Subject of Challenge

Unidentified and misidentified prescription pills present challenges for patients and professionals. Unidentified pills can be found by family members, health professionals, educators, and law enforcement. The nine out of 10 U.S. citizens over age 65 who take more than one prescription pill can be prone to misidentifying those pills. Taking such pills can result in adverse drug events that affect health or cause death. To reduce such errors, any person should be able to easily verify—or not—that a refill that has a different color, shape, or text imprinted on the pill is a different generic version of equivalent drugs he or she was already taking.

To help address these problems, the NLM Computational Photography Project for Pill Identification (C3PI) is developing infrastructure and tools for identifying prescription pills. The infrastructure includes photographs of such pills taken under laboratory lighting conditions, from a camera directly above the front and back faces of the pill, and at high resolution. Specialized digital macro-photography techniques were then used to capture JPEG pill images. The NLM RxIMAGE database contains these high-quality images and associated pill data such as appearance (color, shape, size, text imprinted on the pill, etc.), ingredients, and identifiers such as its National Drug Code (NDC) [http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm]. RxIMAGE images and data are freely available. The freely accessible RxIMAGE API provides text-based search and retrieval of images and data from the RxIMAGE database. By contributing their algorithm and software, Challenge participants will take part in a broader NLM effort to develop a freely usable software system and a freely accessible API for image-based search and retrieval from a mobile device.

In a typical scenario for a future NLM mobile app, a person will download the app and use it to photograph a prescription pill, possibly under poor lighting conditions, from an angle, or at low resolution. The future app will communicate with the future pill image recognition software system, which may use all or part of any Challenge entry, to compare that photo to reference images in the RxIMAGE database, and will return one or more images of the most likely match the photographed pill along with their associated pill data.
NLM provides two directories of images to Challenge participants for use in preparing their submissions:

- Directory DR contains 2000 JPEG reference images of 1000 pills. For each pill there are two reference images, one of the front of the pill and one of the back of the pill. These pill images are the same as in the RxIMAGE database.
- Directory DC contains 5000 JPEG consumer-quality images of the same 1000 pills that were photographed for DR. However, they were taken with a variety of digital cameras, under various lighting conditions, and at camera angles not necessarily perpendicular to the faces of the pills. They are akin to photos of prescription pills that the general public might take.

For a pill for which there is at least one consumer-quality image in DC, DR has two reference images of that pill, one of the front of the pill and one of the back of the pill. Conversely, for a pill for which there are two reference images in DR (one of the front of the pill and one of the back of the pill), DC has two or more consumer-quality images of that pill, taken under different conditions.

DR and DC come with a “ground truth table” that is a two-column table with column headers ref images and cons_ images. Each row of the table gives in the first column the name of a reference image and in the second column the name of a consumer-quality image corresponding to that reference image. There is a separate row in the table for each (reference image, consumer-quality image) pair, even when multiple reference and consumer-quality images are all photos of the same pill.

Respondents can use the images in DR and DC, the ground truth table, and the RxIMAGE database in developing, training, and validating their algorithms and software. They can also supplement these data.

Rules for Participating in the Challenge

Teams of one or more members can participate in this Challenge. There is no maximum team size. Each team must have a captain. Individual team members and team captains must register in accordance with the Registration Process for Participants below. The role of the team captain is to serve as the corresponding participant with NLM about the Challenge and to submit the team’s Challenge entry. While NLM will notify all registered Challenge participants by email of any amendments to the Challenge, the team captain is expected to keep the team members informed about matters germane to the Challenge.

(1) To be eligible to win the Challenge prize, a team—
   a. Shall have registered to participate in the Challenge under the rules promulgated by the NIH as published in this Notice;
   b. Shall have complied with all the requirements set forth in this Notice;
   c. In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States. However, non-U.S. citizens and non-permanent residents can participate as a member of a team that otherwise satisfies the eligibility criteria. Non-U.S. citizens and non-permanent residents are not eligible to win a monetary prize (in whole or in part). Their participation as part of a winning team, if applicable, may be recognized when the results are announced.
   d. May not be a Federal entity;
   e. May not be a Federal employee acting within the scope of the employee’s employment and further, in the case of HHS employees, may not work on their submission(s) during assigned duty hours. Note: Federal ethical conduct rules may restrict or prohibit Federal employees from engaging in certain outside activities, so any Federal employee seeking to participate in this Challenge outside the scope of employment should consult his/her agency’s ethics official prior to developing an submission;
   f. May not be an employee of the NIH, a judge of the challenge, or any other party involved with the design, production, execution, or distribution of the Challenge or the immediate family of such a party (i.e., spouse, parent, step-parent, child, or step-child).
   g. All team members must be at least 18 years old at the time of submission.

(2) Federal grantees may not use Federal funds to develop their Challenge submissions unless use of such funds is consistent with the purpose of their grant award and specifically requested to do so due to the Challenge design, and as announced in the Federal Register.

(3) Federal contractors may not use Federal funds from a contract to develop their Challenge submissions or to fund efforts in support of their Challenge submission.

(4) By participating in this Challenge, each individual (whether competing singly or in a group) and entity agrees to assume any and all risks and waive claims against the Federal government and its related entities (as defined in the COMPETES Act), except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

(5) Based on the subject matter of the Challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, property damage, or loss potentially resulting from Challenge participation, no individual (whether competing singly or in a group) or entity participating in the Challenge is required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.

(6) By participating in this Challenge, each individual (whether competing singly or in a group) and entity agrees to indemnify the Federal government against third party claims for damages arising from or related to Challenge activities.

(7) An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during the Challenge if the facilities and employees are made available to all individuals and entities participating in the Challenge on an equitable basis.

(8) By participating in this Challenge, each individual (whether participating singly or in a group) and entity grants to the NIH, in any existing or inchoate copyright or patent rights owned by the individual or entity, an irrevocable, paid-up, royalty-free, nonexclusive worldwide license to use, reproduce, post, link to, share, and display publicly on the Web the submission, except for source code. This license includes without limitation posting or linking to the submission, except for source code, on the NLM Pill Image Recognition Web site [http://pir.nlm.nih.gov/challenge]. In developing its future software system and future API, NLM may include algorithms and software from Challenge entries and may consult with individuals or teams that submitted entries. Thus, the license also permits NLM to develop the future software system and the future API, independently or with others, using any algorithms or software from Challenge entries, including those obtained from other Challenges or solicitations, and NLM may freely use, reproduce, modify and distribute the resulting future software system and API without restriction. NLM may work with individuals or teams that submitted entries to write articles about pill image recognition and submit them to peer-
preferably also its source code to the
source code NLM encourages every
distributes their executable code or
available to the public. If the submitter
of the Challenge to make results widely
consistent with the principal objective
information.
horses, or other potentially harmful
timebombs, cancelbots, worms, trojan
malicious code such as viruses,
confidential, or sensitive information.
include proprietary, classified,
reporting or royalty obligation to any
rights to use and improve. In addition,
is an improved version of an existing
wholly original with the participant or
comprises, that the submission is
copyrightable work that the submission
party. Each individual (whether
participating singly or in a group) and
entity agrees to follow all applicable
federal, state, and local laws,
regulations, and policies.
(10) Each individual (whether
participating singly or in a group) or
entity participating in this Challenge
must comply with all terms and
conditions of these rules, and
participation in this Challenge
constitutes each such participant’s full
and unconditional agreement to abide
by these rules. Winning is contingent
upon fulfilling all requirements herein.
(11) Each individual (whether
participating singly or in a group) and
entity grants to NLM and NLM
contractors assisting NLM with C3PI the
right to review the submission, study
the algorithms and the code, and run the
software on other sets of images.
(13) Submissions must not infringe
upon any copyright, patent, trade
secrets, or any other rights of any third
party. Each individual (whether
participating singly or in a group) or
entity warrants that he/she or the team
is the sole author and owner of any
copyrightable work that the submission
comprises, that the submission is
wholly original with the participant or
is an improved version of an existing
work that the participant has sufficient
rights to use and improve. In addition,
the submission must not trigger any
reporting or royalty obligation to any
third party. A submission must not
include proprietary, classified,
confidential, or sensitive information.
(14) The submission does not contain
malicious code such as viruses,
timebombs, cancelbots, worms, trojan
horses, or other potentially harmful
programs or other material or
information.
(15) Notwithstanding the above and
consistent with the principal objective
of the Challenge to make results widely
available to the public. If the submitter
distributes their executable code or
source code NLM encourages every
individual and team to distribute their
submission’s executable code and
preferably also its source code to the
public under an Apache 2.0 License that
permits the public to benefit from and
improve upon the submission. In this
case and by mutual agreement, NLM
may also post or link to the code from
the Pill Image Recognition Web site. The
entry must include a description of how
and under what license terms it intends
to make any code that is part of the
entry available to the public.
(16) Challenge participants are free to
discuss their submission and the ideas
and technologies that it contains with
other parties, except as stated in #7
above and are free to contract with any
third parties so long as they do not sign
any agreement or undertake any
obligation that conflicts with any
agreement that they have entered into,
such as with any team members, or do
enter into regarding their submission for
the Challenge. For the purpose of
clarity, Challenge participants
acknowledge that the intent of the
Challenge is to encourage people to
collaborate and share ideas and
innovations.
Registration Process for Participants
To participate in this Challenge, team
captains must register their teams,
including providing the names and
email addresses of all team members, at
register. Early registration is encouraged
in order to be able to receive email
notifications if this Federal Register
notice is amended to change the
timeline or the rules of this Challenge.
Submission Requirements
Participants must provide a complete
submission as defined below to be
considered for the prize. The
submission must be saved to a USB
storage device containing a virtual
machine and must be received (not
simply post-marked) by NLM by May
31, 2016, 5 p.m. EDT. Submissions must
be mailed to: Pill Image Recognition
Challenge, Computational Photography
Project for Pill Identification (C3PI),
National Library of Medicine, Building
38A, Room B1–N30, 8600 Rockville
Pike, Bethesda, MD 20894.
The Submission is defined to include:
1. Executable software for ranking
how well consumer images of pills
taken by digital cameras match
reference images. The software shall
be a batch-mode program or a script
whose input consists of a directory
of consumer images and a directory of
reference images. The output shall be
a comma-separated-value (csv) M-by-N
matrix $M_{RC}(I,J)$ that for $I = 1,...,M$
compares consumer image $i$ with
reference images $j = 1,...,N$. For each
consumer image, no rank can appear
more than once. The software does not
need to identify pills by name.
2. Source code for the executable that
is both human- and machine-readable.
The source code can be written in any
programming language(s).
3. A .csv file containing the matrix
$M_{RC}(I,J)$ of ranks that is the
output from executing the
eXecutable using DC and DR as input. In
this case $M_{RC}(I,J)$ is a matrix that has
at least 5000 rows and has 2000 columns.
For each row $I$, $M_{RC}(I,J)$ will rank how
well reference image $j$ matches
consumer-quality image $I$, for $j =
1,...,2000$. If reference image $j$ best
matches consumer-quality image $I$ then
$M_{RC}(I,J) = 1$, and if reference image $K$
is the worst match to consumer-quality
image $I$ then $M_{RC}(I,K) = 2000$.
4. A text file written in English and
containing the algorithm in pseudo-code
that the source code implements, and a
description of how it works and any
tools or packages that it uses. The
pseudo-code is to have the complete
pipeline from the input directories to a
matrix of ranks, and also include any
code that implements features or does
offline training.
5. A one-page text file written in
English that contains the following:
a. Title of entry
b. Names and email addresses of the
team captain and all team members
c. A five or more character identifier for
the entry that is used as a prefix in the
names of all of the team’s submitted
files
d. A brief description of the submission
Amount of the Prize; Award Approving
Official
Up to five monetary prizes may be
awarded: $25,000 for 1st Place, $15,000
for 2nd Place, $5,000 for 3rd Place, and
two $2,500 prizes for Honorable
Mention for a total prize award pool of
up to $50,000. The names of the winners
and the titles of their entries
will be posted on NLM Web sites. The
Award Approving Official is the
Director of the National Library of
Medicine.
Payment of the Prize
Prizes awarded under this Challenge
will be paid by electronic funds transfer
and may be subject to Federal income
taxes. HHS/NIH will comply with IRS
withholding and reporting
requirements, where applicable.
Basis Upon Which Winners Will Be
Selected
NLM will first review submissions to
determine their suitability for judging
and eligibility to win the prize. An
eligible submission (a) complies with the rules in this Federal Register notice, (b) follows the detailed submission instructions at http://pir.nlm.nih.gov/challenge/, (c) is complete (e.g., meets the Submission Requirements above), and (d) is confirmed by NLM that the executable is an implementation of the submitted source code, can be run on the submitted virtual machine using directories DC and DR as input, and the output matrix is the same as the submission’s matrix MRC.

Eligible submissions will proceed to the judging process, and will be evaluated based on how well the submissions can match pill images across a large number of queries. NLM has developed evaluation software and created directories of images to use in selecting the Challenge winners. For example, directories DRJ and DCJ (J for Judging) contain reference and consumer-quality images similar to those in directories DR and DC provided to potential Challenge participants, and the ground truth matrix for judging MGTJ has MGTJ[i,j]=1 if DCJ[i] and DRJ[j] are photos of the same pill, else MGTJ[i,j]=0. The evaluation software calculates the mean average precision (MAP) for directories and ground truth matrix such as DRJ, DRC, and MGTJ. Mean average precision is a widely used information retrieval metric for evaluating software process and being used in the Challenge, including its instructions. NLM appreciates the work done by the parties that responded to the RFI.

Dated: January 11, 2016.

Betsy L. Humphreys, Acting Director, National Library of Medicine, National Institutes of Health.

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel; Palliative and End-of-Life Care Research.

Dated: January 11, 2016.

Sylvia Neal, Program Analyst, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meetings

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Name of Committee: National Institute of Nursing Research Special Emphasis Panel; MHealth Tools for Underserved Populations.

Dated: February 9, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Weiqun Li, MD, Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd., Ste. 710, Bethesda, MD 20892. (301) 594–5066, wli@mail.nih.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; DDK–D Member Conflict SEP.