FUTURE TRENDS IN MEDICAL DEVICE TECHNOLOGIES:
A Ten-Year Forecast

Wm. A. Herman [1] and Gilbert B. Devey [2]

This forecast is dedicated to the memory of the late Gilbert B. Devey, of the National Science Foundation – a friend and colleague of all of the participants in this study.

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[1] At the time of this study, Wm. A. Herman was Deputy Director of the Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, FDA

[2] At the time of this study, Gilbert B. Devey was a senior Program Director with the National Science foundation's Directorate of Engineering

ABSTRACT

From 2007 through 2008, the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) analyzed emerging medical device technologies to identify major trends projected over the next ten years. This anticipatory study was undertaken to support CDRH's scientific preparation for upcoming generations of products.

The project included a survey of both (A) CDRH technical managers and (B) a group of fifteen non-FDA experts. This report details the results of that expert survey. Non-FDA participants included physicians, engineers, healthcare policymakers, manufacturers, futurists and technology analysts.

Six major technology themes were identified and elaborated as highly likely to prefigure medical device innovation over the next decade: (1) electronics technology; (2) detection, diagnosis, and monitoring technologies; (3) decentralized care technologies; (4) minimally invasive technologies; (5) synthetic organs, tissues, and combination device/biological and device/drug technologies; and (6) demographically oriented technologies. The predictions made within this thematic framework ultimately encompassed twenty-four technology areas; and, within those twenty-four, ninety-one even more specific product groups. Among these predicted technology areas and products, high-likelihood developments were identified.

KEYWORDS

Devices, technology, medical, trends, forecast

1. INTRODUCTION

The U.S. Food and Drug Administration (FDA) is, by statute, responsible for regulating the safety and effectiveness of new medical devices in the United States. Within FDA, the Center for Devices and Radiological Health (CDRH) has primary regulatory responsibility for medical devices. To meet these responsibilities, FDA performs scientific assessments of many pioneering devices and leading-edge technologies. Many of these advanced technologies hold significant potential for benefit to the U.S. public health.

The medical device universe encompasses a particularly imposing spectrum of constant technological innovation, including hundreds of different technologies and thousands of types of products. In such an environment, one essential CDRH priority is the strategic preparation for informed decision-making for pioneering products. That, in turn, entails the ability to anticipate the types of device technologies that will emerge to pose new questions and challenges. This report describes the results of CDRH's most recent technology forecasting initiative to enable that anticipatory approach. No confidential information from regulated manufacturers has been employed in the preparation of the forecast.

To achieve a comprehensive view of developments affecting the medical device landscape, we have cast a broad technological net. Hence, there is no implication that every technology or product examined in this forecast will necessarily be subject to regulation by CDRH or FDA.

Finally, it is important to note that, for methodological and other reasons, the analysis below does not attempt a confident identification of areas in which significant developments are highly unlikely to occur over the next decade (a broad set and a monumental task, indeed). Thus, the absence of any particular device or technology from this forecast does not imply any confident conclusion about its unlikelihood.

2. METHODOLOGY

The project started in the Spring of 2007, and included an initial survey of both (A) CDRH technical managers and (B) a group of fifteen non-FDA experts to identify a broad set of possible medical device trends, technologies and products that might have the potential for significant development over the next decade. Non-FDA participants included physicians, engineers, healthcare policymakers, manufacturers, futurists and technology analysts.

STRATEGY

In this analysis, we have attempted to identify a constellation of medical devices and medical-device-related technologies that are likely to generate significant innovation over a ten-year period. In general, we aim to identify technical areas in which future innovation can be projected with reasonable confidence, forgoing the costs and benefits of positing a more conjectural list of speculative possibilities. We have, nevertheless, sought to avoid dogmatic preconceptions at every turn, covering and re-covering the territory of interest; using whatever tools were necessary to foster participants' creative output, then persistently re-examining the results to cull the most promising insights.

To that end we have employed a multi-pronged methodology to evoke, illuminate and combine the personal and institutional insights of an exceptional group of fifteen distinguished expert participants, supported and assisted by the senior technical managers of CDRH. The collective career experience of this group encompasses essentially all major aspects of medical device innovation.

Aside from voluminous (and current) career experience, expert participants brought two key characteristics. First, in general, participants were individually accomplished scientists with in-depth expertise related to specific medical-device innovations. Participants have, for example, been recognized by membership in the Institute of Medicine, the National Academy of Engineering, the Royal Society of London, etc. Second, each participant has an extremely broad familiarity with the leading technological frontiers of the medical device universe. Most had extensive experience as broad-based program directors, senior scientists and clinicians of major organizations, biomedical foundation directors, academic department directors, and the like.

Strategically, then, we focused on two principles that reflect the participants' unusual strengths. First, to optimum predictive reliability we have grounded our analysis in specific fine-grained judgments by each expert participant on exactly those topics in which he/she has most confident knowledge. Each participant provided a list of independently-identified product-specific predictions; a critical numerical rating of those specific product groups; and a set of detailed individual projections in areas of his/her own choosing during an individual interview. Second, to optimize insight into the broader trends represented by the product-specific predictions, we grouped the individual predictions into Technology Area categories. Those conceptual groupings represent the consensus perspectives of our broadly-experienced participants both before and after they knew the collective rating results described below.

The final mechanics of our process cover three interlocking phases. The first phase of our process entailed the iterative solicitation and refinement of working Trend Themes and Technology Areas. The Trend Themes served to guide the ensuing discussion, and to promote the search for predictions. The Technology Areas served as a provisional categorization scheme for the specific-product predictions to be identified by participants; these technology categories were re-reviewed throughout the process and modified as necessary, as specific predictions emerged. Participants developed and provided numerical ratings reflecting their individual expectations about likely 10-year medical device innovations. These scores were aggregated for individual product groups, Technology Areas, and Trend Themes. The combined results were fed back to participants in a modified Delphi scheme, iteratively allowing each participant opportunities to modify his/her original ratings.

In the second phase, every expert participant was interviewed individually to elaborate on his/her ratings, and to supplement those ratings with additional projections and expectations. As with the numerical ratings, group summaries were provided to participants but anonymity was maintained for all individual inputs.

Finally, all of the experts participated in a one day workshop during which highly interactive discussions took place, and final modifications and additions were solicited to complement and modify the inputs from the questionnaires and interviews.

PARTICIPANTS

The non-FDA expert participants appear in Table 1. The panel included representatives from the medical device research, futurist, engineering, manufacturing, clinical, and healthcare policy communities.   General principles for participant selection included long-standing and extensive involvement with a very broad spectrum of device-related technologies; in-depth familiarity with the frontiers of those technologies; and established professional recognition in the scientific, engineering, and/or clinical communities involved in medical device innovation. Participants came from the research, clinical, engineering, industry, payer, public interest, government, technology forecasting, and academic sectors.

CATEGORIES

TREND THEMES: A consensus set of "Trend Themes" was generated iteratively by the participants, in conjunction with senior CDRH scientific managers.[3] The final set (Table 2) is drawn from a heterogeneous collection of conceptual schemes: some Trend Themes are broad technology areas, some are patient groups, some are clinical product types, etc. This reflects two considerations: (1) it embodies an expedient decision to forgo preliminary conceptual neatness in favor of retaining the themes that participants believed would point to the most fertile ground for prediction; (2) it is a reminder that the six themes comprised a tool – not a prediction. (Even as a tool, the set of Trend Themes could have been counter-validated by the participants' actual subsequent predictions; but, as the participants had anticipated, they were not.) Subsequent verification of the Trend Themes' effective validity is illustrated in Table 3, and in Figure 1.

TECHNOLOGY AREAS: Our substantive predictions appear at the levels of the Specific Product Groups, and the Technology Areas that encompass those specific products. An initial set of 22 provisional Technology Areas was developed by the expert participants and senior CDRH scientific managers in the same iterative consensus manner as the initial Trend Themes. These categories were modified somewhat and expanded to 24 during the study to match the product-specific predictions that were developed by the individual participants. The final set of 24 appears in Table 2. We have characterized the overall likelihood of significant innovation (and other descriptors) of each Technology Area based on the combined characteristics of the specific product groups that constitute that area. Those characteristics are reflected in the specific product innovations projected for the particular Technology Area; and by the expert participants, the numerical rating process, and the interview comments that address those specific product innovations.

SPECIFIC PRODUCT GROUPS: Each Specific Product Group corresponds to a particular product type predicted by two or more of the participants. These groups consolidate specific predictions from different participants that are identical, or very similar. It is the individual participants' ratings of these entities that constitute the bedrock of the numerical ratings described below.

NUMERICAL RATINGS

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[3] No confidential or proprietary information was used at any point in our process; this was doubly assured by checking all topical inputs to verify their ready availability in the public domain.

The numerical rating process was designed to allow each individual participant to identify and make predictions regarding just those specific product groups for which he/she had confident input – without obligation to exceed individual bounds of confidence. This was intended to generate the most reliable results possible for particular devices.

The process also locates these specific examples within the two-tiered framework of (telescoping) technology categories, described above. Table 2 shows the relationships between the Trend Themes, and the Technology Areas subsumed by each. Within this framework, after duplications among inputs from the group were consolidated, 91 distinct product groups were ultimately identified and rated by two or more participants.

Within the framework's categories, each individual participant – working separately -- predicted what he/she viewed as the "most significant examples" of likely innovative products over the next ten years. Each individual also provided numerical ratings for his/her specific examples (Appendix B).

In particular, participants were asked to assign numerical scores to each of seven parameters:

- *Likelihood of being successfully introduced within 5 years*
- *Likelihood of being successfully introduced in 5-10 years*
- *Likelihood of ever being successfully introduced (i.e., >10 years)*
- *Expected size of the affected patient population*
- *Expected magnitude of benefits associated with introduction of the example*
- *Expected magnitude of risks associated with introduction of the example*
- *Overall importance of the introduction of the example for future health care*

Finally, composite ratings were generated by aggregating all participants' scores for each Technology Area and each Trend Theme.

The ultimate validity of these numerical rating methods in capturing the views of the participants was confirmed through solicitation of individual and group comments on the results during individual interviews and in the interactive workshop. This feedback was substantially confirmatory (see Figures 1 and 2a through 2f); all skeptical comments have been explicitly reflected in our final predictions (see below).

Table 1. Non-FDA Technology Forecast Participants

Participant	Affiliation
Susan Alpert, M.D., Ph.D.	Advamed
Elise Berliner, Ph.D.	Agency for Healthcare Research and Quality
Clement Bezold, Ph.D.	Institute for Alternative Futures
Joseph F. Coates	Joseph Coates Consulting Futurist, Inc.
Molly J. Coye, M.D.	Health Technology Center
Kenneth Curley, M.D.	U.S. Army Medical Research and Materiel Command
Gilbert B. Devey	National Science Foundation
Warren Grundfest, M.D.	UCLA
William Heetderks, M.D., Ph.D.	National Institutes of Health
Peter Katona, Ph.D.	Whitaker Foundation, George Mason University
Jack Lasersohn	National Venture Capital Association
John Linehan, Ph.D.	Stanford University
John Parrish, M.D.	CIMIT, Harvard University
Diane Robertson	ECRI
Peter Wells, F.R.S.	Cardiff University, UK

INTERVIEWS

After the initial numerical results were analyzed and distributed to participants, each expert participant was individually interviewed. The interviews employed an open format, to complement the highly structured nature of the numerical rating process. The participant was asked to identify and discuss whatever he/she understood to be the most important anticipated medical-device technology developments over the next ten years. Two senior CDRH technical managers participated in each interview, and kept a record of every product and technology spontaneously mentioned by the interviewee. No prompts of any kind were provided to the interviewee. Audio recordings were used to supplement the note-takers records. A composite digest was developed indicating the predictions (either optimistic or skeptical) offered by all participants for each technology and product group.

The notes and recordings for each interview were subsequently evaluated to identify confirmatory (or nonconfirmatory) citations of specific Trend Themes, Technology Areas, and individual Product Groups associated with the questionnaire data. More specifically, results of each interview were analyzed for (positive or negative) citations of particular examples from these various categories.

During the interviews, each participant was offered a Delphi-process opportunity to make changes in his/her initial numerical ratings. Only one participant made any modifications; these modifications were quantitatively minor, and did not result in any changes for the conclusions described below.

WORKSHOP

A workshop was convened on February 20, 2007 to enable participants to discuss, clarify and, if necessary, modify the provisional results of the questionnaires and interviews. All fifteen survey participants were present. Several senior CDRH scientific and regulatory managers participated as discussion facilitators in this workshop, as well.

In a highly interactive format, forecast participants reviewed and elaborated on the data from the numerical ratings. The combined (and anonymized) group results from the interviews were also provided to all participants at this final workshop phase of the process. Workshop participants provided final comments and clarifications regarding the interview results. Workshop discussions included both small group sessions and plenary gatherings.   The smaller working groups focused specifically (and separately) on the emerging views of each of the Trend Theme topics. FDA note-takers recorded participant comments for subsequent analysis.

Table 2. Trend Themes and Technology Areas

TREND THEMES	TECHNOLOGY AREAS
ELECTRONIC TECHNOLOGIES	Computerized devices, IT systems Robotic devices Wireless systems

SYNTHETIC ORGANS/TISSUES
  and COMBINATION PRODUCTS
	Artificial organ, organ assistive devices
	Combination products;
	  Device + biological/pharmaceutical
	Materials-based devices
	Biocompatibility technologies
	
	Infection-inhibiting devices

INVASIVENESS REDUCING
  TECHNOLOGIES
	Photonic devices
	Acoustic devices
	Molecular therapies
	Minimally invasive Tx technologies
	  non-photonic, non-acoustic, non-"omic"
	Miniaturized devices
	Imaging Devices/Systems

DECENTRALIZED-CARE TECHNOLOGIES	Home/self care devices Portable/mobile devices Telemedicine systems
DEMOGRAPHIC TECHNOLOGIES	Aging-related devices Enhancement/augmentation products

DETECTION, DIAGNOSTIC,
  and MONITORING TECHNOLOGIES
	Genomics, proteomics, metabolomics,
	  epigenomics
	Early detection and diagnosis
	  (non-"omic" technologies)
	Personalized medicine,
	  "Customizable" devices
	Sensor technologies
	Patient monitoring systems

3. RESULTS

Within each Technology Area, confirmatory participant-to-participant similarities were evident among the specific examples of predicted product innovation. Indeed, the results showed that 76% of the participants' 501 examples fell into one of 91 Product Groups. (See Appendix C)

NUMERICAL RATING RESULTS

93% of the participants completed the questionnaire. Individual participants identified a total of 501 specific examples of what they believed to be the "most significant" future products in the various Technology Areas. The resulting 501 examples represent an average of 1.49 from each participating expert for each of the 24 Technology Areas. (The questionnaire instructions had suggested two examples for each Technology Area.)

217 (43%) of the 501 product examples scored in the questionnaires actually exemplified more than one Technology Area – e.g., "transcranial ultrasound for brain lesion ablation (HIFU) with MR control", and "thin film nitinol for stents, vascular grafts; allowing percutaneously deliverable heart valves". (The average participant example appears in 2.0 Technology Areas.) In such cases, the ratings provided for the example have been applied to each of the Technology Area categories to which the example applies.

INTERVIEW RESULTS

During the 15+ hours of individual interviews, participants related their (optimistic or skeptical) expectations for 306 specific products and technologies that fell within the domain of the 24 Technology Areas and the 91 Product Groups within them. This represents an average of 20.4 such projections in each (nominally) 1-hour interview. Hence, in the interviews, each participant gave about one such projection (0.85) for each of the 24 Technology Areas. 86% of these citations expressed optimism about the products that were being addressed. 14% expressed doubt or skepticism. It is noteworthy that, at this stage, participants were no longer simply assessing the likelihood of their own inputs; their 86% rate of expressed concurrences refers to the entire group's inputs. Results of the interviews are summarized in Figures 1 and 2a through 2f, and are cited in the sections below.

WORKSHOP RESULTS

Working groups focused separately and intensively on topics within each of the six Trend Themes. For the product and technology categories within each Trend Theme, the working groups expressed general concurrence with the overall results of the questionnaires. The working groups provided more specific feedback on the questionnaire scores for 2 of the 24 Technology Areas, and for 21 of the Product Groups. In fourteen (61%) of these comments the groups explicitly concurred with the questionnaire findings. In six (26%) the working group raised the possibility that the questionnaire results might be too optimistic. In three (13%) the possibility was noted

that the questionnaire might be too pessimistic. Further details regarding this feedback are discussed below.

In plenary sessions, the workshop participants provided additional input related to factors driving the development of new types of medical devices, and issues associated with particular technologies and product areas. These, too, are discussed further below.

SIX TREND THEMES: AN OVERVIEW

Table 3 presents the average ratings describing all participants' examples of the 6 major Trend Themes. (See Appendix B for rating definitions.) As seen in Table 3, participants indicated a very high likelihood (> 4.0) of significant new product development for every one of the Trend Themes.

In general, this optimistic assessment was confirmed in the interviews (Fig. 1). Five of the six Trend Themes were spontaneously noted by at least 87% of the interviewees -- either directly or by reference to technologies and products contained within them.   77% or more of the interview comments regarding each of the six Trend themes confirmed that each of those themes is likely to generate significant new medical device products in the next decade. The comments (optimistic and skeptical) of 67% or more of the interviewees indicated a net positive outlook for each Trend Theme (i.e., more optimistic comments than skeptical comments). Hence, our analysis' ultimate results confirm the utility of the original heterogeneous set of Trend Themes as a tool for facilitating the identification of future products and technologies – a conclusion borne out by Table 8 which shows that all of the Trend Themes generated high-likelihood product and/or technology area developments among our final predictions.

Fewer examples and participant interview citations were associated with "Demographic Technologies" than with other Trend Themes – though even here, significant developments were seen as highly likely within 10 years. Comments from expert participants suggested that relatively few of the predictable innovations are limited in their applicability to any special demographic group.

Overall, then, the interview data confirm the high likelihood ratings given to each of the six Trend Themes, and discussions in the plenary and working group "breakout" sessions at the Workshop also provided general concurrence for the Trend Themes.

("General workshop concurrence" for an individual Technology Area or Product Group was inferred from fulfillment of at least two conditions: (1) the individual Technology or Product was part of a menu of topics for which the relevant Working Group expressed concurrence as a whole in its report to the plenary Workshop; and (2) no Working Group report specifically expressed reservations about the 10 year prospects for the individual Technology Area or Product Group.)

TABLE 3 – Major Trend Themes (by 10 year likelihood)
SCORED BY 100% OF PARTICIPANTS ON QUESTIONNAIRES [4]

MAJOR TREND THEMES Questionnaires: Scored by 100 %	Likelihood < 10 yrs	Likelihood > 10 yrs	Affected pt population	Benefit	Risk	Importance	Examples cited by participants	Panelists citing in questionnaire	Panelists Citing in interviews	Confirmatory interviews (+ expectations)	Citations in interviews
INVASIVENESS REDUCING TECHNOLOGIES	4.41	4.75	3.61	4.24	2.33	3.92	156	100%	100%	67%	70
ELECTRONIC TECHNOLOGIES	4.23	4.81	3.73	4.16	2.44	3.93	137	100%	100%	93%	58
DECENTRALIZED-CARE TECHNOLOGIES	4.21	4.81	3.87	4.18	2.13	4.17	85	100%	93%	86%	42
DETECTION, DIAGNOSTIC, and MONITORING TECHNOLOGIES	4.21	4.72	3.95	4.13	2.19	4.13	144	100%	87%	85%	31
SYNTHETIC ORGANS/TISSUES and COMBINATION PRODUCTS	4.16	4.72	3.30	4.32	2.58	3.83	162	100%	100%	93%	96
DEMOGRAPHIC TECHNOLOGIES	4.00	4.58	3.71	4.00	2.29	3.75	49	86%	47%	100%	9

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[4] % of 14 participants who completed the questionnaire scoring form. One participant did not complete the questionnaire.

FIGURE 1: TREND THEMES (incl. ALL TECHNOLOGY AREAS)

FIGURE 1:   Technology Forecast: Interview Results
Technology Areas

Dx & MONITORING TECH
DEMOGRAPHIC TECH
DECENTRALIZED-CARE TECH
INVASIVENESS RED TECH
ORGANS/TISSUES & COMB PROD
ELECTRONIC TECH

□ Optimistic interview comments
□ Skeptical interview comments

-100%   -80%   -60%   -40%   -20%   0%   20%   40%   60%   80%   100%

% total forecast participants
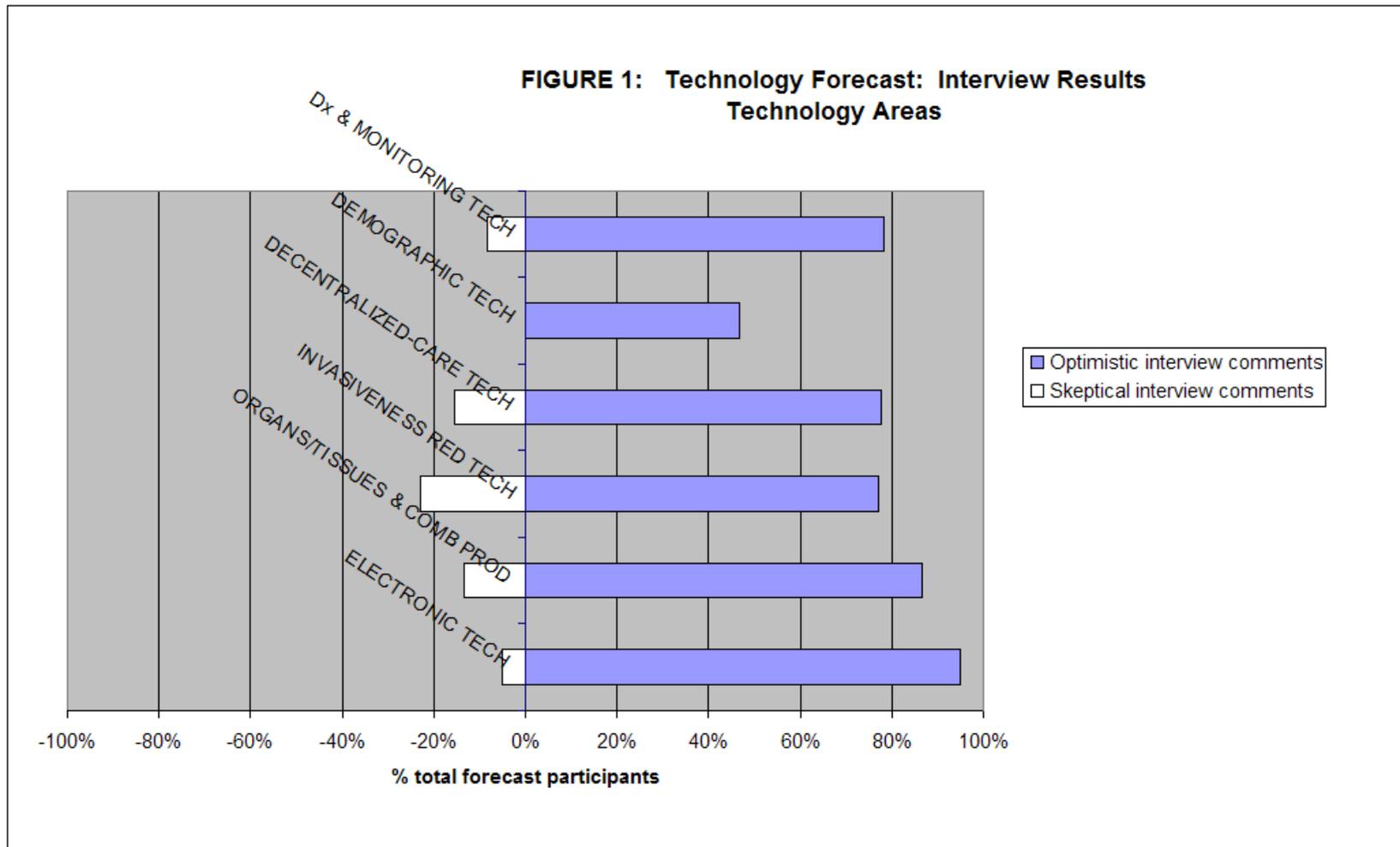
TWENTY-FOUR TECHNOLOGY AREAS: AN OVERVIEW

The average scores assigned to each of the 24 Technology Areas appear in Table 4.

Averaged numerical ratings for the Technology Areas mirror the Trend Themes that contain them: almost all of the 24 Technology Areas in Table 4 are rated as very likely ($\geq$ 4.0) to generate significant developments within the 10-year time horizon of the present analysis. Interview results are illustrated in Figure 2.

However, at this more granulated level of technology characterization participants' projections and confirmations of 10-year successes in the Technology Areas are noticeably less unanimous than for the larger Trend Themes. Unlike Table 3, Table 4 reveals significant variation in the number of participants who explicitly identified the various Technology Areas in the numerical ratings (50% to 100% of participants), and who opted to raise them in the interviews (7% to 100%). In the interviews, explicit confirmations of particular Technology Areas also varied widely (0% to 100%) from one Technology Area to the next, when these areas were mentioned by the interviewee.

In short, at this more detailed level of technology differentiation, participants' assessments show useful distinctions in unanimity concerning which Technology Areas were expected to produce significant developments areas in the next decade. Indeed, Table 4 undergoes a substantial transformation when we focus on the subset of Technology Areas for which a majority view is discernibly positive.

Table 5 lists the Technology Areas (from Table 4) for which (1) more than half of participants provided numerical ratings, giving an average rating that was very high (> 4.0) for the 10 year likelihood of significant developments in the area; and (2) more than a third of participants provided spontaneous comments in the interviews, giving a high rate of confirmation   (> 80% of the interviews) of net positive expectations in the area over the next 10 years.

Although these seem to represent reasonable break-points in the data, there is some inevitable arbitrariness in the choice of such criteria. For the purposes of this analysis, the resulting selection of approximately the top half of the technology areas (based on their relative characterization by the expert participants) seems appropriate – neither so lax as to encompass every area mentioned by the participants, nor so restrictive as to produce a set too small to have practical utility. (Moreover, the data provided here also allow the interested reader to explore the effect of alternative criteria for other applications than ours.)
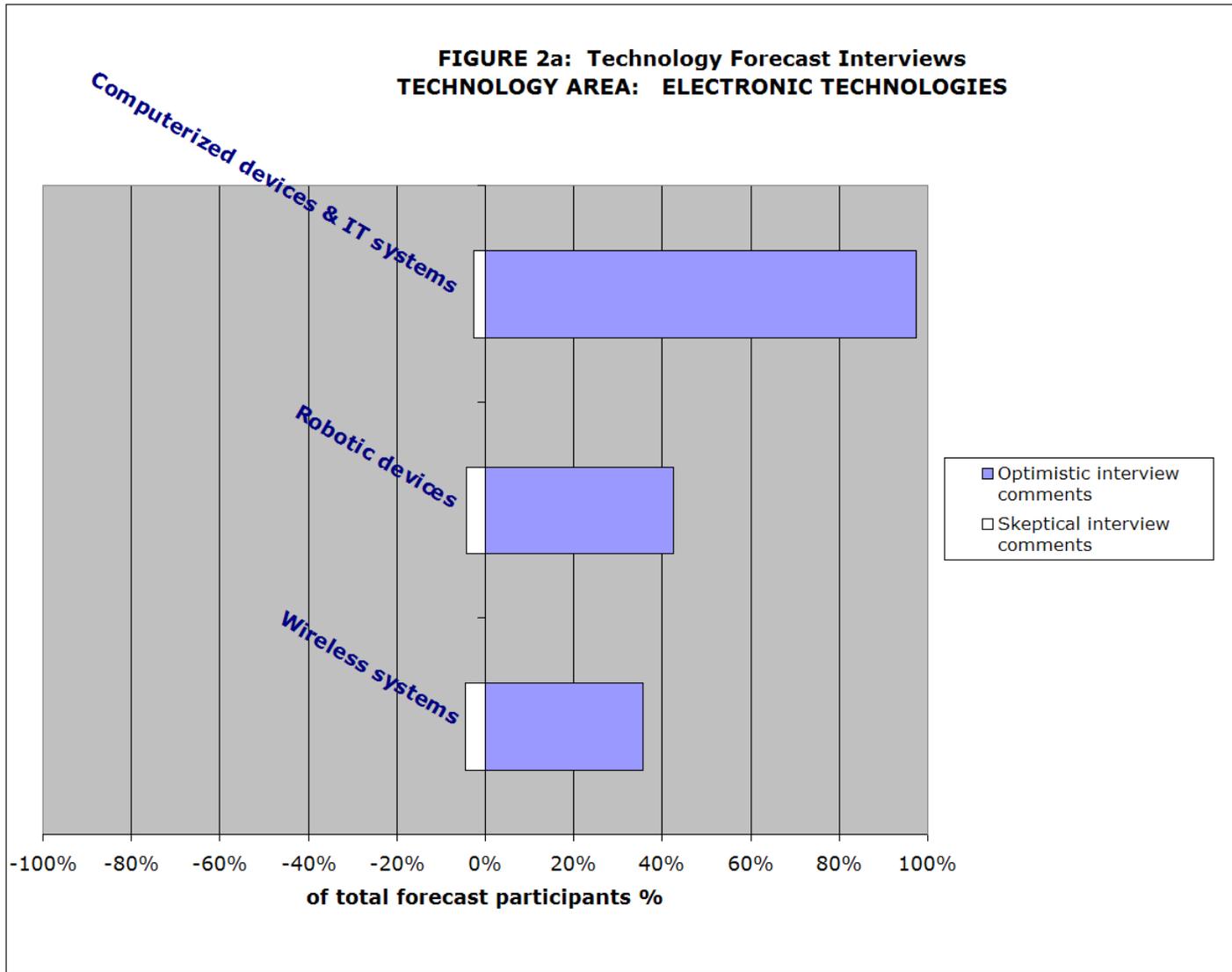
Finally, discussions at the Workshop provided general concurrence for the Technology Areas in Table 5.
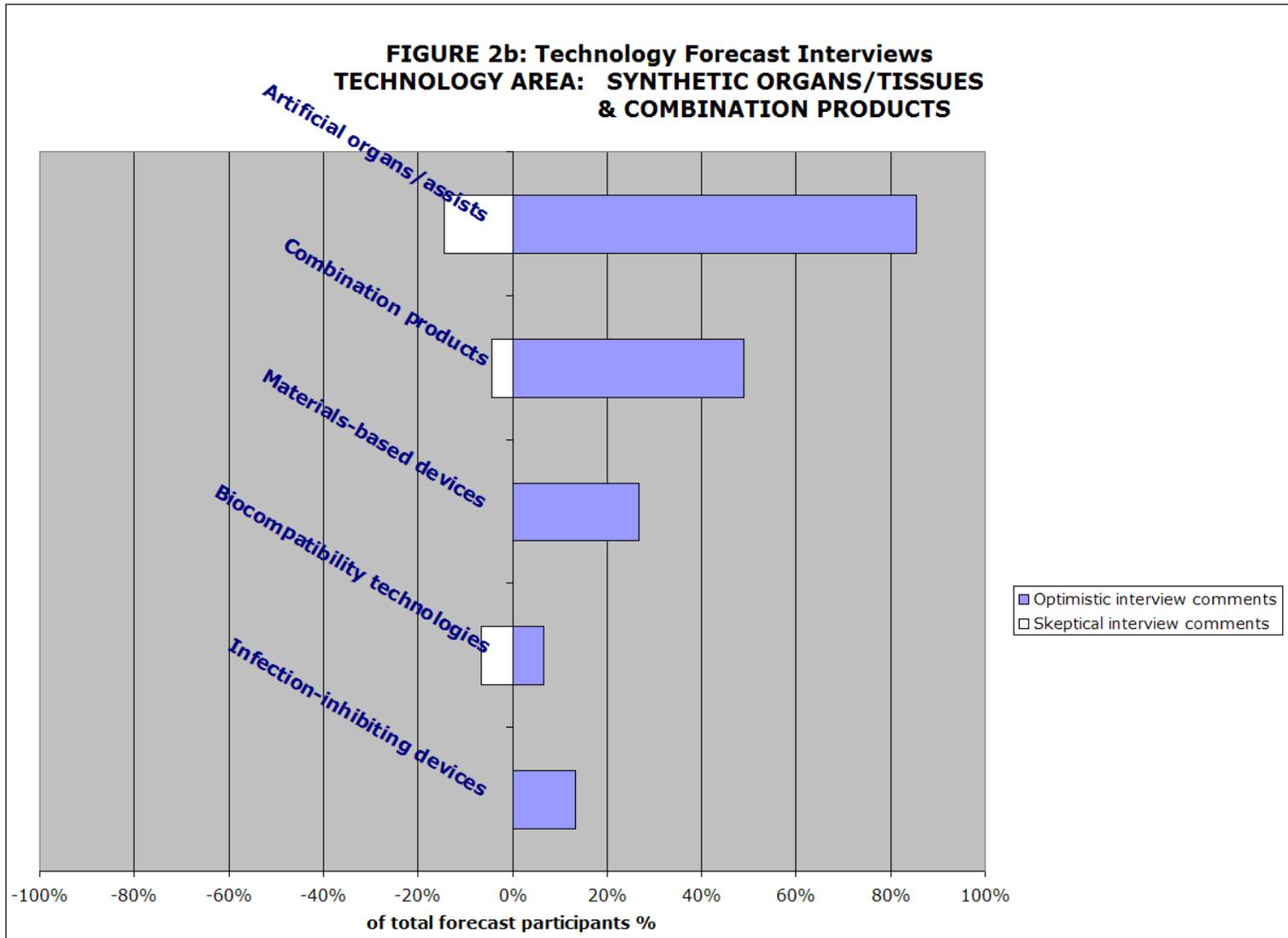
TABLE 4 – 24 Technology Areas (by 10 year likelihood)
SCORED BY > 50% OF EXPERT PARTICIPANTS [5]

Table 4 TECHNOLOGY AREAS All Areas Scored by > 50 %	Likelihood < 10 yrs	Likelihood > 10 yrs	Affected pt population	Benefit	Risk	Importance	Examples cited by participants	Panelists citing in questionnaire	Panelists Citing in interviews	Confirmatory interviews (+ expectations)	Citations in interviews
Acoustic devices	4.71	5.00	3.52	4.38	1.76	3.86	21	57%	13%	100%	3
Telemedicine systems	4.56	4.88	3.68	4.08	1.96	4.16	25	71%	47%	57%	10
Imaging Devices/Systems	4.50	4.84	3.88	4.21	2.06	4.10	68	93%	67%	100%	21
Photonic devices	4.50	4.80	3.67	4.33	2.07	4.00	31	86%	40%	100%	10
Wireless systems	4.35	4.87	3.58	4.00	2.13	3.71	24	79%	40%	83%	9
Minimally invasive Tx technologies non-photonic/acoustic/omic	4.32	4.76	3.24	4.20	2.96	3.72	24	93%	53%	100%	10
Combination products device + biological/pharmaceutical	4.32	4.74	3.34	4.28	2.68	3.80	47	79%	53%	88%	12
Molecular therapies	4.30	4.60	3.50	4.40	2.70	4.00	10	50%	47%	0%	8
Computerized devices, IT systems	4.29	4.81	4.05	4.17	2.43	4.19	80	100%	100%	100%	38
Materials-based devices	4.28	4.67	3.67	4.47	2.47	3.67	19	71%	27%	100%	4
Home/self care devices	4.26	4.79	3.85	4.13	2.17	4.17	45	100%	80%	83%	23
Genomics, proteomics, metabolomics, epigenomics	4.21	4.63	4.17	4.08	2.25	4.22	24	79%	33%	100%	6

[5] % of 14 participants who completed the questionnaire scoring form. One participant did not complete the questionnaire.

Table 4 TECHNOLOGY AREAS All Areas Scored by > 50 %	Likelihood < 10 yrs	Likelihood > 10 yrs	Affected pt population	Benefit	Risk	Importance	Examples cited by participants	Panelists citing in questionnaire	Panelists Citing in interviews	Confirmatory interviews (+ expectations)	Citations in interviews
Biocompatibility technologies	4.19	4.69	3.06	4.00	2.50	3.75	16	57%	13%	50%	2
Patient monitoring systems	4.18	4.76	3.75	4.05	2.22	4.02	56	100%	73%	91%	10
Aging-related devices	4.17	4.69	3.66	3.91	2.03	3.69	35	86%	40%	100%	6
Infection-inhibiting devices	4.17	4.50	3.58	4.50	2.25	3.50	12	50%	13%	100%	2
Artificial organ, organ assistive devices	4.09	4.76	3.26	4.36	2.74	3.89	91	100%	100%	87%	76
Sensor technologies	4.08	4.68	3.80	4.16	1.76	4.20	26	86%	53%	88%	7
Robotic devices	4.04	4.78	3.19	4.22	2.67	3.52	27	93%	47%	86%	11
Personalized medicine, "Customizable" devices	4.00	4.68	4.06	4.50	2.11	4.47	19	79%	40%	50%	7
Early detection and diagnosis (non-"omic" technologies)	4.00	4.53	4.18	4.12	2.18	4.06	18	71%	7%	100%	1
Miniaturized devices	3.97	4.41	3.52	4.21	2.62	3.68	35	93%	93%	57%	18
Portable/mobile devices	3.94	4.77	3.89	4.23	2.23	4.09	36	93%	60%	100%	9
Enhancement/augmentation products	3.69	4.44	3.63	3.88	2.88	3.63	17	64%	20%	100%	3

FIGURE 2a: Technology Forecast Interviews
TECHNOLOGY AREA: ELECTRONIC TECHNOLOGIES

FIGURE 2b: Technology Forecast Interviews
TECHNOLOGY AREA: SYNTHETIC ORGANS/TISSUES
& COMBINATION PRODUCTS

FIGURE 2c: Technology Forecast Interviews
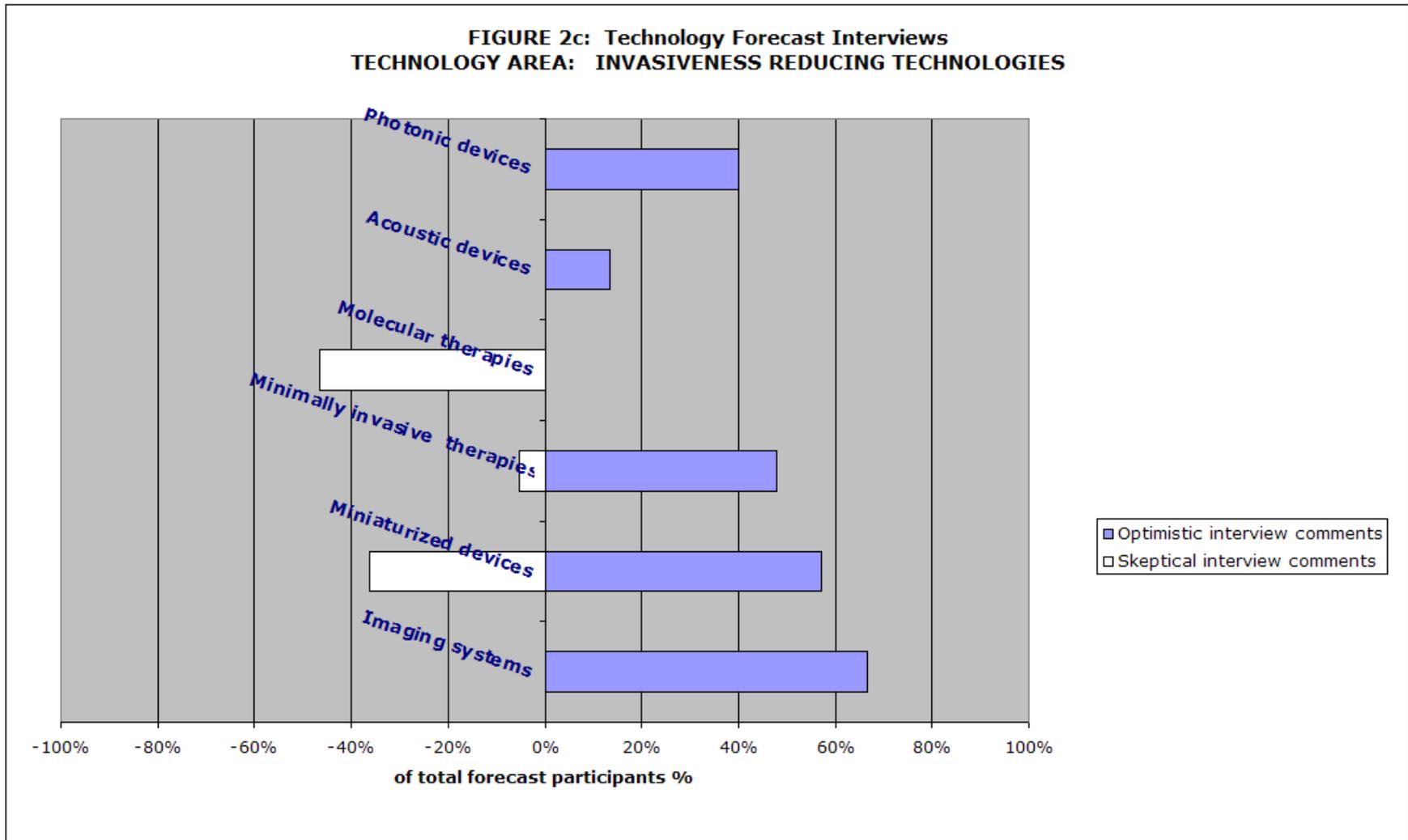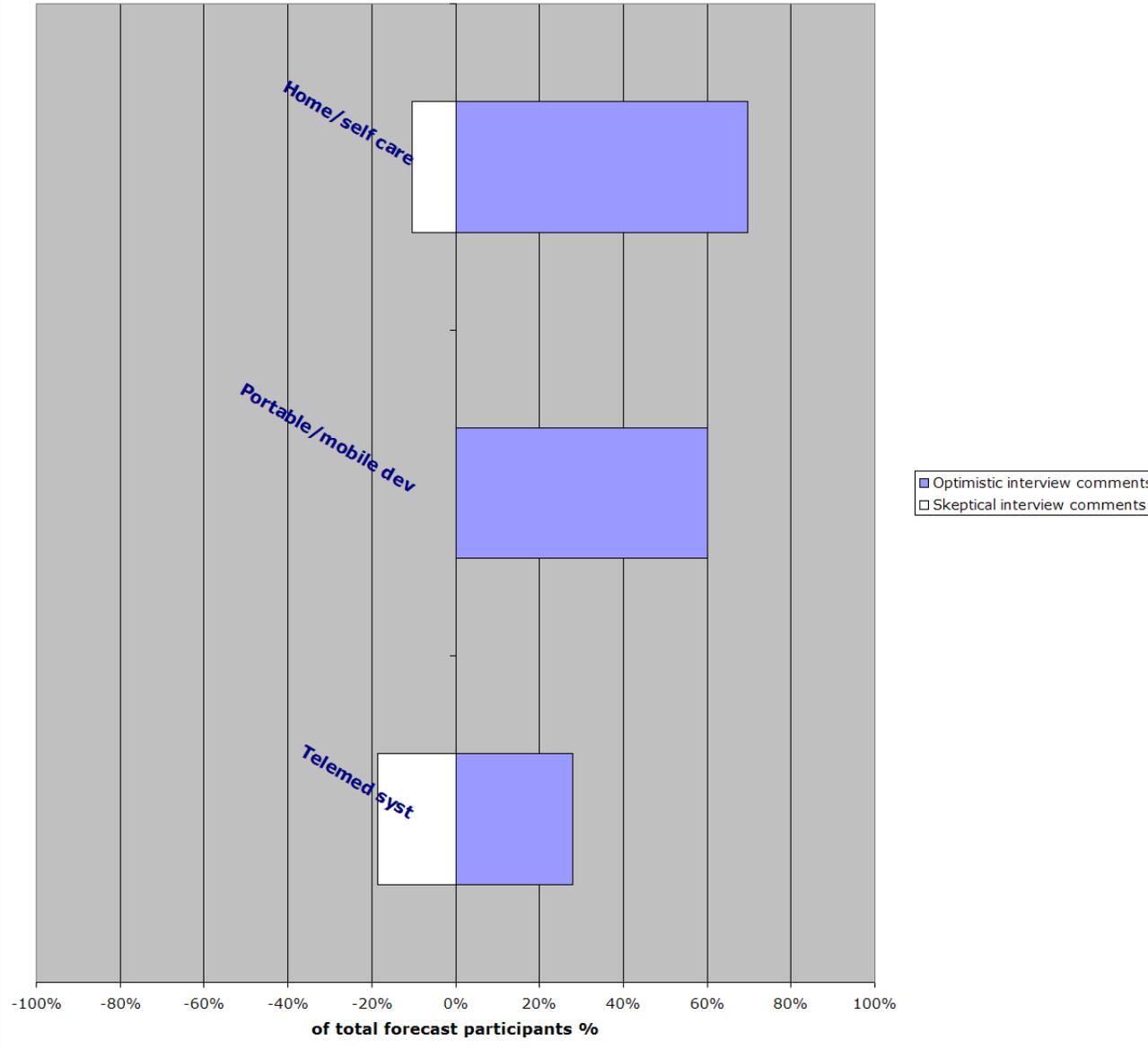TECHNOLOGY AREA: INVASIVENESS REDUCING TECHNOLOGIES
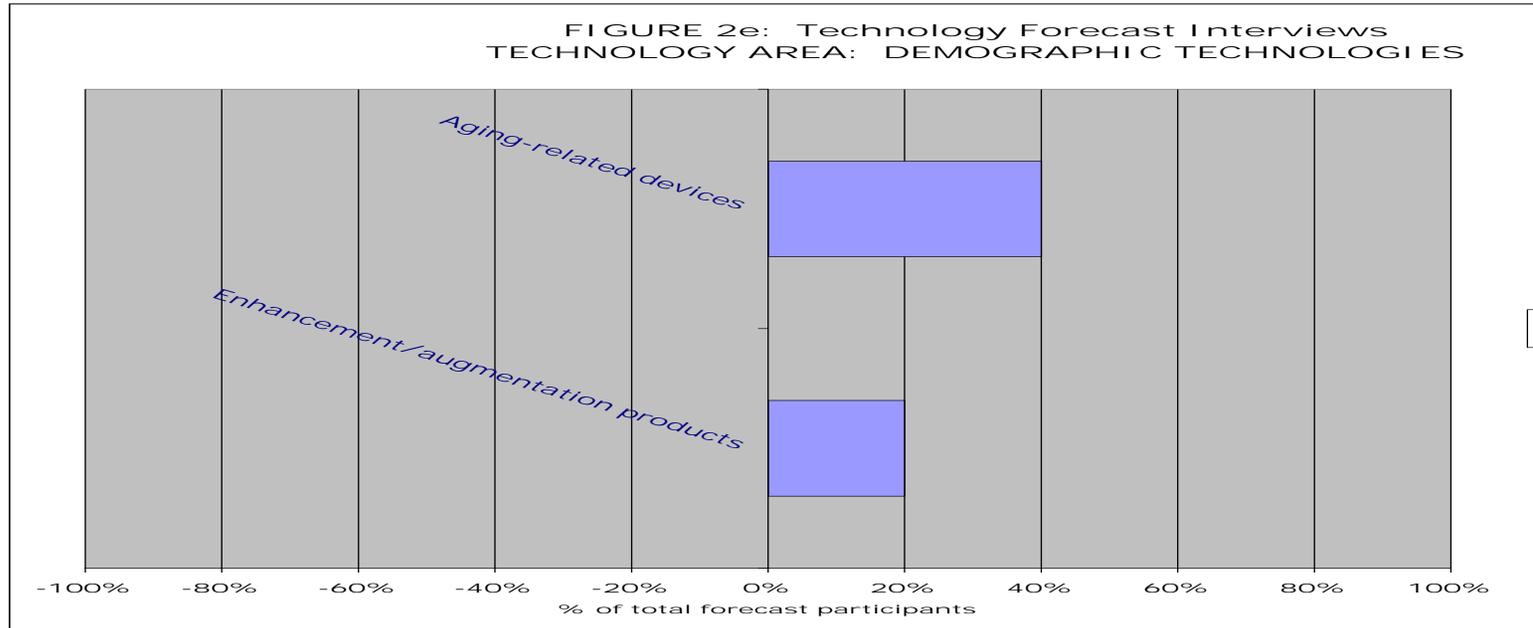
FIGURE 2d: Technology Forecast Interviews
TECHNOLOGY AREA: DECENTRALIZED CARE TECHNOLOGIES

FIGURE 2e: Technology Forecast Interviews
TECHNOLOGY AREA: DEMOGRAPHIC TECHNOLOGIES

**FIGURE 2f: Technology Forecast Interviews
TECHNOLOGY AREA: DIAGNOSIS, DETECTION,
& MONITORING TECHNOLOGIES**

Genomic, proteomic, metabolomic, epigenomic technologies

Early diagnosis technologies

Personalized medicine & Customizable devices

Sensor technologies

Patient monitoring systems

■ Optimistic interview comments
□ Skeptical interview comments

-100%   -50%   0%   50%   100%

% of total forecast participants
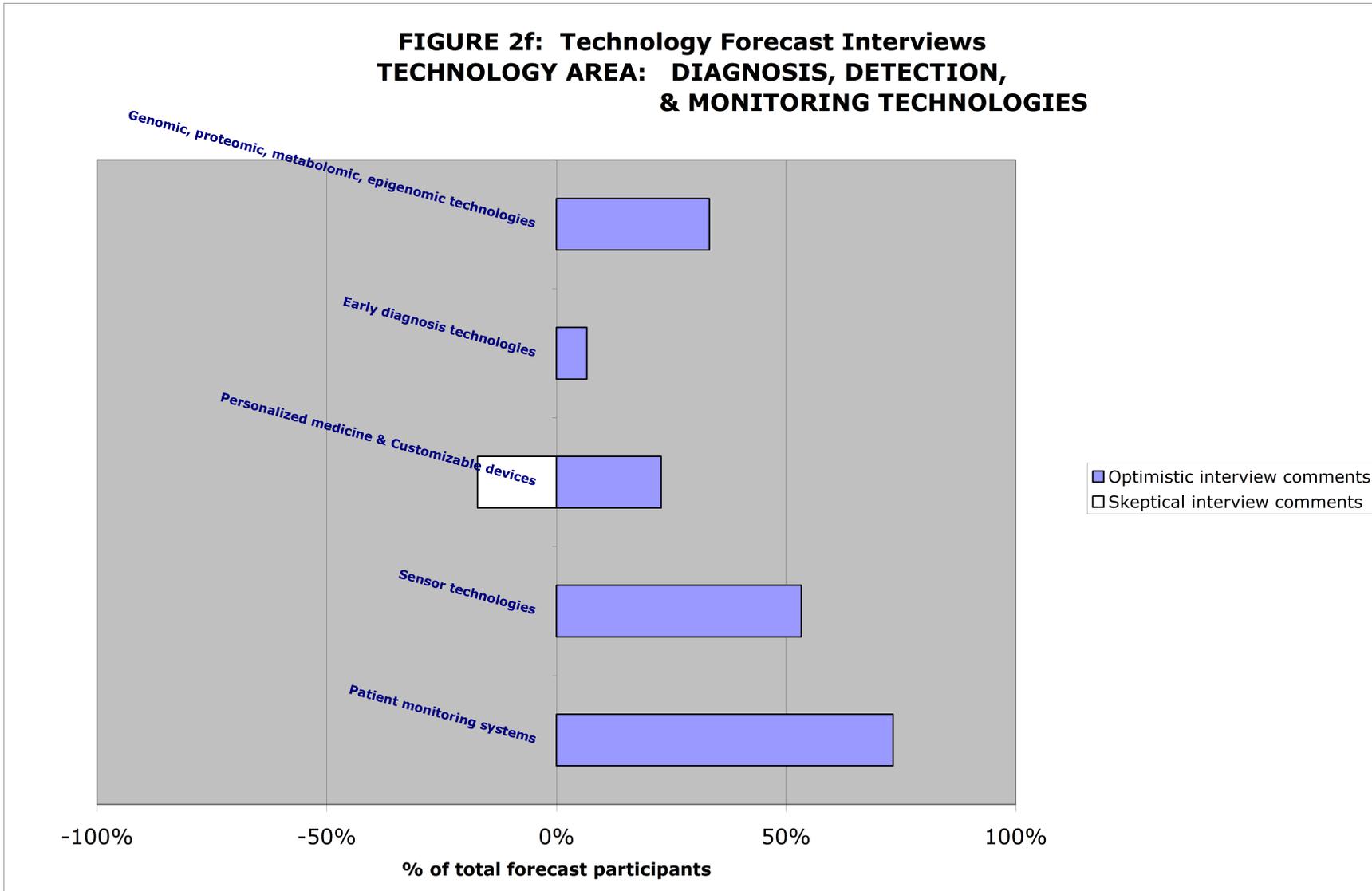
```
TABLE 5: SIGNIFICANTLY INNOVATIVE TECHNOLOGY AREAS
                     LIKELY BY 2018

  ▪ Imaging devices and systems
  ▪ Minimally invasive therapeutic products
  ▪ Combination device and drug/biological products
  ▪ Computerized devices and medical IT systems
  ▪ Home- and self-care products
  ▪ Patient monitoring systems
  ▪ Artificial organs and organ-assistive products
  ▪ Sensor technologies
  ▪ Photonic products
  ▪ Wireless products and systems
  ▪ Genomic, proteomic, metabolomic, and epigenomic technologies
  ▪ Aging-related products
  ▪ Robotic products and systems
```

NINETY-ONE PRODUCT GROUPS: AN OVERVIEW

76% of the participants' examples fell within one or more of the final set of 91 Product Groups that appears in Appendix C. To maintain the focus on confident prediction of high-likelihood developments, we have focused on these 96 multiply-validated specific product groups.

As noted above, selection criteria for Technology Areas in Table 5 included being spontaneously raised by > 33% of the expert participants in the individual interviews. The sheer number of Product Groups in Appendix C makes it obvious that practical constraints on the time for each interview (one hour) precluded the same high rates of interview identification and confirmation that characterized the Technology Areas. Similarly, the large number of Product Groups (91) that were identified by at least two expert participants is far larger than the number of specific examples provided by each participant (36 on average). This significantly reduces the number of opportunities for large numbers of repetitions of any single Product Group in the ratings of multiple participants. In general, as predictive granularity increases, the time constraints for each expert inevitably limit the degree of verification that is possible – particularly as the size of the expert group is increased to extend the scope of predictive inputs.

In accommodation to these unavoidable constraints, Table 6 lists those Specific Product Groups (from Appendix C) for which (1) 20% or more of participants provided numerical ratings, giving an average rating that was very high (> 4.0) for the 10 year likelihood of significant developments in the area; and (2) 20% or more of participants provided spontaneous comments in the interviews, giving confirmation in the majority of those interviews (> 50% of the interviews) of net positive expectations in the area over the next 10 years.

30 of the 32 resulting Product Groups in Table 6 also received general concurrence from the Workshop Working Groups.

One Working Group also suggested that the average numerical likelihood ratings for surgical robotics and advanced prosthetic limbs were too high. In both cases, however, this judgment was balanced by the interview data: interviewees who discussed these two Product Groups (33% and 40% of all participants, respectively) were unanimous in their positive expectations for both areas. Taking both of these inputs together, and noting that the high questionnaire scores were provided by a total of 12 (86%) and 8 (57%) of the participants respectively, we conclude that the questionnaire scores are, in fact, representative of the participant group view as a whole. Consequently, these two products have remained in the list above. All other Product Groups above received general concurrence from the relevant Working groups.

The resulting set of 32 Product Groups in Table 6, then, comprises the top 35% of the 91 Product Groups identified in this forecast as likely to emerge or develop substantially over the next decade.

TABLE 6: SIGNIFICANTLY INNOVATIVE PRODUCT GROUPS
LIKELY BY 2018

- Point-of-care products
- Computer-assisted diagnostic systems
- Neuro-sensory devices
- Optical diagnostic products
- Integrated electronic patient medical records
- Glucose monitoring products
- MEMS/MOTES devices
- Remote patient monitoring systems
- Robotic surgical systems
- Tissue engineered products
- Advanced prosthetic limbs
- New sensors
- Electrostimulation products
- New types of stents
- Minimally invasive implants (e.g., percutaneous or natural orifice delivery)
- Image-guided therapy systems
- Advanced ultrasound imaging systems
- Internet-based medical device systems
- Optical therapeutic devices
- Joint replacements
- Advanced optical imaging systems
- Minimally invasive radiotherapy systems
- Virtual reality systems for immersive training and other applications
- Genetic diagnostic products
- New (non-eluting) drug delivery systems
- New types of insulin pumps and delivery systems
- Robotic prosthetics
- Networks and systems of devices
- New types of home sensors
- Smart homes
- Advanced MR imaging systems
- Advanced RFID systems

4. DISCUSSION

ELECTRONIC TECHNOLOGIES

The Electronics Technology Theme is, unsurprisingly, characterized in this process as having high likelihood for generating significant new medical device developments.   This area continues to be driven by the acceleration of silicon technology, in large measure. In our evaluation scheme, it comprises three main areas relevant to future medical devices: computerized devices and IT systems, robotic devices, and wireless systems.   Every one of these categories was seen as highly likely to produce significant new medical devices within the next decade.   That assessment was strongly confirmed by the participants' interviews for Electronics Technology as a whole, and for each of the three component topics.

For computerized devices and IT systems, confidence seemed justified about advances related to (1) integrated electronic patient medical record systems, (2) computer-assisted diagnostic systems, (3) internet-based medical systems, (4) virtual-reality immersive medical training systems, and (5) networks and systems of devices. Other areas commonly identified were potential developments in closed loop systems (initially extracorporeally, later in implanted applications), and computational modeling of disease (generally and, eventually in patient-specific models). Issues included software reliability in complex systems, the difficulty of predicting behavior of interactive systems of intelligent devices, data security and confidentiality issues, and in limitations in bioinformatics capabilities to cope with gargantuan amounts of patient information (records, monitoring information, etc.).

For robotic systems, highest confidence was associated with developments over the next decade in (1) robotic surgery, and (2) robotic prosthetics. Interviews confirmed expert confidence the general area and the two subsets. Significant military initiatives were noted in both areas. Issues mentioned included complex maintenance, long-term mechanical reliability, and – for robotic prosthetics – bio-integration challenges. Again, the rapid development of this technology area and the associated issues are evident in technical literature outside the universe of medical devices.

Wireless products and systems were also accorded a significant level of confidence in the development of significant new medical devices during the ten years period of the forecast. The most commonly identified product area for new developments was RFID technology. Both the general area and RFID received confirmation in the interview data. Issues mentioned included EMI and signal penetration.

SYNTHETIC ORGANS/TISSUES AND COMBINATION PRODUCTS

Both major subdivisions of this Trend Theme – (1) artificial organs and organ/assistive devices, and (2) combination device/drug/biological products -- received high ratings for

likelihood of producing significant new medical device developments within the decade. The general area and each of those two subcategories also received solid confirmation in the interview data, as well. In at least one sense, it continues to be driven by the limited availability of donor organs and tissue for transplantation.

In the Technology Area of Artificial Organs and Organ-Assistive Products, the data suggest relatively strong confidence in advances for (1) tissue-engineered products, (2) neurosensory devices, (3) glucose-monitoring products, (4) electrostimulation-based devices, and (5) prosthetic limbs with advanced bio-integration properties. Expert participants indicated that new insulin delivery systems, new types of stents, and new joint replacements may also be developed in this time period covered by this forecast. Issues mentioned include major uncertainties about the source of cells for tissue engineered and other bio-based synthetic organs, biocompatibility of implants, complexity of bio-integration, and long-term durability.

For the Combination Product Technology Area, the primary development that garnered both high 10-year likelihood scores for significant new product development, and strong confirmation in the interviews was the area of drug-delivery systems. Potential issues included questions about impact of new delivery systems on safety and efficacy of pharmaceuticals.

INVASIVENESS REDUCING TECHNOLOGIES

The data suggested relative confidence for the 10-year emergence of significant new medical devices in three Technology Areas within this Trend Theme. The first area encompasses Imaging Devices and Systems where developments may emerge in image-guided therapy, and in advanced ultrasound, MR, and optical imaging systems. The second area is Minimally Invasive Therapeutic Products including minimally invasive implants (e.g., percutaneous or natural-orifice delivery) and minimally invasive radiotherapy systems. The third is Photonics, including optical diagnostic devices and optical therapeutic devices. One other individual Product Group is MEMS/MOTES-based miniature devices. Each of these areas received questionnaire scores indicating high likelihood for significant new medical devices of this type within the next decade; confirmation in the interviews that ranged from suggestive to strong. Both molecular therapies (especially gene therapy) and nanotechnology were seen as important areas but, in general, as entailing a longer time horizon than the 10-year scope of this report. The potential issues are as varied as the technologies in this rapidly emerging area, although multiple participants noted the typically higher skill requirements for high quality minimally invasive procedures.

DECENTRALIZED CARE TECHNOLOGIES

The dominant Technology Area in this Trend Theme, in likelihood for generating significant new developments, is Home- and Self-Care Products including new types of home sensors at the small end and smart homes at the larger scale. Each of these categories received high scores for 10-year likelihood from the questionnaire data, and

confirmation from the interview and workshop comments. Potential issues that were raised include human factors and ergonomic concerns regarding use by physically and cognitively impaired patients.

For home telemedicine, interviews did not provide strong confirmation for the high 10-year likelihood scores from the questionnaire primarily because of concerns about the real-life availability of healthcare professionals on the other end of the line.

One specific Product Group received very high 10-year likelihood ratings and strong confirmation in the interview phase: new point-of-care devices.

DEMOGRAPHIC TECHNOLOGIES

Taken as a whole, this Trend Theme was accorded a reasonable likelihood of producing significant new medical devices within the next ten years, but with a somewhat lesser rating than the other five Trend Themes. Similarly, it received confirmation in the interviews, but at a lower level than the other Trend Themes. This may be, at least in part, explained by a comment that came from multiple participants (including some who rated this category highly): for many products it is difficult to draw a clear line between likely uses by a particular demographic group as opposed to the larger general patient population. In the present forecast, the structure of this category effectively limited category's interpretation to (1) products for an older population, and (2) enhancement products associated with a somewhat younger population. Pediatric and gender dimensions were not successfully engaged.

The primary Technology Group identified as likely to produce new products was "Aging Technology". Although this category was scored highly for such likelihood, the scored examples were highly varied and, hence, thematically non-convergent.

DETECTION, DIAGNOSTIC, AND MONITORING TECHNOLOGIES

This Trend Theme, and many of the Technology Areas it encompasses, received both high numerical ratings for 10-year likelihood, and significant confirmation in the interview phase. The strongest confirmation of high likelihood scores was associated with (1) Sensor Technologies including a wide range of new sensors; (2) Patient Monitoring systems, especially remote monitoring systems; and (3) Genomic, Proteomic, Metabolomic, and Epigenomic technologies – especially genetic diagnostic products. Computer-assisted diagnostics were, again, emphasized in the Workshop discussions. Issues included liability concerns related to false-negative findings, and concerns about the availability of realistic therapies for diagnoses.

GENERAL OBSERVATIONS

The developments in Table 6 may have several significant ramifications.

For Federal Agencies and other institutions involved in the evaluation, funding, and clinical use of medical devices, it is clear that the landscape of these activities will be changing in substantive ways. The emergence of more and more highly intelligent systems of interactive devices, for example, will necessitate very different evaluation and selection strategies. Similarly, the increasing prevalence of wirelessly communicating nodes (within and between product systems) will pose growing challenges of data reliability – hence, diagnosis and treatment with medical devices. The practical feasibility of tissue engineered devices, after the long period of unrealized expectation, will soon lead to serious concerns about the sources, availability, and quality of the required biological cells for these products. The increasing trend toward combination device-drug-biological products is sure to pose growing operational challenges to institutional systems that revolve around traditional product categorizations.

On the other hand, the increasing availability of minimally invasive methods and devices seems poised to reduce the personal burdens of lengthy recoveries for many types of illness and trauma. The likely incorporation of some form of computer-assisted diagnosis in many "smart" products, more advanced and sensitive diagnostic "omic" techniques, and the growing sophistication of electronic medical information systems appear to hold the potential for substantially better-informed diagnoses and treatments. Yet, these same developments will generate increased pressure for more effective bio-informatic systems and methods to handle the awesome data burdens they will bring. Developments in decentralized care – in homes, in ambulatory patients, and elsewhere – portend a far better optimized distribution of capabilities throughout the health care system.

Clearly, informed preparation for these developments is possible. Such preparation will enable major gains in the optimization of medical device contributions to health care. It is, however, equally clear that inadequate preparation will open the way to many foreseeable problems – some of them with potentially serious consequences for individuals and for health care systems. It is our hope that the information in this analysis will provide a valuable tool in the shepherding of many new capabilities onto the health care scene.

5. CONCLUSIONS

Our conclusions appear in Table 6, which summarizes the analysis described above. These conclusions comprise our predictions of 13 technology areas and 32 specific product groups in which significant innovation is highly likely in the course of a decade.

The technologies and products in Table 6 have been culled from much larger universes of each. It is noteworthy that, taken as a whole, our expert participants were generally optimistic about almost <u>all</u> of the Technology Areas discussed in this study -- eventually. (See Table 4 >10 yr ratings.) Similar views were evident about very many of the individual product areas. However, the 10-year time horizon for this forecast was just deemed to be too soon for the realization of some of the products and technologies.

Finally, we note that, as in our previous 10-year forecast, our conclusions can be no better than the expertise of the individual participants with whom we collaborated. In our view, this group of participants brought an extraordinary collection of knowledge and insights to the forecast process. It is hard to imagine a better group for the task.

TABLE 7: 10-YEAR MEDICAL DEVICE INNOVATION:
PREDICTED TECHNOLOGY AREAS AND PRODUCT GROUPS

Computerized devices and medical IT systems
- Integrated electronic patient medical records
- Computer-assisted diagnostic systems
- Internet-based medical device systems
- Virtual reality systems for immersive training and other applications
- Networks and systems of devices

Robotic products and systems
- Robotic surgical systems
- Robotic prosthetics

Wireless products and systems
- Advanced RFID systems

Artificial organs and organ-assistive products
- Tissue engineered products
- Neuro-sensory devices
- Glucose monitoring products
- Electrostimulation products
- New types of insulin pumps and delivery systems
- Advanced prosthetic limbs
- New types of stents
- Joint replacements

Combination device and drug/biological products
- New (non-eluting) drug delivery systems

Imaging devices and systems
- Image-guided therapy systems
- Advanced ultrasound imaging systems
- Advanced optical imaging systems
- Advanced MR imaging systems

Photonic products
- Optical diagnostic products
- Optical therapeutic devices

Minimally invasive therapeutic products
- Minimally invasive implants (e.g., percutaneous or natural orifice delivery)
- Minimally invasive radiotherapy systems

Home- and self-care products
- New types of home sensors
- Smart homes

Aging-related products
Genomic, proteomic, metabolomic, and epigenomic technologies
- Genetic diagnostic products

Sensor technologies
- New sensors

Patient monitoring systems
- Remote patient monitoring systems

Other
- Point-of-care products
- MEMS/MOTES devices

APPENDIX A:

The original (blank) questionnaire

(Note: The original questionnaire format has been modified to fit onto standard 8 ½" by 11". Column and row sizes have been modified, and a column for "Comments" does not appear in the following Appendix.)

MEDICAL DEVICE TECHNOLOGY AREAS	ILLUSTRATIVE EXAMPLES	YOUR MOST SIGNIFICANT FUTURE EXAMPLES	PROBABILITY in < 5 yrs	PROBABILITY in 5-10 yrs	PROBABILITY in > 10 yrs	AFFECTED PATIENT POPULATION	BENEFIT	RISK	OVERALL IMPORTANCE
COMPUTER-RELATED TECHNOLOGIES			SCORE EACH ITEM 1 (LO) TO 5 (HI)						
Computerized devices, IT systems	* devices incorporating very complex software (i.e., complex systems potentially intractable to reliability analysis -- requiring new software validation/verification tools) * computer-aided diagnosis systems (incl. portable patient monitoring/diagnosis based on massive personal/reference data) * computer-aided radiology, pathology reading/interpretation * closed loop systems (incl. implants) * systems of interacting devices (with system performance/reliability issues -- e.g., emergent properties) * advanced computer models, algorithms (e.g., disease, devices, device-body interactions) * web-accessible software	Enter 1 example of "computerized medical devices or IT systems" in this cell and 1 or more in (b) thru (g) below							
		(b)							
		(c)							
		(d)							
		(e)							
		(f)							
		(g)							

	* more comprehensive integrated electronic patient medical record
	  systems (incl. web-accessible)
	* advanced/comprehensive computer-based physician order entry
	  (CPOE) systems
	* Cell/net phone based devices
	* VR/immersive training simulators
	* implanted patient smart-card/medical record
	* automated diagnostic laboratories, pharmacies
	* systems/technologies that generate massive data collection									

Robotic devices	* surgical robotic devices * robotic prosthetics * carebots	Enter 1 example of "robotic devices" in this cell and 1 in (b) below								
		(b)								
Wireless systems	* wireless device networks * systems with wireless linkage to implants for data, reprogramming * devices designed for compatibility with changing electromagnetic environment * advanced/comprehensive RFID in implants	Enter 1 example of "wireless systems" in this cell and 1 in (b) below								
		(b)								

MEDICAL DEVICE TECHNOLOGY AREAS	ILLUSTRATIVE EXAMPLES	YOUR MOST SIGNIFICANT FUTURE EXAMPLES	PROBABILITY in < 5 yrs	PROBABILITY in 5-10 yrs	PROBABILITY in > 10 yrs	AFFECTED PATIENT POPULATION	BENEFIT	RISK	OVERALL IMPORTANCE
SYNTHETIC ORGAN/TISSUE TECHNOLOGIES			SCORE EACH ITEM 1 (LO) TO 5 (HI)						
Artificial organs/assists	* neuro/sensory devices (retinas, cortical controllers and sensory/neural prostheses) * artificial joints * advanced limb prosthetics * artificial liver * artificial pancreas * artificial kidney * bio/non-bio hybrid devices (e.g., osseointegration, tissue integration) * implanted devices with new/longer-life ("permanent") batteries that extend operating lifetimes (e.g., glucose fuel cells, human body power source) * devices using the human body as conduction/transmission medium for power/data * erodible/biodegradable implants (e.g., polymers in cardiovascular uses) * complex tissue allografts * devices implantable by percutaneous (and minimally invasive) techniques [tissue engineering -- see below]	Enter 1 example of "artificial organs/assists" in this cell and 1 or more in (b) thru (g) below (b) (c) (d) (e) (f) (g)							
Combination devices --	* new drug-eluting devices	Enter 1							

device with drug/ biologic agent	* implants with growth factor * new drug delivery technologies (ventilators, nebulizers, microspheres)	example of "combination devices" in this cell and 1 in (b) below (b)							

Materials-based devices	* devices based on new (e.g., smart) polymers * devices based on new nitinol applications * new polymer/therapeutic composites as implant coatings [see "infection inhibiting devices", "combination products"]	Enter 1 example of "materials-based devices" in this cell and 1 in (b) below (b)							
Tissue engineering technologies	* TE implants with cell-seeded scaffolds * stem cell products * TE bladders, urethra, uteri * advanced cell differentiation patterning technologies (e.g., bioprinting)	Enter 1 example of "tissue engineering technologies" in this cell and 1 in (b) (b)							
Biocompatibility technologies	* improved biocompatible devices incorporating significant advances in mechanistic understanding of immune phenomena * biomimetic surface modifications of implants	Enter 1 example of "biocompatibility technologies" in this cell and 1 in (b) (b)							
Infection-inhibiting devices	* biofilm-resistant implants (e.g., non-fouling surfaces) * devices employing controlled release of biocides * implant surfaces that chemically inhibit "quorum" sensing process to limit bacterial virulence	Enter 1 example of "infection inhibiting devices" in this cell and 1 in (b) below (b)							

MEDICAL DEVICE TECHNOLOGY AREAS	ILLUSTRATIVE EXAMPLES	YOUR MOST SIGNIFICANT FUTURE EXAMPLES	PROBABILITY in < 5 yrs	PROBABILITY in 5-10 yrs	PROBABILITY in > 10 yrs	AFFECTED PATIENT POPULATION	BENEFIT	RISK	OVERALL IMPORTANCE
INVASIVENESS REDUCING TECHNOLOGIES			SCORE EACH ITEM 1 (LO) TO 5 (HI)						
Minimally invasive technologies	* transdermal ultrasound surgery (i.e., HIFU) * gated stereotactic radiosurgery (e.g., gamma knife, accelerator, particle beam) * embolic microspheres * optical diagnostic, therapeutic devices	Enter 1 example of "minimally invasive technologies" in this cell and 1 in (b) (b)							
Miniaturized devices	* nanotechnology products - therapy particle delivery/tags, antimicrobial particles, implant coatings, combination image-able therapeutic particles, diagnostic tags * devices incorporating micro-electromechanical systems (MEMS) * miniaturized fluid and mechanical devices [see "artificial organs" above]	Enter 1 example of "miniaturized devices" in this cell and 1 in (b) below (b)							
Photonic devices	* hyperfine laser surgery systems * light-activated tissue growth technologies * light-activated neural stimulation * femtosecond laser ablation * photoactivation technologies for localized drug delivery * optical diagnostic devices [see "detection/diagnostic technologies"]	Enter 1 example of "photonic devices" in this cell and 1 in (b) below (b)							
Molecular therapies	* gene therapy technologies	Enter 1							

	* RNA interference technologies	example of "molecular therapies" in this cell and 1 in (b) below						
		(b)						

Imaging Devices/Systems	* image guided therapy * high resolution ultrasound * low cost ultrasound imaging devices * miniaturized MR systems * multimodality image fusion * functional imaging * multidimensional imaging/display * molecular imaging (e.g., new molecular beacons) * fluorescence imaging * image storage systems (e.g., holographic) * optical coherence tomography * impedance imaging * 2-photon technologies * terahertz imaging * x-ray imaging with synchrotron radiation	Enter 1 example of "imaging" products in this cell and 1 or more in (b) thru (e) (b) (c) (d) (e)							

MEDICAL DEVICE TECHNOLOGY AREAS	ILLUSTRATIVE EXAMPLES	YOUR MOST SIGNIFICANT FUTURE EXAMPLES	PROBABILITY in < 5 yrs	PROBABILITY in 5-10 yrs	PROBABILITY in > 10 yrs	AFFECTED PATIENT POPULATION	BENEFIT	RISK	OVERALL
DECENTRALIZED-CARE TECHNOLOGIES		SCORE EACH ITEM 1 (LO) TO 5 (HI)							
Home/self care devices	* consumerized devices (e.g., automatic external defibrillators) * sensor-laden smart homes * continuous passive monitoring/diagnosis * home neurodiagnostics (e.g., Alzheimer's) * home dialysis * general home diagnostics (e.g. urine glucose in toilet, saliva and breath diagnostics) * cost-reducing monitoring/therapy technologies * smart home-use "health coach" devices with sensor reading/interpretation ability	Enter 1 example of "home/self" products in this cell and 1 or more in (b) thru (c) (b) (c)							
Portable/mobile devices	* implanted sensor-based diagnostic/monitoring devices * advanced portable therapy delivery devices (incl. implants) * advanced point-of-care (POC) diagnostic systems (e.g., bedside, ER, internists' offices)	Enter 1 example of "portable/mobile" devices in this cell and 1 in (b) below (b)							
Telemedicine systems	* home care devices * surgical systems * radiology/diagnostic systems * internet-linked telemedicine systems	Enter 1 example of "telemedicine" devices in this cell and 1 in (b) below (b)							

MEDICAL DEVICE TECHNOLOGY AREAS	ILLUSTRATIVE EXAMPLES	YOUR MOST SIGNIFICANT FUTURE EXAMPLES	PROBABILITY in < 5 yrs	PROBABILITY in 5-10 yrs	PROBABILITY in > 10 yrs	AFFECTED PATIENT POPULATION	BENEFIT	RISK	OVERALL IMPORTANCE
DEMOGRAPHIC TECHNOLOGIES			SCORE EACH ITEM 1 (LO) TO 5 (HI)						
Aging-related devices	* sensory aids * mobility aids (incl. orthopedic implants) * cardiovascular devices * cancer-related devices (e.g., radiotherapy systems) * memory aids (e.g., drug regimen reminders) * incontinence management technologies (e.g., artificial sphincters)	Enter 1 example of "aging-related" devices in this cell and 1 in (b) below (b)							
Enhancement/ augmentation products	* brain/cognitive enhancement technologies * cosmetic devices	Enter 1 example of "enhancement" devices in this cell and 1 in (b) below (b)							

MEDICAL DEVICE TECHNOLOGY AREAS	ILLUSTRATIVE EXAMPLES	YOUR MOST SIGNIFICANT FUTURE EXAMPLES	PROBABILITY in < 5 yrs	PROBABILITY in 5-10 yrs	PROBABILITY in > 10 yrs	AFFECTED PATIENT POPULATION	BENEFIT	RISK	OVERALL IMPORTANCE
DETECTION/DIAGNOSTIC TECHNOLOGIES			SCORE EACH ITEM 1 (LO) TO 5 (HI)						
Early detection/diagnosis technologies	* computer assisted diagnosis (CADx) * vulnerable plaque detection (OCT, acoustic, temperature) [see "genomics" below]	Enter 1 example of "early detection" technologies in this cell and 1 in (b) (b)							
Genomics, proteomics, metabolomics, epigenomics	* routine genomic testing devices/systems * high dimensional genomic data analysis systems * larger and larger gene chips * protein arrays * fast diagnostic genomics-in-a-box (biowarfare-monitoring driven)	Enter 1 example of "omics" devices in this cell and 1 in (b) below (b)							
Personalized medicine, "Tailorable" devices	* personalized and dynamic "situationalized" devices * continually learning devices * individualized patient computational simulations * genetically customized drugs/carriers [see "genomics" and "computerized devices" above]	Enter 1 example of "tailorable"" devices in this cell and 1 in (b) below (b)							
Sensor technologies	* biosensor-based devices * electromechanical-sensor devices * implanted sensors * body sensor networks * home sensor networks [see "home/self care", "portable/mobile" above]	Enter 1 example of "sensor" based devices in this cell and 1 in (b) below (b)							

APPENDIX B:

Instructions and definitions for the questionnaire.

FUTURE TRENDS IN MEDICAL DEVICE TECHNOLOGY – 2007
INSTRUCTIONS FOR QUESTIONNAIRE

Thank you for participating in our 2007 forecast initiative.

These instructions tell you how to complete the accompanying "Technology Questionnaire", in Excel spreadsheet format.

ELEMENTS OF THE QUESTIONNAIRE:

- "Medical Device Technology Areas" (column A): These are 23 categories of medical devices which may emerge or undergo major growth in the next 5-10 years. These categories have been combined in the questionnaire into related groups for your convenience (e.g., "Computer-Related Technologies").
- "Examples" (column B): Illustrative examples of possible newly emerging (or high-growth) devices are provided here for each "Medical Device Area". These examples and the Medical Device Technology Areas are taken from input provided by the forecast panel experts, and from FDA's scientific staff.
- "Most Significant Future Examples" (column C): In this column you will enter at least two of your own examples of the indicated "Medical Device Area". These may be taken from your own judgment of the area or, if you prefer, from the list of examples provided. Your entries should represent what you believe to be the most significant new device/technology developments that you expect in this "Medical Device Area" over the next 5-10 years.
- "Probability", "Population", "Benefit", "Risk", and "Overall Importance" (columns D-J): In these columns you will enter your rating of the indicated parameter. Definitions for each scoring factors are given below.
- "Comments" (column K): Space is provided here for any additional remarks you may wish to make about the example you are rating.

INSTRUCTIONS FOR COMPLETING THE QUESTIONNAIRE:

1. Please take a moment to look at the "Sample Questionnaire" provided. This is just to show you what the completed form might look like; please do not use this for your responses to this survey activity. (The ratings in the sample are purely fictitious.)
2. You can complete the questionnaire electronically (adjust the "zoom" on your monitor for most convenient image size). If you prefer, you can also print it out on legal size paper ("landscape setting") and complete it manually.
3. For each "Medical Device Technology Area" enter under "Most Significant Future Examples" two (or more) examples of the most significant devices/technologies that you expect in the next 5-10 years.
4. Then score 1 (low) to 5 (high) each of the factors in columns D-J. Scoring is further defined below.
5. Please E-mail the completed questionnaire (or a scanned version of your manually-completed questionnaire) to William.herman@fda.hhs.gov. If you have questions or difficulties you can also call Bill Herman at (301) 827-4777.

NOTE: If you need additional space for your input, please use the "overflow space" sheet included in the questionnaire.

SCORING FACTOR DEFINITIONS

- **PROBABILITY**   [columns D, E, F]

  What's the likelihood that your examples in each device-technology area will be successfully introduced into regular (i.e., noninvestigational) clinical use during the indicated time periods (i.e., < 5 years, 5-10 years, > 10 years)?

  highly unlikely to be   1___2___3___4___5   almost certain to be
  successfully   moderately   successfully
  introduced into use   likely   introduced into use

- **AFFECTED PATIENT POPULATION**   [column G]

  For each device-technology area, what's the ultimate size of the annual patient population likely to be affected by your examples during the next decade?

  very small fraction of 1___2___3___4___5   very large fraction of
  total patient population   total patient population

- **BENEFIT** [column H]

For each device-technology area, if your examples do materialize as predicted, what is the expected benefit in additional lives saved, serious disabilities avoided/alleviated, etc.?

almost no reduction in   1___2___3___4___5   potentially large
present rates of death   moderate   reduction in present
or serious disability   reduction   rates of death or
                                                        serious disability

- **RISK** [column I]

  For each device-technology area, if your examples do materialize as predicted, what is the magnitude of the potential risk associated with substantial new developments?

  almost no potential 1___2___ 3___4___5   potentially high risk
  risk for patients   moderate   for patients (possibly
                                  risk   offset by benefits)

- **OVERALL IMPORTANCE**   [column J]

  Considering all factors, what's the likely importance of each of your examples for future health care?

  highly unlikely to   1___2___3___4___5   almost certain to
  portend significant   moderately   portend significant
  change from present   likely   change from present
  health care practices   health care practices

APPENDIX C: TREND THEMES, TECHNOLOGY AREAS, PRODUCT GROUPS

TREND THEMES	TECHNOLOGY AREAS	PRODUCT GROUPS
ELECTRONIC TECHNOLOGIES	Computerized devices, IT systems	CADx
		CLOSED-LOOP SYSTEMS
		NETWORKS AND SYSTEMS
		INTEGRATED ELECTRONIC PATIENT RECORDS
		EPR IMPLANTED CHIPS
		DATA-MINING SYSTEMS
		INTERNET-BASED SYSTEMS
		LABORATORY AUTOMATION
		COMPUTATIONAL MODELING
		VR -- IMMERSIVE TRAINING SIMULATORS, Tx
	Robotic devices	ROBOTIC PROSTHETICS
		ROBOTIC SURGICAL SYSTEMS
		REHAB ROBOTS
		CAREBOTS
	Wireless systems	WIRELESSLY CONNECTED IMPLANTS
		WIRELESS MONITORING SYSTEMS
		CELL-NET PHONE BASED DEVICES
		RFID
SYNTHETIC ORGANS/TISSUES and COMBINATION PRODUCTS	Artificial organ, organ assistive devices	ALLOGRAFTS
		BATTERIES FOR IMPLANTS
		BLADDERS, URETHRA
		CARTILAGE
		ELECTROSTIMULATION PRODUCTS
		GLUCOSE MONITORING
		INSULIN PUMPS/DELIVERY SYSTEMS
		JOINTS

TREND THEMES	TECHNOLOGY AREAS	PRODUCT GROUPS
		KIDNEYS
		LIVERS
		MINIMALLY INVASIVE IMPLANTABLES "see Minimally Invasive Technologies"
		NEUROMODULATION DEVICES Cognitive, affective
		NEURAL CONTROLLERS
		NEURO/SENSORY
		OSSEO-INTEGRATION
		PANCREAS
		PROSTHETIC LIMBS
		RESORBABLES
		STENTS
		STEM CELLS
		TISSUE ENGINEERING TECHNOLOGIES
	Combination products *device + [biological/pharmaceutical] products*	DEVICE-BIOLOGICAL COMBINATIONS
		DRUG-ELUTING DEVICES
		OTHER DRUG DELIVERING DEVICES
		PHOTODYNAMIC THERAPIES
	Materials-based devices	NEW NITINOL-BASED DEVICES
		NEW POLYMER-BASED DEVICES
	Biocompatibility technologies	NEW BIOMIMETIC SURFACE TECHNOLOGIES
		DEVICE IMMUNOSUPPRESSIVE TECHNOLOGIES
	Infection-inhibiting devices	SURFACE-MODIFIED INFECTION-RESISTANT DEVICES
INVASIVENESS REDUCING TECHNOLOGIES	Photonic devices	OPTICAL Dx DEVICES
		OPTICAL Tx DEVICES
		NEURO-OPTICAL STIMULATION DEVICES
	Acoustic devices	ACOUSTIC Dx DEVICES
		ACOUSTIC Tx DEVICES
	Molecular therapies	GENE Tx PRODUCTS
		RNAi PRODUCTS

TREND THEMES	TECHNOLOGY AREAS	PRODUCT GROUPS
	Minimally invasive Tx technologies non-photonic, non-acoustic, non-"omic"	MINIMALLY INVASIVE CRYO TECHNOLOGIES
		MINIMALLY INVASIVE RADIOTHERAPY TECHNOLOGIES
		MINIMALLY INVASIVE ROBOTIC SURGERY SYSTEMS
		MINIMALLY INVASIVE IMPLANTS percutaneous and natural-orifice implantability
	Miniaturized devices	MEMS/MOTES DEVICES
		NANOTECH DEVICES
	Imaging Devices/Systems	FUNCTIONAL IMAGING DEVICES
		IMAGE FUSION DEVICES
		IMAGE-GUIDED Tx DEVICES
		IMPEDANCE IMAGING DEVICES
		MOLECULAR IMAGING DEVICES
		ADVANCED MR DEVICES
		OPTICAL IMAGING DEVICES
		ADVANCED U/S IMAGING DEVICES
		HOLOGRAPHIC IMAGING
DECENTRALIZED-CARE TECHNOLOGIES	Home/self care devices	CONTINUOUS PASSIVE MONITORING
		HOME HEALTH COACH
		HOME TELEMEDICINE *(also under "Telemedicine")*
		SMART HOME
	Portable/mobile devices	HOME SENSORS
		POINT-OF-CARE DEVICES
		IMPLANTS -- FOR Dx/Tx OF DISEASE
	Telemedicine systems	TELERADIOLOGY
		TELESURGERY
		INTERNET TELEMEDICINE

TREND THEMES	TECHNOLOGY AREAS	PRODUCT GROUPS
		HOME TELEMEDICINE *(also under "Home/self care")*
DEMOGRAPHIC TECHNOLOGIES	Aging-related devices	SENSORY AIDS
		MEMORY AIDS
	Enhancement/augmentation products	COSMETIC DEVICES
DETECTION, DIAGNOSTIC, and MONITORING TECHNOLOGIES	Genomics, proteomics, metabolomics, epigenomics	GENETIC Dx
	Early detection and diagnosis *(non-"omic" technologies)*	FAST, PORTABLE GENETIC TESTS
		PROTEOMIC Dx
		VULNERABLE PLAQUE
		EARLY DETECTION CADx
	Personalized medicine, "Customizable" devices	BIOLOGICALLY/DRUG CUSTOMIZED Tx
		ELECTRONICALLY CUSTOMIZED Tx
	Sensor technologies	NEW SENSORS
	Patient monitoring systems	REMOTE MONITORING e.g., home, implanted, portable, wireless