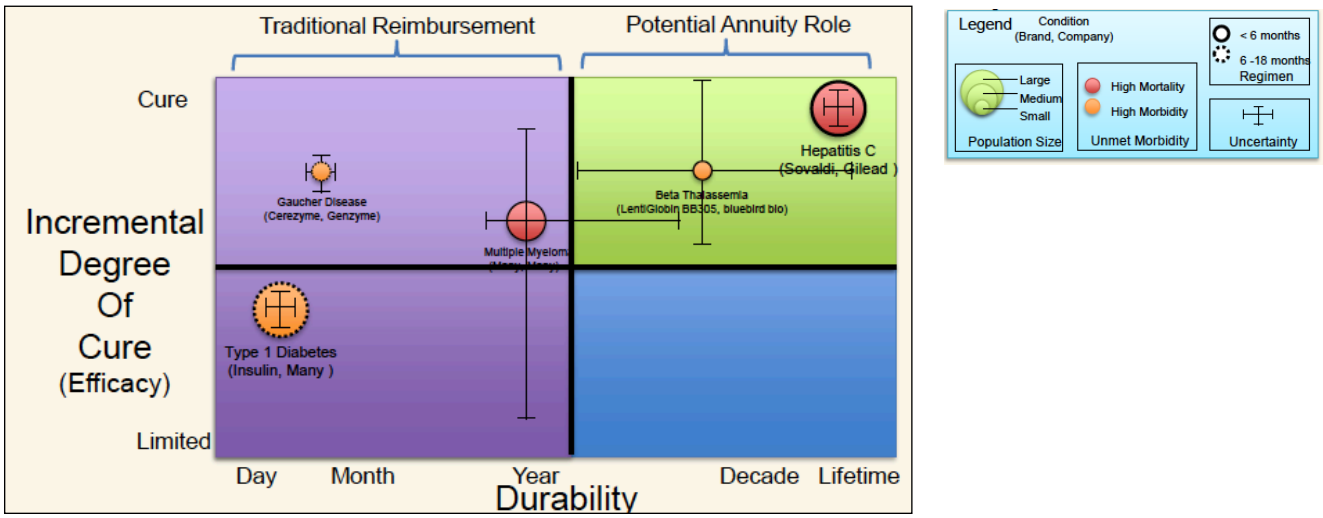
Participants reviewed the modified and enhanced May 3rd toolkit that will be used to establish and apply financing mechanisms for specific situations. The toolkit currently comprises four components:

1. Cure characterization framework
2. Payer segmentation tool
3. Financing tools
4. A decision tree that helps to systematically apply the above tools in ways that support strategic decision-making (e.g., prioritization) by the design teams

Cure Characterization Framework

At this FoCUS session, the cure characterization framework was extended from the May 3rd work to consider "cure traits" that can be manifest among any of the therapeutic categories and that can have a bearing on financing mechanism considerations. These traits included curative effect, durability, patient population size, unmet medical need in conjunction with natural history of disease, and treatment duration. All of these traits come with varying amounts of uncertainty. In Figure 1 below, products within a specific class are laid out on a grid with axis of durability and curative effect. Durability is categorized as very short (a day or less) or lifetime. Curative effect is 'limited' to 'cured'. Examples at opposite ends of the spectrum show Type 1 Diabetes with short durability and limited curative effect to the lifetime cure offered by Sovaldi and Gilead for Hepatitis C. The position of a drug in this matrix will be a design driver in any modeling exercise and serves as a catalyst of discussion for where exactly a particular product may sit.

Figure 1 Cure Characteristics

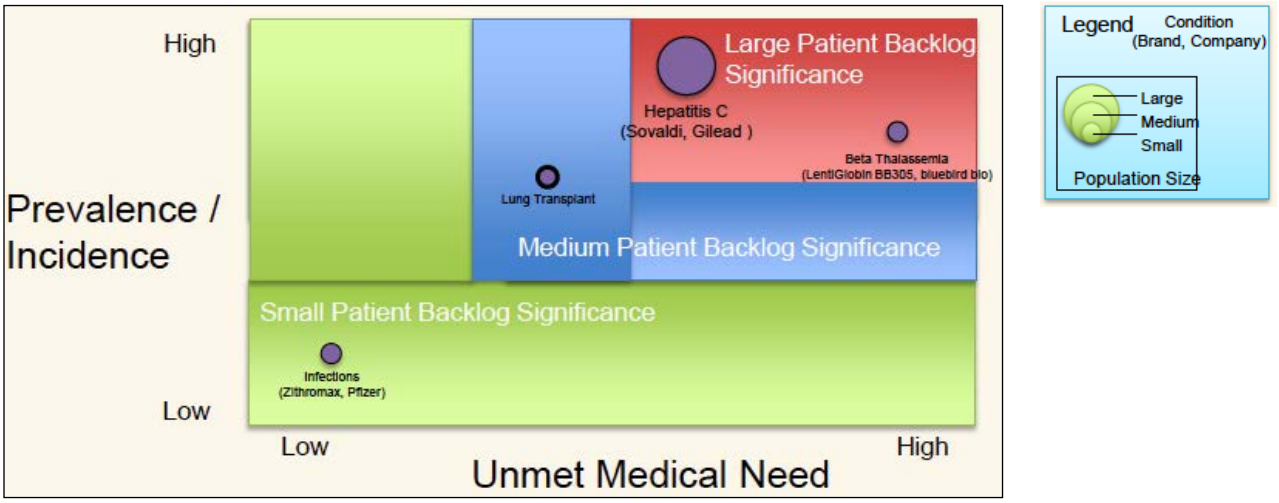


Cure characteristics, as a pilot design driver will impact applicable financing and reimbursement schemes. For instance, Payers may not favor incentive methods requiring full payments at the time of treatment without some form of risk protection when the degree and duration of cures are unknown; products with limited and short cure characteristics will be treated very differently on the financing paradigm than those expected to be highly curative with extended durability of decades or a lifetime. In the case of the latter, payers would likely favor financing mechanisms that spread payments over the time of patient benefit; treatment developers however may prefer full payment at time of treatment. Therefore, while cure traits can drive payer preferences in financing methods, those methods may not work for developers; to reach agreement alternative financing mechanisms will need to be explored, including such concepts as pay for performance and annuities.

Disease Characteristics

Cure traits alone, however, will not be sufficient to predict demands for a particular treatment over time. For example, a new treatment can unleash a spike in demand from a backlog of patients. The magnitude of a surge when a cure becomes available will depend on incidence and prevalence of the disease treated plus the degree of unmet medical need. Payers could thus prefer different payment methods for different phases of demand across a patient population (see Figure 2 below). A new treatment for a small population such as an ultra-orphan disease would have a smaller surge effect than the release of a drug for a disease with a large population, such as hepatitis C which has a large pent-up demand. Some Payers would be concerned with the small population when the cost of the drug is very high while others would be less concerned because of their premium base. This idea brings up the issue of payer segmentation which will be explored in the next section.

Figure 2 Backlog Significance



Payment segmentation tool

Payer segmentation will also drive preferences for finance mechanisms. Segments include managed care organizations which provide fully insured plans; self-insured employers; health insurance carriers; government employee programs (federal and state); unions and retirement systems; risk-bearing providers; and government social programs (e.g., Medicare, Medicaid, Veterans Health Administration).

The segmentations presented to the participants were derived from the different reasons payers cover medical treatments; the different treatment coverage impact measures they follow; and the various philosophies, structures, processes, and traditions that affect their payment method preferences. Other influences also affect payer segment positions and preferences, such as management consultants, policy centers, patient advocacy groups, professional medical societies, pharmaceutical manufacturers, and political pressures.

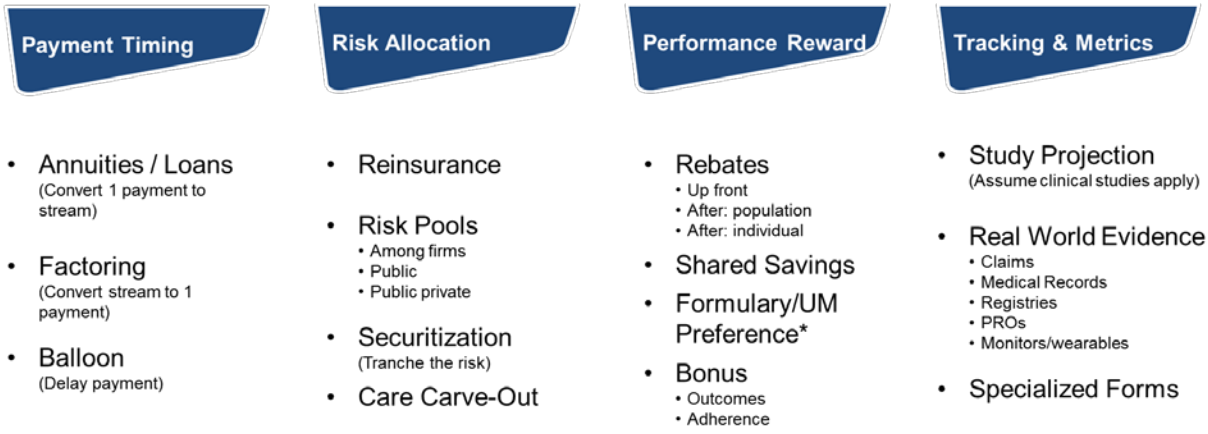
One FoCUS task is to determine how well payment method preferences conform to payer segmentation based on motivations for treatment coverage, CEO and CFO attitudes, or financial transaction capabilities. Surveys across the payer segments could help to formulate acceptable financing mechanisms. The project will need to instill processes that ensure payer segment representation on pilots, as this input will be necessary to test any financing mechanisms developed.

Financing tools

Financing tools developed at the May 3 design lab session were further refined for this session. The financing tools offered were aggregated into four categories: payment timing; risk allocation; performance reward; and tracking and metrics (see Figure 3 below). Subtypes within each category are provided as examples and for further clarification of terms. As shown, techniques already exist to transform payment timing, actuarial risk, performance risk and provide objective triggers. Specific strategies combine & refine these techniques for appropriate use within a payer segment for a specific case of cure characteristics. This tool will continue to be refined as the project is moves forward and

additional financing schemes become apparent. More information on financing tool considerations can be found in the May 3rd white paper.

Figure 3: Financing Tools

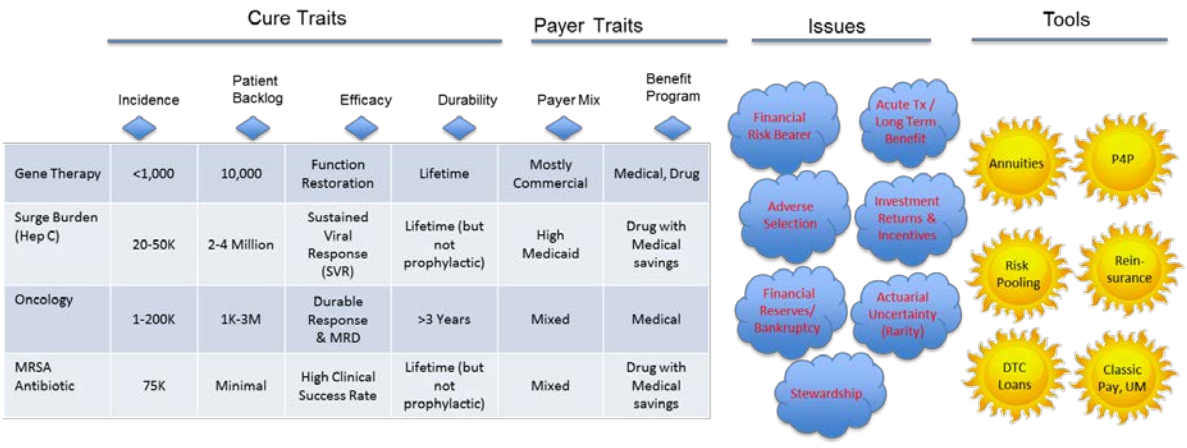


*Formulary/UM (utilization management) Preference: situation in which payers actively switch patients to preferred drugs via physician and pharmacy intervention

Toolkit use and assessment

The four elements of the toolkit (cure characterization framework, payer segmentation & financing tools, with the decision tree framework) reflect the complexity involved in finding the best financing method for a given treatment situation. For each treatment for which conventional coverage and payment conditions are not adequate, the toolkit lays out the cure characteristics, payer segment and potential financing methods to allow for systematic consideration of the best most appropriate tools to apply to a particular treatment. (Figure 4 below gives examples for cure traits, payer traits, issues for consideration and possible financing options for four scenarios.)

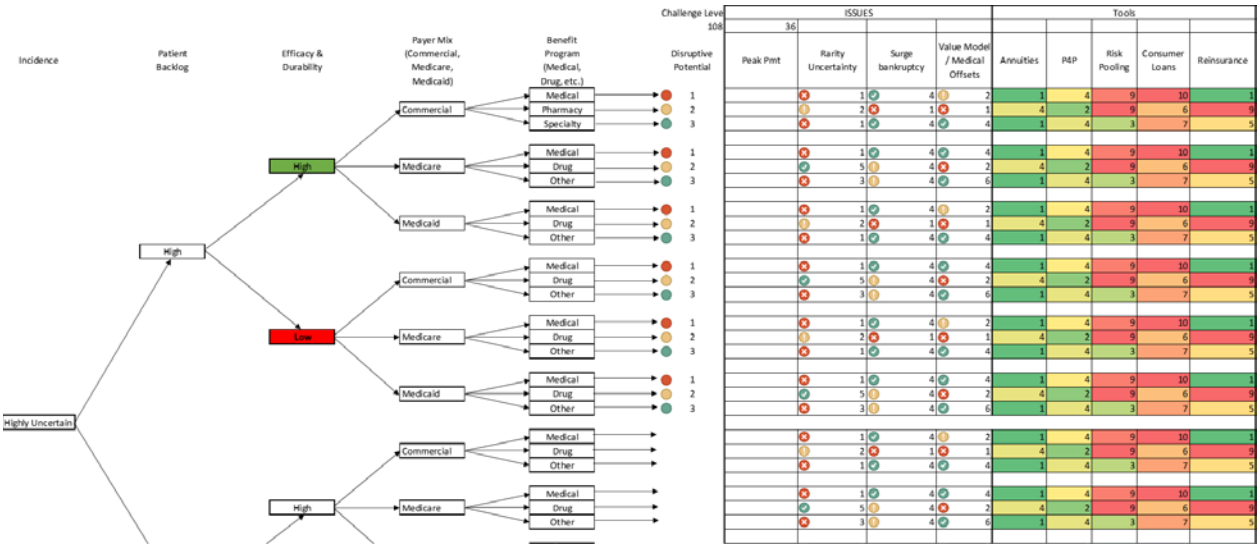
Figure 4



	Cure Traits				Payer Traits	
	Incidence	Patient Backlog	Efficacy	Durability	Payer Mix	Benefit Program
Gene Therapy	<1,000	10,000	Function Restoration	Lifetime	Mostly Commercial	Medical, Drug
Surge Burden (Hep C)	20-50K	2-4 Million	Sustained Viral Response (SVR)	Lifetime (but not prophylactic)	High Medicaid	Drug with Medical savings
Oncology	1-200K	1K-3M	Durable Response & MRD	>3 Years	Mixed	Medical
MRSA Antibiotic	75K	Minimal	High Clinical Success Rate	Lifetime (but not prophylactic)	Mixed	Drug with Medical savings

Financing tools may be appropriate across multiple therapy types and solve different issues for specific payers in the mix. These factors are mapped to the decision tree framework shown in Figure 5. For instance the impact of high patient backlogs, with high efficacy and durability will lead to different tools being utilized based on the payer segment under consideration.

Figure 5



Emerging Themes

Session participants were asked to consider the individual toolkit components and the components in aggregate and as they could be applied to gene therapies, durable oncology treatments, and antibiotics in scenarios where current payment methods are not adequate or effective. Separate consideration was given to perspectives from risk-bearing providers, HTAs, and payers.

Some emerging themes about FoCUS aims:

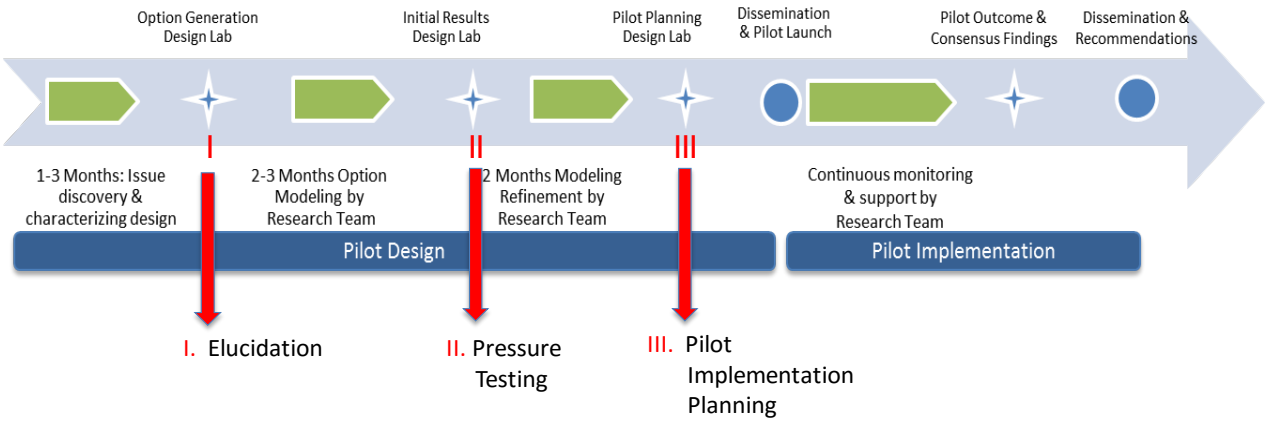
- The right financing and reimbursement mechanisms will obviate motivations for payers to restrict access to these therapies due to price, and may also require regulatory and/or financial accounting changes.
- Scalability and efficiency of financing and reimbursement mechanisms are required for broad applicability and uptake across the portfolio of products and across global regions.
- Implementation of these tools requires consideration of the broader environmental factors (e.g., impacts on coverage policies, patient preferences and capabilities, and contract terms between employers and unions) and the strategies needed to accommodate those factors.
- Speed of iteration is important.
- The dynamics among all stakeholders from manufacturers to providers to payers to patients will need to be accommodated in any payment and reimbursement mechanism.
- Antibiotics represent a different scenario than those for gene therapies and durable oncology treatments because they have not drawn the same degree of interest for development.

Therefore, financing and reimbursement strategies for antibiotics should function to drive innovation as well as provide patients access to them.

The Work

FoCUS proposes to have three target area groups or TAGs: gene therapy, durable oncology treatments, and antibiotics. During this Design Lab, participants interested in each of these therapy areas broke out into discussion groups to review the cure characteristics that make the area unique, identify issues and articulate asset characteristics that would make a product a good candidate for a case study to be presented in the next FoCUS Design Lab taking place in April of 2017. Participants were reminded that each TAG will need 3 sponsors (can be from industry, non-profit or payer segments), as well as representatives from each stakeholder group in order to have fully rounded perspective on the issues under consideration. While there was under- representation in the patient and patient advocate stakeholder groups present, each TAG will make a specific effort to ensure their perspectives are taken into account and strive for greater attendance in the April Lab.

Figure 6



The work will be divided into three phases; Elucidation, Pressure Testing and Pilot Implementation Planning as shown in Figure 6. Elucidation will be the first phase and encompasses using the cures and financing frameworks discussed previously in this paper to correctly size the issues and propose appropriate financing solutions. This phase may take more than one asset case study review to complete. The second phase will utilize the asset from the case study to model the proposed financial solution(s). The modeling and simulation work will be performed by the NEWDIGS FoCUS team using the parameters laid out by the TAG. Once the pressure testing of a financial solution is complete, inclusive of adjustments and retesting as needed, the model would be ready for pilot implementation planning. At this stage, partners consisting of asset owners and payers will have been identified.

Gene Therapies

Gene therapies envisioned as a once-administered treatment for a lifetime cure or amelioration are not a new health care delivery scenario for health care purchasers in form, but they do represent a new level of intensity. Organ transplants, stem cell transplants, bariatric surgery, and other life-saving surgeries offer lifetime cures as well, but these well-established therapies are not the result of same level of investment and are not expected to return on investment as will gene therapies. Furthermore, gene therapies probably will initially target rare diseases and generate costs higher than current financing and adjudication mechanisms can accommodate.

Decision Factors

The gene therapies TAG identified population size and therapeutic area as crucial factors that will determine the potential impact on both providers and payers. Payer segmentation also becomes important because while sporadic incidence of a very-high-cost gene therapy for a rare disease may not have a significant effect on a large national health care insurer, it could put a small employer or insurer out of business. More importantly, the mix of Medicare, commercial and Medicaid patients will likely vary significantly among the gene therapies.

The gene therapies TAG is also considering durability. While the hope and anticipation is that these therapies will be lifelong, the duration of their effects is yet to be determined, and duration of effects could play into financing options (e.g., risk sharing arrangements). This TAG also is evaluating other considerations, such as:

- For extremely rare diseases, how many different therapies are being developed?
- How large is the patient backlog?
- What does the overall disease management plan look like once the therapy is introduced?
- What's the site of service and are these therapies considered medical treatments or drugs?

The gene therapies TAG is initially considering the following categories:

- Hemophilia and liver
- Ophthalmology
- Central nervous system
- Muscle diseases
- Hemoglobinopathies
- Gene editing

Design

Given that gene therapies may generate costs that are not accommodated by current coverage policies and adjudication methods, the TAG recommended that policy evaluations accompany work on portfolio and product levels. Policy level evaluations entail reviews of laws and regulations applicable to government payers and the coverage policies and processes of commercial payers. Working at a portfolio level would then include simulating how a provider or payer would approach the financing and reimbursement of these therapies within likely policy contexts. Particular examples of possible directions include partnering with a Medicaid program around a particular disease and gene therapy, and leveraging local resources in Massachusetts across multiple payers, including a proposal to the state legislature and insurance commissioner.

Next Steps/Action Items for Gene Therapies

The proposed deliverables are as follows:

1. **A proposal for specific policy changes** to enable practical progress on issues from healthcare affordability to implementing creative reimbursement (and coverage/ benefit design) mechanisms that preserve payer diversity and incentives for all.
2. **A suite of business models and practical implementation mechanisms** that are clearly tied to the curative product/payer combination situations to which they apply. The models should be designed and tested (likely via simulations) at sufficient detail to inform stakeholder decision making in their specific circumstances.
3. **Tracking results and disseminating the learnings of the marketplace**.

An immediate next step includes:

- **Pipeline analysis to estimate possible ranges of the financial (and health) impacts**

Durable Oncology

The durable oncology TAG agreed to a working definition for "curative" as an effect of at least an 18-month or longer with a regimen as close to monotherapy as possible. Further to be reconciled with cure are relapse-free survival, the need for secondary interventions, and occurrence of secondary primary malignancies.

The TAG will consider whether financing should incorporate these other cure characteristics. This is particularly important given the relative uncertainty of duration, emergent secondary disease and consequent interventions.

Given the definition, the durable oncology TAG is targeting a CAR-T/ B cell interventions asset in development. If none can be made available for a prospective pilot program, the TAG agreed that in this particular situation that a simulation method would be used.

Key elements which deliver value from the pilot:

- Opportunity to understand the "therapeutic journey" which is very different for these personalized treatments.
- Mapping secondary events and understanding the impact on financing arrangements
- Mapping the patient journey
- Understanding tools which could fund the therapy and thus ensure access

Action Items/Next Steps for Durable Oncology

The proposed deliverables for this group were as follows:

- Examine other materials already in the field on the topic of patient journey and oncology financing needs to inform the study design
- Determine if a product sponsored prospective or a retrospective case study will be designed. Target a group call for early December to discuss options
- Design and execute a survey for all stakeholders to ensure we have a 360 view – all segments- This work would be designed so that it could be published
- Create a list of policy questions and issues that would need to be addressed

Immediate next steps include:

- Identify partners as needed to acquire asset for Design Lab case study, to respond to the survey in 1Q2017 and for added expertise on financing models.

Antibiotics

New mechanisms for financing and reimbursing antibiotics will need to address some elements specific to antibiotics. One distinction has to do with antibiotic use patterns for individual patients and another involves public health needs that do not conform to typical clinical scenarios.

For good reasons, antibiotics are used in a judicious manner to prevent or slow resistance development, and they are used for as short a period as possible. Thus, patient populations for antibiotics, especially antibiotics used for serious infections, are small. Small patient populations constrain revenues that can be put towards research and development, and create more risk for developers.

Antibiotics, more than most other drug categories, also have important public health applications that are not always connected to a typical health care purchaser. In particular, the threat of bioterrorism or infectious plagues necessitates strategic stockpiles of antibiotics (e.g., anthrax, influenza). No individual health care insurer of any segment will pay for stockpiles, and ordinary payment processes are not configured to manage rapid deployment of these stockpiled agents when they are needed. In contrast, governments have an interest in these stockpiles and their deployment. Therefore, financing and reimbursement mechanisms for antibiotics should include those needed for governments supporting antibiotic stockpile use cases.

In a similar way, particularly threatening bacteria (e.g., *C. difficile*, methicillin-resistant *S. aureus*) and growing bacterial resistance to antibiotics (e.g., Gram-negative *Enterobacteriacea*) are public health issues as much as they are individual patient issues. Governments have an interest in facilitating use of antibiotics that are effective against bacterial strains resistant to multiple agents. Therefore, financing and reimbursement mechanisms for antibiotics should also consider how governments can provide incentives or assistance to payers covering patients needing antibiotics in this use case.

Also distinguishing antibiotics is that financing and reimbursement mechanisms will not have to account for potential patient surges from backlogs or for the potential for portability across payers.

Design

The FoCUS project comes as two major initiatives wrapping up within the next year offer promising ideas for new incentives and financing models. These initiatives are at the Duke Margolis Center[1] in the US and DRIVE-AB[2] led by the EU Innovative Medicines Initiative (IMI) in Europe. The ideas and recommendations that come from these initiatives will be at a macro level; therefore, FoCUS offers an opportunity to pilot some of these in an integrated application environment.

Pilot selection criteria will first draw from priority areas of unmet need and high disease burden. Two foci for the pilots are under consideration:

Hospitalized patients with MDR infection	Ambulatory patients
Important variables might include: • Flow of patients with chronic illness • Co-morbidities, as in nursing homes • Agency staff versus provider staff • Availability of reliable pathogen testing • Current incentives for quality performance	Goal: demonstrate prevention of hospitalization • Key challenge: how to demonstrate prevention of hospitalization
Payers will likely include hospitals or related facilities working off of fixed reimbursement or bundled arrangement.	*Payers will include representation from a range of payer segments.*

Decision Factors

The current environments for antibiotic development and clinical use are relevant to financing and reimbursement mechanisms for antibiotics, both directly and indirectly. How these environments can affect new financing mechanisms for clinical use of antibiotics, and how any new financing mechanisms can affect these environments, should be part of planning and evaluation. Here are some particular aspects of the current environments:

- Very few drug manufacturers are still funding or conducting research
- Current initiatives focus on:
    - Generics
    - Repurposing
    - Formulations (e.g., subcutaneous versus intravenous administration)

- Health care provider organizations are putting significant efforts into antibiotic stewardship to preserve effectiveness. The practical effect of these efforts is deliberate and judicious use of antibiotics, resulting in a narrow patient population. Small patient populations may not generate sufficient revenues to induce development of new agents, a limitation that stanches the flow of new antibiotics always needed to meet emerging resistance patterns.

[1] Duke Margolis Payment Reform Evidence Hub- https://healthpolicy.duke.edu/payment-reform-evidence-hub
[2] Driving Reinvestment in Antibiotics and advocating their responsible use http://drive-ab.eu/

- Hospital accreditation requirements, entrenched treatment protocols and preferences, regional variations in antibiotic susceptibility patterns, regulations around hospital-acquired infection management, and patient movements among health care institutions for treatment of infections can affect antibiotic use and narrow patient populations.
- Health care professionals and provider organizations do not fully appreciate current trends and rates of antibiotic resistance, so there is a need to educate the relevant constituencies about the growing threat of multi-drug resistant (MDR) infections.

Action Items/Next Steps for Antibiotics

Proposed deliverables for this group include the following:

1. Case involving hospitalized patients with MDR infection
2. Case involving ambulatory treatments that prevent hospitalization

Immediate next steps include

- Landscape analysis of key public-private partnership initiatives in antibiotics, and inventory of emerging tools/recommendations in order to avoid duplication and leverage synergies
- Potential test case might involve a new treatment with a novel mechanism of action for oral use in treating UTI and gonorrhea, and with potential indications for bio-threat pathogens (plague, anthrax, and tularemia).

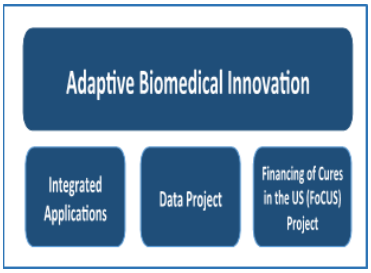
Session Summary

Overall, the October 27 FoCUS Design Lab made important progress in advancing the work on defining appropriate frameworks and tools, as well as planning for pilot initiatives in three proposed TAGs. Next steps will be to prepare for the elucidation phase Design Lab which will be held in April 2017. During the lab, a case study (whether using real products nominated by sponsors or hypothetical information) will be presented by each TAG, dissected and discussed in depth to determine if the financial solutions proposed are suitable and ready for the next round of pressure testing through modeling and simulation exercises. A tools refinement team will continue to work on refinements to the cures and disease characteristics, payment segmentation and decision trees analysis methods. Issues and opportunities common across all TAGs will be collected and reported on. After the April Lab, each TAG will determine whether or not they are ready to move to the next phase or would wish to repeat the current one.

About:

MIT NEWDIGS Initiative

NEWDIGS is a unique collaborative, a pre-competitive "think and do" tank led by the MIT Center for Biomedical Innovation (CBI). Under the auspices of CBI, NEWDIGS takes a systems engineering approach to critical challenges across the biomedical innovation chain that are too cross-cutting and complex to be addressed by any single stakeholder. Through its unique case based Design Labs, NEWDIGS brings together diverse thought leaders and change agents within a neutral "safe haven" setting for open discourse on a wide range of relevant and urgent topics. It further leverages MIT expertise such as systems and financial engineering to rigorously evaluate concept prototypes. NEWDIGS fuels the design, testing, and implementation of sustainable patient-centered change across the global industry.



FoCUS Project

Novel, potentially curative treatments are now coming to market. This is an exciting time for patients in terms of new, long awaited treatment options. But with over 600 curative treatments in clinical development, payers may struggle to afford them. Biopharma companies can no longer assume the market will support full value pricing for effective, innovative medicines. There is an urgent need for new financing and reimbursement models that ensure 1) patient access to needed treatments 2) public and private payer affordability and 3) innovator sustainability. The FoCUS initiative will result in workable policy and business solutions for providing affordable access to curative therapies. Those who participate in this process will have the opportunity to shape the immediate and long-term future of both medical innovation and financial solutions to chronic illness.

FoCUS aims to develop and validate innovative, scalable financing and reimbursement models that are tailored to specific classes of curative treatments; models that are patient-centered; and that "work" for all stakeholders. Successful solutions deliver treatments appropriately to the right patients in a timely manner while providing both payer affordability and rewards to present and future innovators. Well-formulated, analyzed, rigorously vetted, modeled and simulated pilot ideas will be trialed by real world partners identified through this process. NEWDIGS FoCUS will assist with pilot trials evaluation through longitudinal studies and dissemination of learnings throughout that process.