Fair Market Value of Engaging Patients

Patient Engagement Open Forum
19.9.2019

PATIENT FOCUSED
MEDICINES DEVELOPMENT

NATIONAL HEALTH COUNCIL

National Health Council Fair-Market Value Calculator

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Agenda

- Introduction and Rationale
- Project Partners
- Overview and Update
- Next Steps
- Interactive Exercise
    - Activities List
    - Barriers and Solutions

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American Heart Association
Learn and Live
American Diabetes Association
Cure • Care • Commitment
National Alopecia Areata Foundation
American Kidney Fund
FIRST
Foundation for Ichthyosis & Related Skin Types
Educate • Inspire • Connect
COPD FOUNDATION
ALPHA-1 FOUNDATION
NATIONAL PSORIASIS FOUNDATION
American Autoimmune Related Diseases Association, Inc.
Huntington's Disease Society of America
PKD FOUNDATION
Polycystic Kidney Disease
Tourette Association of America
Awareness. Research. Support.
NATIONAL Eczema ASSOCIATION
alzheimer's association
AMERICAN LIVER FOUNDATION
Your Liver. Your Life.
amputee coalition
THE MARFAN FOUNDATION
Know the signs. Fight for victory.
resolve
THE NATIONAL INFERTILITY ASSOCIATION
colorectal cancer alliance
aafa Asthma and Allergy Foundation of America
MGFA MYASTHENIA GRAVIS FOUNDATION OF AMERICA, INC.
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IDF Immune Deficiency Foundation
Arthritis Foundation
Champion of Yes
National Foundation for Ectodermal Dysplasias
American Cancer Society
WomenHeart
The National Coalition for Women with Heart Disease
Celiac Disease FOUNDATION
Sjögren's Syndrome Foundation
BEYOND CELIAC
awareness • advocacy • action
NATIONAL OSTEOPOROSIS FOUNDATION
ALS ASSOCIATION
nfed
Supporting you. Supporting each other.
NATIONAL FOUNDATION FOR ECTODERMAL DYSPLASIAS
Barth Syndrome Foundation
MS National Multiple Sclerosis Society
Spina Bifida Association of America
OSTEOGENESIS IMPERFECTA FOUNDATION
Unbreakable Spirit
American Foundation for Suicide Prevention
The LAM Foundation
A BREATH OF HOPE
Prevent Blindness
Our Vision Is Vision
prevent cancer FOUNDATION
Mended Hearts
Hydrocephalus Association
NATIONAL HEMOPHILIA FOUNDATION
for all bleeding and clotting disorders
THE MYOSITIS ASSOCIATION
National Blood Clot Alliance
Stop The Clot
LUPUS FOUNDATION OF AMERICA
LUNG CANCER ALLIANCE
Parent Project Muscular Dystrophy
LEADING THE FIGHT TO END DUCHENNE
NORD
National Organization for Rare Disorders
CMTA
Charcot-Marie-Tooth Association

NHC FMV Project Sponsors to Date

Organization	Level
Johnson & Johnson	Platinum Premier
Merck & Co., Inc.	Platinum Premier
Novartis Pharmaceuticals Corporation	Platinum Premier
Patient Focused Medicines Development	Platinum Premier
Pfizer Inc.	Platinum Premier
Allergan	Premier
Biogen	Premier
Boehringer-Ingelheim Pharmaceuticals	Premier
People-Centered Research Foundation	Premier
Sangamo Therapeutics	Premier
Celgene Corporation	Leading
Servier Pharmaceuticals	Leading

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Project Steering Committee

Members
Kate Avery, Director of Research, Beyond Celiac
Valerie Barton, Chief Data Strategy Officer, People-Centered Research Foundation
John Boyle, President & CEO, Immune Deficiency Foundation
Nicholas Brooke, Founder & Executive Director, Patient Focused Medicines Development
Katherine Capperella, VP, Global Patient Engagement Leader, Janssen Pharmaceuticals, Johnson and Johnson
Barbara Collura, President & CEO, RESOLVE
Louisa Daniels, Vice President & Assistant General Counsel, Chief Counsel Global Product Development, Pfizer
Tracy Hart, Chief Executive Officer, Osteogenesis Imperfecta Foundation
Jan Nissen, Vice President, Patient Innovation, Merck
Amber Spierer, Executive Director, Patient Advocacy and Strategic Alliances , Novartis
Louise Vetter , President & Chief Executive Officer, Huntington's Disease Society of America

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Review Committee Members

Members
Rebekah Angove, Vice President, Patient Experience & Program Evaluation, Patient Advocate Foundation
Jason Harris, Director, Public Policy, Lupus Foundation of America
Dory Kranz, Chief Executive Officer, National Alopecia Areata Foundation
Nancy Law, Chief Executive Officer, Myasthenia Gravis Foundation of America
Christeen Moburg, Senior Director, Patient Advocacy, Sangamo
Karen M. Morales, Associate Director of Engagement, The PATIENTS Program, PHSR, University of Maryland School of Pharmacy
Jessica Riviere, Senior Director of Patient Advocacy, Biogen
Susan Stone, Executive Director, Alliance Advocacy, Allergan, & Board Member, Allergan Foundation
Keri Yale, Director of Patient Advocacy and Professional Relations, External Affairs, Boehringer-Ingelheim Pharmaceuticals

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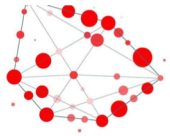
Transatlantic Collaboration

Ensuring alignment between the NHC FMV Project and PFMD & WECAN projects:

- Representation on the Steering Committee
- Adapt deliverables

PATIENT FOCUSED MEDICINES DEVELOPMENT



WECAN

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Project Overview

- FMV Calculator for patients/patient groups
- Principles for compensation/reimbursement
- Contract and conflict-of-interest templates

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Why Create an FMV Calculator?

- Patient group and industry member feedback
- Methods and inputs for determining appropriate rates for clinicians and researchers not applicable for patients

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Developing the FMV Calculator

Guidance from a multi-stakeholder Steering Committee

Compare/reconcile US market rates collected from NHC member organizations

Easy to use, No expensive or proprietary software

Define the breadth of activities to be captured in the calculator

Input from PFMD and WECAN partner projects

Market compensation data for positions requiring similar skills

Excel

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Getting FMV Right

FMV Input

EUROPE

- WECAN — Patient Survey
- PATIENT FOCUSED MEDICINES DEVELOPMENT — Extension to other stakeholders
- efpia — Patient Think Tank Guiding. Principles
- PATIENT FOCUSED MEDICINES DEVELOPMENT — PE Activity List
- WECAN & PATIENT FOCUSED MEDICINES DEVELOPMENT — **Legal Contract Input** Guiding Principles + Contract Template

USA

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60 Interviews

- **FMV Patient Compensation Principles**
- **FMV Calculator**
- **US reference contracts**

Plan European version and roll out

How to bring to Europe: WECAN, PATIENT FOCUSED MEDICINES DEVELOPMENT, efpia

Observations from Patient Organization Interviews

- No uniformity in terms of frequency or structure around industry interaction
- Most, at a minimum, receive grants and/or sponsorships from industry
- Most common service provided is clinical-trial recruitment assistance with varying levels of support
- Some believe industry may be involving patients or patient organizations as a “check the box activity”

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Observations from Patient Organization Interviews (cont.)

- Some not comfortable receiving payment or charging for services
  - Avoid perception of being influenced or favoring one company over another
  - See provision of services as part of a “partnership” or believe they are providing in-kind benefits
  - Some believe most fruitful way to engage with industry is through sponsorships or annual memberships where engagement activities are defined upfront
  - Ad hoc services may continue; however, these are structured as fee-for-service

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Observations from Industry Interviews

- All in favor of considering the patient voice
  - However, wide disparity between companies in terms of formal policies and/or processes
- Generally compensate patients for involvement across the product development spectrum
- Some have tiered patient/advocate rates reflecting the nature of the activity (primarily survey participation vs. other activities) and/or the experience
- Policies to reimburse patient expenses frequently mirror those for HCPs

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Observations from Industry Interviews (cont.)

- Generally there is an understanding that additional travel accommodations are necessary when engaging with certain patient populations
- Generally not concerned about placing caps on patient payments or number of times a patient is contracted
- Most have process for determining if grant/sponsorship/fee-for-service when engaging patient organizations
- Cognizant of the need to monitor the amount and type of payments going to patient organizations

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Suggestions for Useful NHC Project Outputs

- Many companies have tried unsuccessfully to find standards or guidelines when developing their patient-engagement policies and procedures, including compensation.
  - Stressed they would like external guidelines to reference
  - Mixed response in terms of how prescriptive/detailed they would like the guidelines to be
- Want truly patient-friendly contracts and templates
- Want guidelines for when and how industry should engage patients
- Suggested a “patient bill of rights” such that patients know what to expect from interactions with industry and from companies and organizations engaging them
- Best practices for industry funding of patient organizations

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The WECAN Patient FMV survey

Summary of WECAN FMV Survey

- **Patient community strongly agreed** that the individual expertise, community insight, community leadership, complexity of tasks, total time invested should **increase FMV value rate**
- **Factors for measuring individual expertise** should include specifically advocacy track record, disease and treatment knowledge, healthcare/research systems knowledge, personal skills, completion of training programmes, personal experience
- **Different rates by country of residence** were viewed with skepticism
- **Patient community disagrees** that factors like networking opportunities, travel, learning, prestige, visibility, access to treatments or HCPs should **decrease the FMV rate**
- **Travel time** should be compensated, either full or at least partial. Only 16% think no compensation for travel time is fair.
- **Right to opt out from financial compensation, and right of choice of recipient** (PAG or patient advocate) has strong support

The PFMD extension to all stakeholders

PARADIGM
Patients Active in Research and Dialogues for an Improved Generation of Medicines

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Patient Engagement open forum Beyond Aspiration

EUPATI
European Patients' Academy on Therapeutic Innovation

Key figures

Online survey - open from December 17 till March 4		
Stakeholders		
Patient community (Patients/ Patient advocates, Patient organisations)	29	39,1%
Industry	36	31,5%
Research and Academia	6	6,5%
Consultants (in communication, PE, legal advice)	5	1,1%
Health system	1	5,4%
Unknown	15	16,3%

Overall summary

- ❑ 2/3 of the respondents provide financial compensation to patients
- ❑ Half of the surveyed organisations have a patient-specific guidance in place
- ❑ FMV rate to be priorly based on the time invested, as well as individual training & expertise
- ❑ Strong agreement caregiver travel & expenses should be taken into consideration, followed by covering daycare costs
- ❑ A patient's personal experience with the disease is a key factor to consider, closely followed by disease and treatment knowledge and systems knowledge
- ❑ Compensation of travel time is considered most fair if consistent with travel policy consultants or other collaborators
- ❑ The majority of the respondents believe adequate arrangements should be made when inviting disabled people rather than adapting financial compensation.
- ❑ Guidance should address conflict of interest as a priority, as well as the right to opt out from any financial compensation
- ❑ Majority of respondents believe patients should be paid within 2 weeks after the activity

Main learnings comparing WECAN/PFMD survey

Strongly aligned	Significant differences
Financial compensation in place in ⅔ of the cases	Factors for measuring individual expertise
Key factors for FMV calculation: time invested and individual training/expertise	Compensation for travel time
Most fair to receive full compensation or at least partial compensation of travel time	Topics to consider in FMV guidance

150 + PE activities

+150 patient engagement activities identified from 20 sources*

	DISCOVERY	PRECLINICAL RESEARCH	CLINICAL RESEARCH	REGULATORY APPROVAL	POST LAUNCH ACTIVITIES
Patients	**35** PE activities: Identifying unmet needs and patient-relevant added value and outcomes, setting research priorities, benefit/risk expectations	**34** PE activities: Characterising the disease, guidance on study design and recruitment, input on meaningful clinical endpoints, identifying potential barriers for participation	**44** PE activities: Co-design and review protocols, assisting in selecting optimal sites, recruiting, support in advocacy and patient education, sering on data safety monitoring boards, trial steering committee	**22** PE activities: Provide public testimony at regulatory hearings, co-prepare submissions, usability, accessibility and comprehension information, prepare lay summaries, co-present study results, PAGs	**24** PE activities: Help return study results to participants, co-presenting results, patients' provide feedback and context on economic and counselling info, cooperate with payers
Patient organisations	Research funding, provide translational tools (biosamples), develop natural history DBs, patient registries, explore biomarkers	Fundraising, define study eligibility criteria, support in informed consent process, accompanying to regulatory meetings	Clinical infrastructure support, conduct patient preference studies, review patient related material, matchmaking, advice on relevancy of data	Fundraising, define study eligibility criteria, support in informed consent process, accompanying to regulatory meetings	Collaborate with sponsors and payers for reimbursement, advice on gaps from earlier CTs, assis in post-marketing surveillance

"PE catalogue" integrated into SYNaPsE Mapping and Networking Tool (2019)

Methods for Estimating FMV Hourly Rates for Patients

- FMV hourly rates for patients should reflect:
  - Types of **activities** for which the patients are engaged
  - **Experience and skills** expected to perform those activities
- Methods need to clearly exclude any potential influence a patient may have on the purchase of the engaging party's products
- Rates are using annual market compensation as the base, adjusted to a "consulting" rate
- Historical market payments to patients
  - Are considered
  - But, not directly relied upon as there is no insight into how they were determined

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Process for Developing FMV Hourly Rates for Patients

1. **Determine Patient Activities:**
   - Breadth and depth determined through
     - PFMD Survey
     - Stakeholder interviews
     - Steering and Review Committee input

2. **Identify Appropriate Benchmarking Data**:
   - No directly comparable compensation benchmarking data for “patients”
   - Benchmark compensation used for positions requiring similar experience, knowledge, and skills, such as:
     - Hospital patient representatives
     - Marketing positions
     - Research Positions
     - Health Educators
   - National income averages are considered as a reasonableness check

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Estimating FMV Hourly Consulting Rates for Patients

- **Estimate an Hourly Consulting Rate:**
  - Benchmark annual compensation adjusted to reflect that the patient is providing independent consulting services
  - A consulting rate will includes salary, benefits, overhead, and profit based on market data
  - Total annual fair-market compensation is converted to an hourly rate by dividing by the number of work hours in a year
    - The standard number of work hours in the U.S. is 2,080, which is adjusted to exclude holidays and vacation
- **A range of rates is developed**

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Patient and Caregiver Experts

	Personal Disease Experience – Living With or At Risk for a Disease	Population Disease Experience	Other Knowledge: R&D, Regulatory, Market Access, Health Care Systems (1 or more)	Communication Skills
Individual Patient	X			X
Expert Patient	X	X		X
Advanced Expert Patient	X	X	X	X

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Corresponding Principles for Compensating Patients for Engagement Activities (currently under review)

- Type of Patient Engagement Participant
- General Compensation Principles
- Administrative/Logistical Principles
- Time Commitment
- Travel and Reimbursement Considerations
- Declining Compensation
- Other Considerations

Example:

Reimbursement for travel or other expenses required to participate in an activity should be viewed as separate and distinct from compensation, as the reimbursement represents expenses incurred by the patient that would not otherwise be incurred.

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- CTTI Recommendations: Effective Engagement with Patient Groups Around Clinical Trials. https://www.ctti-clinicaltrials.org/files/pgctrecs.pdf
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- IFPMA, Code of Practice. https://www.ifpma.org/wp-content/uploads/2018/09/IFPMA_Code_of_Practice_2019.pdf
- IFPMA, Consensus Framework for Ethical Collaboration between Patients' Organisations, Healthcare Professionals and the Pharmaceutical Industry. https://www.ifpma.org/wp-content/uploads/2014/01/Consensus-Framework-FINAL.pdf
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Patient-Friendly Contract Templates Needed

NHC patient group and industry member feedback

- Too lengthy
- Complicated clauses
- Limited resources to hire an attorney to review

Legal Agreements Between Patients, Patient organisations and pharma

Legal Guiding Principles & Reference Contracts

Most contracts patient advocates receive are excessive in length, with inappropriate clauses on e.g. intellectual property, confidentiality, liability, adverse event reporting, travel restrictions, use of our name and of recordings, payment terms for expenses.

Delivered → Guiding principles on reasonable agreements between pharma and patients & Patient Advisory Board reference contract

OBJECTIVES

Deliver 4 preferred reference contract co-created with pharma and patients

- ➔ Consultancy agreement
- ➔ Collaboration agreement
- ➔ Advisory board agreement
- ➔ Community speaker agreement

Confidentiality	Intellectual property	Data protection	Compensation	Meeting recordings	Indemnification	Conflict of Interest

Adapting Contract Templates for US

1. Work with PFMD and WECAN to leverage EU templates in process
2. Review templates to discuss nature/scope, evaluate any legal differences
3. Provide a draft and discuss with Steering Committee and additional stakeholders to review the draft(s)

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Next Steps

- Finalizing Principles
- Finalizing FMV Calculator
- Review and adapt contract templates
- Other items:
  - Principles for compensating children and adolescents for engagement activities

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Questions?

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Interactive Session

NHC Patient Activities in Medical-Product Development Framework

- Framework for the assumptions to be considered in determining FMV compensation
- Also presents other considerations and potential compensation modifiers not directly factored into the FMV calculator, but that should be given attention in compensation decisions
- Assumes a clearly defined, specific need for which patient or patient-organization engagement is desired and the type and scope of the activity, expertise required to perform the activity, and type of participant have been determined
- For new activities, serves as a tool to ensure the engagement need is clearly articulated in advance

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1. Type of Participant: Begin by describing the type of participant you would like to engage. This could include a patient, caregiver/family member or patient-organization staff member.

Type of Patient/Caregiver/Representative	Definitions/Descriptors
Individual Patient	A person living with a condition or with a known risk of having a condition who can speak to their individual/personal experiences with the disease and related treatments, if applicable. May or may not work for or be affiliated with a patient organization. However, would not be speaking on behalf of a patient organization. Payment for the engagement is made directly to the individual (or payment is through a third part to a patient).

1. Select the type of patient

- ☐ Patient with condition with confirmed diagnosis
  Diagnosis has been confirmed by a qualified health care professional
- ☐ Patient with condition, self-reported diagnosis
  Diagnosis can be self reported
- ☐ Patient at risk for the condition
  Does not yet have the condition but is at risk for the condition

Select any specific characteristics needed (select all that apply)

- ☐ Treatment naïve
  Diagnosed but never treated
- ☐ Treatment experience
  Can speak to personal treatment experiences

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#1 - Type of Participant, Cont.

Type of Patient/Caregiver/Representative	Definitions/Descriptors
Individual Caregiver/Family Member	A person that can speak to their individual/personal experience as a caregiver/family member of someone with a condition. Payment for the engagement is made directly to the individual.

2. Select the type of caregiver

- ☐ For a patient with condition
  Patient cared for must have a diagnosis that is confirmed by a qualified healthcare professional
- ☐ For a patient with condition
  Patient cared for can have a diagnosis that is self reported
- ☐ For a patient at risk for the condition
  Patient cared for does not yet have the condition but is at risk for the condition

3. Patient group representative (select all that apply)

- ☐ Is a patient with the condition
  Can speak to individual/personal treatment experiences
- ☐ Patient advocacy senior leadership experience
  Has experience as a senior leader in a patient organization (e.g., CEO, CMO, VP)
- ☐ Patient advocacy experience
  Works for a patient organization, but is not in a leadership role

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2. Expertise Required: Indicate here the skill set required for the activity

Living with or at risk for the condition:

- ☐ Personal/individual experience living with a known risk for a condition
- ☐ Personal/individual experience living with condition and the treatments
- ☐ Personal/individual experience caring for someone with the condition and treatments

Subject Matter Expert:

- ☐ Expertise on a specific subject such as clinical trials, epidemiology, policy, reimbursement, etc.
- ☐ Specific training on a subject

Knowledge about the condition beyond individual/personal experience:

- ☐ Expertise on the entire population, subpopulations, subgroups in terms of experiences and other characteristics

Communications:

- ☐ Experience with speaking engagements, addressing small or large groups, media training, etc.

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3. Type of Activity: In this section, indicate the type of activity the participant is being asked to take part in.

☐ **Interview participant**
Take part in a one-on-one interview. Typically includes a trained interviewer who follows a discussion guide.

☐ **Focus group participant**
Participate in an organized focus group with other participants. Typically includes a trained facilitator who follows a discussion guide.

☐ **Provide consultation/co-development expertise**
Provide expert advice, guidance, consultation on a topic; take part in co-development discussions; could include writing or creating text, visuals, etc.

Note: Audience size and type of presentation can impact the amount of preparation time needed (See #4). e.g., someone giving a keynote presentation to a large audience would be expected to require more preparation time than someone giving a brief testimonial on their experiences before a small group.

☐ **Presentation/speaker:**

- ☐ Testimonial
  Speak to personal experience; typically a short presentation to a small or medium size group
- ☐ Keynote
  Provide an extended speech, as the sole speaker, on a thematic topic. Typically the opening, luncheon, or closing speaker
- ☐ Panel
  Speak for a short period as part of a small group (2 or more) of presenters; typically each speaker addresses the same topic from various perspectives
- ☐ Conference/Roundtable/ Symposium speaker
  Speaking as an expert at medium to large size gathering, typically a scientific or policy theme

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#3 – Type of Activity, Cont.

- ☐ **Mock Trial Participant**
  Walk through the experience of being part of a clinical trial protocol
- ☐ **Survey responder**
  Answer a set of standard questions in a questionnaire
- ☐ **Reviewer**
  Reviews documents/materials to provide input, critic, suggestions, edits, etc.
- ☐ **Advisory/Governance Board or Roundtable Participant**
  Participate as an invited expert in a small-group gathering to provide input on a set topic or questions.
- ☐ **Provide recruitment support**
  Support recruitment of patients/families for a study or other purpose through newsletters, blogs, social media, etc.
- ☐ **Be shadowed in daily life by a researcher**
  Allow a researcher to follow the patient/family member throughout a typical day to understand daily life with a condition
- ☐ **Communications/awareness campaign collaboration**
  Support communication of information to patients/families on a non-branded, health topic through newsletters, blogs, social media, etc.

Note: Communication of branded information would be considered marketing and not engagement.

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4. Interaction Mode: In this section, indicate the method(s) by which the participant will perform the activity.

Mode of interaction	The method(s) by which the participant will perform the activity. e.g., interview by telephone or in-person; focus group by videoconference or in-person.

(Select all that apply)

- ☐ **In person**
- ☐ **Telephone**
- ☐ **Teleconference/videoconference**
- ☐ **Web meeting**
- ☐ **Electronic (e.g. view video, complete survey**
- ☐ **Paper-based/email**
- ☐ **Other**

5. Time Commitment: In this section, indicate the time commitment that will be required by the participant.

Preparation Time:
Total number of hours expected for preparation

_____

Please describe preparation activities, if any:
(e.g., reading materials, watching a video, completing questionnaires, etc.)

_____

_____

_____

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Activity time expected:

Frequency:

☐ Single event, one time only

☐ More than one event, number of events ___ per day week/week/month/year (circle one)

Activity time expected per event:

Minutes: _____

Hours: _____

Days: _____

Recurring:

Indicate start and stop date: Start ___/___/___ Stop ___/___/___

Expected total number of events/interactions: _____

Expected number of activity hours: _____

Expected total number of hours: _____

(Total Preparation Time plus Activity Time)

If travel is required, expected total travel time (hours): _____

Time entered should equate to travel time determined under Section 6, Travel Considerations.

6. Travel Considerations: In this section, indicate the amount of travel expected and travel requirements.

Note, where the participant might be expected to do some parts electronically and some in-person, indicate both.

☐ **No travel expected**
No travel is required, e.g., telephone, web interaction

☐ **Travel is expected**
Face-to-face activity that requires travel

☐ **Local travel**
Local ground travel by car, bus, subway or train is required. Typically, no more than 2 hours each way would be considered local travel. However, the patient's condition and individual condition must be considered on a case-by case basis to determine if they need additional support for extra travel time. Local travel might also include the travel to get to the airport or train station for long distance travel.

Mileage: _____

Tolls: _____

Parking: _____

☐ **Total estimated travel time:**

Minutes: _____

Hours: _____

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#6 - Travel Considerations, Cont.

☐ **Long-distance travel required**

Ground travel over 2 hours each way required, (e.g., a long drive or train ride) or air travel is expected.

Total estimated travel time:

Minutes: _____

Hours: _____

Train or airplane: _____

Hotel: _____

Incidentals: _____

Special Accommodations

- ☐ A caregiver must accompany
- ☐ Travels with a service animal
- ☐ An additional 1-2 days of travel needed due to condition
- ☐ Special dietary requirements
- ☐ Rest breaks needed
- ☐ Other

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7. Recruitment Ease/Difficulty: Indicate here the level of expected difficulty with recruitment and why

☐ **Not Difficult**
Recruitment is expected to be relatively easy due to high prevalence of the condition or for other reasons

☐ **Difficult**
Recruitment is expected to be difficult due to low prevalence of the condition or for other reasons

Cite reasons:

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8. Other Potential Modifiers: Indicate here other potential modifiers that could have an impact on compensation or reimbursement

- ☐ **Risk or liability**
  The activity places the participant at some level of risk in terms of responsibility (e.g., ad board for DSMB)

- ☐ **Wages Lost**
  Since the individual is being compensated for their time commitment for the activity, it would be unusual to compensate them for wages lost. However, this might be a consideration if it impacts recruitment of representative target population. This should be considered on a case-by-case basis.

- ☐ **Childcare or Eldercare Needed**
  To ensure representativeness of a target population, it may be necessary to offer child and elder care reimbursement. This should be considered on a case-by-case basis.

- ☐ **Size of Organization**
  When engaging patient advocacy senior leadership, the size of the organization may need to be considered if it is not captured in the level of expertise required.

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Workshop Session!

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1. Activities: Did we miss anything? (Patient or Patient Group)

- [ ] **Interview participant**
  Take part in a one-on-one interview. Typically includes a trained interviewer who follows a discussion guide.
- [ ] **Focus group participant**
  Participate in an organized focus group with other participants. Typically includes a trained facilitator who follows a discussion guide.
- [ ] **Provide consultation/co-development expertise**
  Provide expert advice, guidance, consultation on a topic; take part in co-development discussions; could include writing or creating text, visuals, etc.
- [ ] **Presentation/speaker:**
  - Keynote
  - Panel
  - Testimonial
  - Conference/Roundtable/Symposium Speaker
- [ ] **Survey responder**
  Answer a set of standard questions in a questionnaire
- [ ] **Reviewer**
  Reviews documents/materials to provide input, critic, suggestions, edits, etc.
- [ ] **Advisory/Governance Board or Roundtable Participant**
  Participate as an invited expert in a small-group gathering to provide input on a set topic or questions.
- [ ] **Mock Trial Participant**
  Walk through the experience of being part of a clinical trial protocol
- [ ] **Provide recruitment support**
  Support recruitment of patients/families for a study or other purpose through newsletters, blogs, social media, etc.
- [ ] **Be shadowed in daily life by a researcher**
  Allow a researcher to follow the patient/family member throughout a typical day to understand daily life with a condition
- [ ] **Communications/awareness campaign collaboration**
  Support communication of information to patients/families on a non-branded, health topic through newsletters, blogs, social media, etc.

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2. What are the barriers to using/adopting an FMV Calculator?

- Legal
- Regulatory
- Compliance
- Cultural

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Thank you!

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